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FINAL REPORT

UNIQUE DEVICE IDENTIFICATION (UDI) FOR MEDICAL DEVICES

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SECTION ONE

EXECUTIVE SUMMARY

The U.S. Food and Drug Administration (FDA) is proposing a rule requiring unique device identification (UDI) for medical devices to meet the requirements of the Food and Drug Administration Amendments Act (FDAAA) and to improve device safety and the reporting of device-related adverse events. A UDI would be a unique numeric or alphanumeric identifier assigned to each device product, consisting of a device identifier, which identifies the product and the labeler, and, in many cases, a production identifier (lot, batch, serial number, or date). Lack of unique identifiers for medical devices hinders identifying devices throughout their distribution and use, the reporting and analysis of adverse event data, and the timely removal of recalled devices from medical uses.

Most of this report analyzes the requirements of a base case alternative that incorporates all of the provisions of the proposed rule, but has more stringent requirements for class I devices. This base case alternative was ultimately rejected by FDA. It would have required all classes of devices to be labeled with both the device identifier and the production identifier (i.e., a variable barcode). FDA has, however, selected an alternative that is identical to the base case except for the treatment of Class I devices. In the selected alternative FDA has reduced the regulatory burden. Class II and Class III devices would be required to have both the device identifier and the production identifier on their labels, but the selected alternative would allow Class I devices to be labeled with just the device identifier (i.e., a static barcode). FDA also added an exclusion to the original list of device exclusions that were used in most of the analyses in this report. This exclusion applies to devices that are exempt from good manufacturing practice (GMP) requirements. Such devices include bed pans and home-use toothbrushes, and FDA proposes that these devices would not to be subject to UDI requirements.

Most of this report, therefore, estimates the costs that would be incurred by industry, UDI issuing agencies, and FDA under a more costly regulatory alternative and uses these costs to assess the impacts of the proposal on affected establishments, firms, and small businesses. This executive summary and Section 6.7 (in a section on regulatory alternatives) discusses the differences between the “base case” presented in most sections of this report and FDA’s chosen alternative. These sections also discuss the costs savings compared to the base case and present the total first year, recurring and annualized costs of the chosen alternative.

1.1 SUMMARY OF THE PROPOSED RULE

The proposed UDI rule would require a numeric or alphanumeric identifier to be placed on the label of most medical devices that are marketed and sold in the U.S., as well as on their device packages.[1] The UDI would be required to appear both in a text format and in automatic identification and data capture (AIDC) format (most typically, a machine-readable barcode). The form of this UDI would be consistent with current barcoding configurations of two major barcoding organizations, GS1 (which is the issuing body for UPC and similar trade-related codes) and the Health Industries Business Communications Council (HIBCC). As noted above, the UDI is considered to consist of a device identifier and a production identifier. The selected regulatory alternative for this proposal would allow Class I devices to use just the device identifier as the UDI on those devices. Certain devices (e.g., implants, reusable surgical instruments (multi-use devices), and standalone software [software that is not an integral component of a device]) would be required to have the UDI directly marked on the device itself.[2] Additionally, the UDI, certain basic identification and contact information, and key attributes of the devices (e.g., sterile, or containing latex) would need to be uploaded to a database that would be created and maintained by FDA. Medical device records throughout the required recordkeeping and reporting systems would need to be modified so that UDIs can be included in such records. Additionally, any dates appearing on medical device labels would need to be presented in a prescribed format.

In the remainder of this report following this executive summary, any mention of proposed rule means the base case, unless specifically noted otherwise.

1.2 LABELER COSTS TO IMPLEMENT UNIQUE DEVICE IDENTIFICATION

ERG identified a number of costs facing medical device labelers as they comply with the proposed rule, including planning costs, equipment costs (such as for digital printers for those establishments needing to print variable barcodes), or increased printing costs (for those printing variable barcodes who outsource printing), costs to obtain a UDI and register barcodes, costs to laser–etch (for example) UDIs on medical devices for which direct marking (DM) is required, costs to change labels to meet the requirements, costs to integrate UDI throughout the information systems at labeling firms to ensure integration among processing systems and to ensure all relevant records contain UDIs, and costs to

[1] Generally, the device package is the package containing one or more labeled devices of the same model or version.

[2] In the case of software, the UDI would need to be contained within the software, such as on a start-up page.

meet data uploading requirements. Costs to all domestic medical device labelers are estimated for the base case to be $396.3 million in the first year and $73.6 million in subsequent years. The chosen alternative reduces these costs to $292.8 million in the first year and $46.7 million in subsequent years.

For comparison purposes with various alternatives and to show the effect of FDA's proposal to have implementation periods of up to 5 years (for Class I devices) and between 3 and 7 years for DM requirements, total annualized costs are presented on two bases: (1) immediate implementation and (2) under the proposed implementation schedule. Because any delay in outlays results in lower costs over time, FDA's proposed implementation schedule results in substantially lower costs than a scenario in which all device labelers must immediately implement UDI, i.e., in the first scenario.[3]

1.2.1 Immediate Implementation Cost Scenario

Under the immediate implementation assumption and with costs annualized at 7 percent over 10 years, first year costs are estimated at $56.4 million per year in the base case. With recurring costs added in, total annualized costs to U.S. industry are estimated at $130.1 million per year in the base case. FDA's chosen alternative reduces these costs to $41.7 (annualized first year costs) and $88.4 million (total annualized costs).

Issuing agencies are given responsibilities under the proposed regulation. Two organizations, GS1 and HIBCC, already perform functions quite similar to the proposed requirements for issuing agencies. Nevertheless, ERG assumed that organizations applying to become accredited issuing agencies would incur costs to ensure that they understand and are comfortable with their legal responsibilities under this proposal. ERG estimates the costs to the issuing agencies at $529,000 in the first year, nearly all of which is allocated to executive and legal reviews of the FDA proposal. The recurring annual costs are estimated at $54,800, including an allowance for ongoing executive and legal reviews. The total annualized costs to the two organizations performing functions similar to issuing agencies are estimated at $130,000 per year. (These costs are assumed to be incurred in the first year after promulgation of the proposed rule, regardless of implementation scenario). FDA has made no changes to these costs under the selected proposed rule. Under the immediate implementation scenario in the base case, total annualized

[3] The immediate implementation scenario is not intended to consider the cost implications associated with the difficulties of implementing such a complex rule in a short time frame. The cost estimated under this scenario, however, is used in Section Six to allow comparisons among several regulatory alternatives. This $130.1 million per year cost is not the regulatory cost of the rule because it does not take into account the additional time proposed by FDA for implementation.

costs to issuing agencies and U.S. industry are $130.2 million per year. The selected alternative is associated with a total costs to issuing agencies and U.S. industry of $88.5 million per year.

ERG also estimates costs for foreign establishments and firms to implement the proposed rule. Because the numbers of foreign labelers are nearly the same as those of domestic labelers, ERG estimates that the costs to foreign labelers would be approximately the same as the costs to domestic labelers. This assumption is very broad and the estimate of costs that might be incurred by foreign establishments is considered very uncertain. We cannot determine the breakdown of employment sizes for establishments by country, nor do we have information specific to what costs would be in each country in which establishments are located. This estimate, therefore, is the best estimate that can be derived with the data available. Total annualized costs for all affected entities (including foreign entities, but excluding any costs to FDA) are estimated to be $260.2 million per year in the base case (see Table 1-1).[4] The selected alternative reduces these costs as shown in Table 1-2. The total annualized costs for all entities under the immediate implementation scenario are $176.9 million per year.

Table 1-1. Costs of the Base Case for All Affected Entities

Entity	One-Time Costs	Recurring Costs	Immediate Implementation		With the Provided Additional Implementation Time
			Annualized One-Time Costs	Total Annualized Costs	
Domestic Industry	$396,286,458	$73,630,111	$56,422,276	$130,052,387	**$92,646,435**
Issuing Agencies	$529,000	$54,800	$75,318	$130,118	$130,118
Foreign Industry (a)	$396,286,458	$73,630,111	$56,422,276	$130,052,387	$92,776,553
Total Non-Federal Costs	**$793,101,916**	**$147,315,022**	**$112,919,870**	**$260,234,892**	**$185,553,106**

(a) Assumes costs to foreign industry are the same as domestic costs, based on number of registrations with FDA

Source: See subsequent tables.

[4] FDA would also incur costs to administer the UDI database system. These costs are presented in the preamble to the proposed rule, but are not discussed here (although an alternative to FDA's chosen method is presented in Section Six).

Table 1-2. Costs of the Class I Static Barcoding Alternative for All Affected Entities

Entity	One-Time Costs	Recurring Costs	Immediate Implementation		With the Provided Additional Implementation Time
			Annualized One-Time Costs	Total Annualized Costs	
Domestic Industry	$292,818,254	$46,672,746	$41,690,732	$88,363,478	**$66,453,716**
Issuing Agencies	$529,000	$54,800	$75,318	$130,118	$130,118
Foreign Industry (a)	$292,818,254	$46,672,746	$41,690,732	$88,363,478	$66,453,716
Total Non-Federal Costs	**$586,165,507**	**$93,400,292**	**$83,456,781**	**$176,857,073**	**$133,037,550**

(a) Assumes costs to foreign industry are the same as domestic costs, based on number of registrations with FDA
Source: See subsequent tables.

1.2.2 Proposed Implementation Schedule

Under FDA's proposed implementation schedule, the costs of the proposed rule are substantially less than those under the immediate implementation assumption. When the proposed implementation schedule is assumed, the costs (at 7 percent over 10 years) for domestic labeling establishments (excluding costs to issuing agencies and foreign establishments) are $92.6 million per year in the base case, or $37.4 million per year less than that estimated for domestic labeling establishments under the assumption that all costs are incurred in the first year after promulgation (see Table 1-1). In the base case, costs to all domestic entities (labelers and issuing agencies) total $92.8 million per year. With costs to foreign labelers added in, the total rises to $185.6 million per year.

Under FDA's chosen alternative, the proposed rule reduces these costs substantially. When the proposed implementation schedule is assumed, the costs (again at 7 percent over 10 years) for domestic labeling establishments are $66.5 million per year, or $26.2 million per year less than that estimated for domestic labeling establishments under the assumption that all costs are incurred in the first year after promulgation (see Table 1-2). Costs to all domestic entities (labelers and issuing agencies) total $66.6 million per year. With costs to foreign labelers added in, the total rises to $133.0 million per year.

1.3 IMPACTS ON LABELING FIRMS AND ESTABLISHMENTS

ERG investigated impacts of the costs to implement UDI on all domestic labeling firms. Measureable impacts were defined as costs as a percentage of revenues exceeding 1 percent. Among all domestic labelers under the base case, costs as a percentage of revenues exceed 1 percent only for a small number of firms that would be required to directly mark certain devices. A total of 32 firms out of an estimated 5,234 firms (0.6 percent) are estimated to incur compliance costs in excess of 1 percent of revenues.[5] If costs for DM are excluded, no firms would experience costs exceeding 1 percent of revenues. DM requirements are associated with costly equipment such as laser markers that must be used to inscribe the device identifier (but not the production identifier) on the device

Among those estimated to experience costs greater than 1 percent of revenues, all are considered small businesses. These 32 firms are also 0.6 percent of an estimated 5,010 small businesses subject to the rule as characterized in the base case.

For establishments, no establishments are expected to incur compliance costs greater than 1 percent of establishment revenues under the base case, unless they must satisfy DM requirements. When DM requirements are considered, 32 establishments are estimated to incur costs greater than 1 percent of revenues. These establishments are all considered single-facility firms and, therefore, are the same 32 entities identified in the firm impact analysis.

The impacts discussed for the base case are not expected to be much different under FDA's chosen alternative for the proposed rule. Because the only establishments that are estimated to incur costs greater than one percent are a subset of those that must meet DM requirements and because DM would be required under this alternative, as well, the impacts on firms discussed above could still occur. However, some multi-use device manufacturers that are required to direct mark these primarily Class I devices, could face substantially reduced total costs if all of their device labels require static barcodes only, rather than the more costly variable barcodes. To the extent that this situation occurs, this alternative could possibly reduce the number of firms estimated to incur costs exceeding 1 percent of revenues. We do not, however, have any information on whether firms that only manufacture Class I devices and must direct

[5] The count of 5,234 firms excludes those that are expected to meet exceptions or are considered to be in compliance with the proposed rule in the baseline due to use of UPCs, but do include counts of those assumed to be in compliance with UDI requirements in the baseline.

mark some or all of those devices are among the groups of firms considered likely to face costs exceeding 1 percent of revenues.

SECTION TWO

INTRODUCTION

2.1 BACKGROUND AND ORGANIZATION OF THE REPORT

The Food and Drug Administration Amendments Act (FDAAA) of 2007 requires FDA to propose a system for uniquely identifying medical devices using a unique device identifier (UDI). FDA has worked for many years with the various stakeholders to create a proposed rule that is effective and is compatible with systems that are in place for identifying medical devices for trade purposes and Department of Defense (DOD) requirements.

This report provides information on the costs and impacts of the proposed rulemaking developed by FDA. Section Two (this section) summarizes the rule. Section Three presents a profile of the entities expected to be affected by the requirements to provide UDIs on medical devices. Section Four provides an estimate of the costs of the proposed rule. Section Five presents the impacts of the rule on the affected entities, both at the establishment and firm levels. Section Six provides costs and impacts of several alternatives to the proposed rule. Section Seven presents the Initial Regulatory Impact Analysis, and Section Eight presents the results of an uncertainty analysis.

2.2 SUMMARY OF THE PROPOSED UDI RULE

FDA is proposing that medical device labels must bear a UDI, and this rule is directed at labelers of those devices. Labelers include both the original labelers of devices (typically the manufacturer of the device) and relabelers (often an importer or a distributor of devices).[6] Labelers are generally those who place a label on a device, but, for the purposes of the proposed rule, some labelers are defined as such because they "cause" a label to be placed (that is, manufacturers, labelers, and packagers acting under contract to another establishment are not the labelers; the other establishments contracting with such entities are the labelers). The requirements set forth in the proposed rule cover all classes of devices, with

[6] Most distributors and many importers would not be considered labelers under this definition. Only those distributors and importers that are subject to registration and listing requirements as relabelers/repackagers because they change the information appearing on a label are considered labelers. Distributors that add a "distributed by" note on a label but change no other information are not considered relabelers subject to registration and listing requirements.

the earliest deadlines applying to Class III devices (1 year after final publication of the rule),[7] and subsequent deadlines for Class II and Class I (and unclassified) devices (3 and 5 years after final publication of the rule, respectively). FDA is defining medical devices to include: (1) kits (which contain two or more devices packaged together for convenience of use) and (2) combination products (i.e., a combination of a drug and a device) that are considered devices.

2.2.1 Components of the UDI

The UDI would comprise two parts: the device identifier and the production identifier. The device identifier must identify both the labeler and the product. These identifiers would remain unchanged as long as the device is manufactured and sold (thus, this portion of the UDI is known as the static portion). The UDI must also identify whatever production identifiers are currently printed or stamped on the labeling, for example, lot, batch or serial numbers, date of manufacture, or expiration date (only one of these is required). Because they change frequently, production identifiers are considered the variable portion of the UDI. Existing numbering systems could be used (assuming their issuing organizations are accredited as issuing agencies by FDA).

2.2.2 Display of UDI on Label

The UDI must be displayed in both easily readable plain-text (alphanumeric) and machine-readable format (e.g., barcode); the machine-readable format (symbology) is not specified in the proposed rule. FDA intends that the proposed rule be flexible and allow for changes in technology over time. By not specifying a particular technology, FDA ensures that as technologies evolve, UDI displays can evolve with them.

Certain items would also need to have the UDI marked directly and permanently on the device if they do not have a label permanently affixed to them. These marks must be either easily read plain text or in a machine-readable format. The devices affected include:

- Implantable devices (those to be implanted for more than 30 days).
- Devices used multiple times and intended to be sterilized (for example, surgical instruments).

[7] Also requires devices licensed under the Public Health and Safety Act (PHSA) to come into compliance within a year; few devices are licensed under this Act.

- Standalone software (i.e., software that is not a component of a medical device), which must be marked by inserting the UDI into the start up screen or into the "about" screen usually located under the help menu.

Reprocessed single-use devices are excluded from direct marking (DM) requirements.

No particular technology for DM is specified to allow for changing technologies; current technologies might include laser etching, for example. The requirements for DM are subject to several exceptions. If it is not technologically possible to mark the device (for example, the device's material is not suitable for DM), or marking the device would interfere with safe and effective use, DM is not required, but an exception must be noted the design history file and notice provided to FDA. Furthermore, exceptions are provided for devices that are intended for implanting for less than 30 days, software that is a device component, and any device that was previously marked (therefore, previously marked devices that are contained in a kit, are a part of a combination product, or are relabeled do not need to be re-marked). In these cases, the reason for not marking the device would be included in the design history file, but notice to FDA would not be required. (Additionally, devices required to be marked that are contained in kits or combination products would not need to bear the same UDI as the kit or combination product label.) Labelers can also choose to mark a UDI on their device that is different from the UDI marked on the label to distinguish the device level from the labeling level.

2.2.3 Exceptions to the Rule

There are a few exceptions to the coverage of the proposed rule. Certain devices[8] would not be subject to the requirement to bear a UDI:

- Class I unit-of-use items (eaches) that are packaged together (e.g., in a shelf pack).[9]
- Custom devices (e.g., those fabricated specifically for an individual patient).
- Other devices that are not in commercial circulation, such as investigational devices, those in research, etc.
- Other exceptions, granted on a case-by-case basis, might be offered by FDA.

[8] In order to be covered by the proposed UDI rule, the item must be regulated as a device. If FDA does not require the item to be listed, it is not a device (e.g., device components, raw materials).

[9] The device package containing these items would need to bear a UDI.

Additionally, kits and combination devices must bear a UDI, but their individual components might meet exceptions from this requirement under certain conditions. For kits, any device within the kit that is intended for more than one single use must bear its own UDI (and if intended to be sterilized, it must be directly marked). However, if it is intended for one single use (e.g., a cotton ball) the item does not need a UDI. For combination products, if the device constituent is physically, chemically, or otherwise combined with other constituents of the combination product in such a way that it is not possible for the device constituent to be used except as part of the use of the combination product, the individual constituents do not need to bear a UDI. Otherwise, they do.

Device packages that themselves contain device packages (in addition to the label on the device itself or the label on the immediate outer packaging of the device) also require UDIs distinct from that on the device packages within them, but shipping containers do not require UDIs. Furthermore, items sold only at retail that bear a UPC are considered to currently meet the UDI requirements (they are allowed, however, to also bear a UDI in addition to the UPC if the labeler chooses to do so).

2.2.4 Issuance of UDIs and Global Unique Identification Database

Either FDA or an accredited agency ("issuing agency") would be authorized to issue UDIs. The proposed rule would require issuing agencies to provide FDA with a variety of information, including how they would ensure the compliance of their system with the requirements of the proposal, in order to be accredited. Renewal applications would also need to be made. FDA would take over issuing of UDIs if warranted (for example, if FDA considers fees charged to small businesses by an issuing agency excessive or to ensure the proper oversight and functioning of the UDI system) and could revoke authorization to issuing agencies, if warranted.

A key requirement of a UDI is that it must not be used to identify more than one version or model of a device (e.g., one UDI cannot be associated with two different models of a device)[10] and only one UDI from an issuing agency must used for each version or model (e.g., two different UDIs from one issuing agency cannot identify one device version or model). However, two or more UDIs, each assigned by two or more issuing agencies, can be used on a label. Generally, the definition of "model or version" is

[10] Additional device packages (packaging configurations with varying numbers of devices within) each are considered a different version or model of device).

left to the labeler, who can continue to define these terms based on catalog number or other trade-based designation, with the following restrictions:

- A change in the specifications, performance, size, or composition of the device to an extent greater than the specified limits requires the device to receive a new UDI.
- A change to the device package (for example, from a package containing 10 devices to one containing 12) or the addition of a new device package would entail a new UDI.
- A change that could significantly affect the safety or effectiveness of the device would require a change in the UDI.
- A change from sterile to non-sterile (or vice versa) would require a change in UDI.
- A device that is relabeled (with a change to a label that entails more than an addition of information such as a distributor's name and contact information) would need to receive a new UDI.

UDIs of discontinued devices could not be used again for any other device, although if the same device is reintroduced unchanged, the former UDI could be reused.

In addition to providing a UDI or UPC on their device labels, all labelers would be required to submit information to FDA specific to each device that bears a UDI or UPC (voluntary users of UDI are not required to submit information but may do so). This information must be provided electronically, unless an exception is made.

FDA would maintain a database of the submitted information, which would be called the Global Unique Device Identification Database (GUDID). The database would be made publicly available, with the exception of device listing number. The information required for submission to the GUDID includes:

- Labeler name and contact information.
- The issuing agency or agencies name(s).
- Information on the model or version of the device.
    - The device identifier portion of the UDI (i.e., the static information).
    - The device identifier previously associated with a device (if a device is relabeled, this would be the manufacturer's original UDI).

- If the device is permanently marked, an indication that the permanent marking is the same UDI as on the label, or, if different, the device identifier marked on the device.
- The brand or trade name of the device.
- The model number, version number, or similar reference that appears on the label of the device.
- Whether the device is sterile or contains natural latex.
- The size of the device (if produced in more than one size; for example, catheters are available in several diameters) and unit of measure.
- Type of production identifier (e.g., batch or serial number).
- Premarket submission number or note of exemption.
- Listing number.
- The Global Medical Device Nomenclature Code (GMDN), which specifies the type of device.[11]
- The total number of individual devices contained in the device package.

Additionally, FDA might permit additional information to be provided voluntarily (ancillary information).

FDA would also require UDIs to be included in device records and reports, such as those required under various device tracking and recordkeeping and reporting regulations (these are the "conforming amendments"). Additionally, the proposed rule adds a paragraph to labeling requirements that standardizes the date format for all labels containing an expiration date, date of manufacture, or any other date. All such dates would be required to be in the format of Month, Day, Year, e.g., (JAN 1, 2012). The date format and conforming amendment provisions would need to be met 90 days after promulgation of the final rule. (The conforming amendment requirements, however, would have no practical effect until UDIs are required to be on labeling.)

[11] Currently the GMDN is managed by an agency that charges a substantial fee for its use. FDA plans to remove the requirement for the GMDN from the rulemaking prior to promulgation if the GMDN information is not free by that time.

SECTION THREE

PROFILE OF THE AFFECTED ENTITIES

3.1 IDENTIFYING THE AFFECTED UNIVERSE OF MEDICAL DEVICE LABELERS

Many different entities handle some aspect of the manufacturing, labeling, and distribution of medical devices. Based on FDA's definition of labeler in the proposed rule, the affected entities are expected to include manufacturers, single-use device reprocessors (which take single use devices, sterilize them, and return them to the end user), specification developers (who oversee the manufacture of devices by contract manufacturers), [12] and relabelers/repackagers (R/Rs).[13] The R/R group includes importers who replace foreign labels with U.S.-approved labels and establishments that package medical devices in kits, break up large packages of unlabeled devices and repackage and label them, etc. The specification developers design the medical devices and provide a contract manufacturer with the exact specifications to manufacture the device. FDA requires all establishments that perform any of these operations on medical devices to register and to list each type of medical device that they handle. This information is compiled into FDA's registration and listing database (FDA, 2010a). The types of entities that must register are shown in Table 3-1. The table indicates which types are considered labelers (and, thus, are considered affected by the proposed rule) and which are not. The rationale for this selection is outlined in Appendix A.

Each registered entity must indicate all of the applicable types of devices it handles by the type of device process in which the entity is involved (e.g., manufacturer, R/R, specification developer). As an example, one entity might manufacture one type of device, remanufacture that same device, import and relabel a second device, and act as a specification developer on a third device. Such an entity would have three unique device listings[14] for the three types of devices it handles, and one listing would indicate two different establishment types (for the one device that the establishment both manufactures and remanufactures). Note that some of the entities considered non-labelers (e.g., a contract manufacturer) might also be classified as a manufacturer or relabeler. Such an entity would be considered a labeler on

[12] The specification developer contracts with the contract manufacturer, who places the label, but the specification developer is the entity considered the party that causes the label to be placed. Therefore, under the definition of labeler, the specification developer is the labeler and the contract manufacturer is not.

[13] Contract labelers and packagers are not subject to the proposed rule. Some FDA registrants are possibly contract labelers and packagers; no adjustments were made to the count of R/Rs to account for these. Actual impacts would fall on the party contracting for the relabeling.

[14] The listing by device type is a broader classification than an individual product; one device listing could relate to dozens of what would be considered different devices under a UDI definition.

the basis of being a manufacturer or relabeler, but not as a contract manufacturer. Therefore, the designation of "non-labeler" applies only to an entity that does not also perform a function that classifies it as a "labeler."

Table 3-1. Affected Entities (Labelers)

FDA Registrant Type	Labeler
Contract Manufacturer	No
Device Sterilizer	No
Exporter to U.S. Only	No
Initial Distributor/Importer	No
Manufacturer	**Yes**
Remanufacturer	No
Relabelers and Repackagers	**Yes**
Reprocessors	**Yes**
Specification Developer Only (no manufacturing)	**Yes**
Manufacture for Export Only	No

Source: FDA, 2010a; ERG estimates.

Specification developers (who are the responsible parties for label information and are considered labelers relative to the definition in the proposed rule) do not manufacture, but are assumed to incur the cost of label changes through cost pass-back from their contract manufacturers. Likewise, specification developers might serve third party labelers (private label distributors, for example), but are assumed to incur the costs of label changes for these parties. This latter assumption might overstate impacts to specification developers (because the majority of label costs might be incurred by the third parties), but would not overstate costs associated with the proposed rule. Specification developers and reprocessors are included in counts of manufacturers because the activities associated with their labeling processes are assumed likely to be similar to those for manufacturers. This entire group (manufacturers, reprocessors, and specification developers) is considered initial labelers.

ERG assumes, however, that non-manufacturing labelers (R/Rs) might have a less complex labeling environment, and alternative assumptions have been made for these entities. Relabelers/repackagers are discussed separately from the manufacturing types of entities. ERG discussions with relabelers/repackagers did not contradict this assumption (see Section Four).

ERG provides a count of foreign establishments broken into the labeling groups in the profile section (Section 3.2 below), but costs to foreign establishments are addressed separately.

3.2 PROFILE OF AFFECTED ESTABLISHMENTS

3.2.1 Manufacturers of Medical Devices

The U.S. medical device industry manufacturing industry is extremely diverse. Medical devices vary dramatically in size, complexity, packaging, and use in medical practices. They include disease screening technologies, therapies, equipment, and supplies—everything from expensive, complex capital equipment (x-ray machines) to simple items (bandages, tongue depressors). Some are packaged individually and others are packaged in boxes of hundreds or thousands. They may be used once and thrown away, used and reprocessed, or used for their lifetimes. Some devices are implanted; these carry a particular set of risks to the patient.

As background for the development of cost estimates, ERG compiled the basic statistics to profile the medical devices manufacturing industry. Table 3-2 and Table 3-3 present U.S. Census Bureau's (2010a,b) 2007 Economic Census information on the medical device industry, as categorized in the North American Industrial Classification System (NAICS). The NAICS shown in the tables are those manufacturing industries expected to be affected by the UDI requirements. Another NAICS category that manufactures medical devices is excluded (Dental Laboratories) because the types of products associated with these establishments are likely to be custom devices or otherwise meet exceptions from the proposed UDI rule.

Table 3-2. Medical Device Manufacturing Industry (2007 Data)

Industry	Companies	Establishments	Value of Shipments ($000)
NACIS 325413, In vitro diagnostic substances manufacturing	201	259	$13,001,194
NAICS 334510, Electromedical and electrotherapeutic apparatus manufacturing	568	660	$22,514,375
NAICS 334517, Irradiation apparatus manufacturing	166	180	$10,772,941
NAICS 339112 Surgical and medical instrument manufacturing	1,174	1,315	$29,616,237
NAICS 339113 Surgical appliance and supplies manufacturing	1,961	2,209	$31,528,866
NAICS 339114, Dental equipment and supplies manufacturing	735	762	$4,368,274
NAICS 339115, Ophthalmic goods manufacturing	519	622	$5,664,577
Total	5,324	6,007	$117,466,464

Source: U.S. Census Bureau, 2010a.

Table 3-3. Number of Medical Device Establishments by Employment Size Class According to Census Bureau (2010b) Data

Industry Code	Industry Code Description	Number of Establishments by Employment Size Class											
		Total Establishments	1-4	5-9	10-19	20-49	Total <50	%<50	50-99	100-249	250-499	500-999	1000 or more
325413	In-Vitro Diagnostic Substance Manufacturing.	244	42	35	31	51	159	65%	27	26	20	6	6
334510	Electromedical and Electrotherapeutic Apparatus Manufacturing	599	182	65	68	100	415	69%	55	63	40	17	9
334517	Irradiation Apparatus Manufacturing	179	52	24	30	25	131	73%	24	10	7	4	3
339112	Surgical and Medical Instrument Manufacturing	1,275	355	185	179	191	910	71%	123	141	61	26	14
339113	Surgical Appliance and Supplies Manufacturing (a)	2,338	794	390	359	325	1868	80%	201	155	78	21	15
339114	Dental Equipment and Supplies Manufacturing	774	333	191	106	74	704	91%	37	22	9	2	0
339115	Ophthalmic Goods Manufacturing	604	249	90	83	87	509	84%	46	31	9	6	3
	Total	6,013	2,007	980	856	853	4,696	78%	513	448	224	82	50

(a) County Business Patterns 2007 data is based on the 2002 NAICS definitions, rather than the 2007 definitions; in the 2007 definitions, the applicable device portion of NAICS 339111 has been merged into NAICS 339113. This table combines the numbers of establishments counted separately for 339111 and 339113 in County Business Patterns into NAICS 339113.
Source: U.S. Census Bureau (2010b).

As the table indicates, there are over 6,000 manufacturing establishments in industries expected to be affected by the proposed rule reported in the 2007 Economic Census. Among these, a large majority (78 percent) are very small establishments, i.e., establishments with fewer than 50 employees (see Table 3-3).

Census data, however, does not correspond exactly with the more precise identification of the affected establishments found in FDA registration data. FDA requires all medical device owner operators of establishments that are involved in the manufacture or distribution of medical devices intended for use in the United States to register, and in most cases, to list the types of devices they handle. ERG investigated FDA's registration database to determine a count of establishments likely to be labeling. This database indicates that 4,901 registrants are U.S. manufacturing establishments (see Appendix A for a detailed description of how the database was used to identify affected establishments and firms). Additionally 4,241 domestic owner operators own manufacturing establishments. All further discussion of affected entities in the remainder of this section focus primarily on domestic firms and establishments.

Neither registrants nor owner operators map precisely to the Census data. Registrants do not map for several reasons. First, we have not considered contract manufacturers in the count of registrants, while Census data places contract manufacturers in the manufacturing NAICS groups. Second, some manufacturers listed in the Census data manufacture only components, not the final device and, thus, do not register and would not be affected by UDI requirements.

Counts of owner operators also do not map to Census firm counts for similar reasons. Some 200 domestic firms with manufacturing establishments own no domestic manufacturing establishments, but only foreign manufacturing establishments. It is also possible that some medical device establishments are not in compliance with FDA registration and listing requirements. Despite this possibility, we judged that the most accurate count of the affected entities is that drawn from the registration data.

The size and industry classifications cannot be determined easily from the FDA data. Therefore, to estimate industry classifications and sizes for the registered establishment, ERG distributed the registrants using the proportions of establishments by industry type and employment size groupings of establishments found in Census data. Table 3-4 presents the numbers of establishments that are registered as manufacturers, reprocessors, repackagers/relabelers, and specification developers according to FDA's database. These establishments are presumed to be the affected labelers that would be subject to a UDI

requirement. Table 3-5 presents the total number of domestic registrants (establishments) identified as manufacturers in FDA's database distributed by NAICS and employment size categories based on Census information as presented in Table 3-3.

Table 3-4. Registrant (Establishment) Counts from FDA's Registration and Listing On-Line Database

Type of Registrant	Total Establishments		Total Registrants
	Domestic	Foreign	
Manufacturers	4,901	6,492	11,393
Reprocessors	21	3	24
Specification Developers	1,346	276	1,622
Relabelers/Repackagers	1,310	320	1,630
Total Labelers	**7,578**	**7,091**	**14,669**
Remanufacturers	49	52	101
Sterilizers	16	49	65
Contract Manufacturers	278	576	854
All Others (distributors, importers, U.S. export only, export only to U.S.	NA	NA	5,453
All Registrants			**21,142**

Note: Two facilities were added to the count of reprocessors. Although FDA's web-based search indicates a firm with two facilities acting as a 3rd party reprocessor, the online database shows the establishments registered but no listings link to these registrations.

Source: FDA Registration & Listing Database, online version, March 4, 2010 (FDA, 2010a). See Appendix A.

Registrants can be traced to owner firms in the FDA database. Table 3-6 presents the numbers of owner firms that are associated with each of the four main labeling types of establishments. Note that there is some double counting of firms when the firms by establishment type have been disaggregated. The total double count is 209 firms.[15] Double counting of firms is adjusted later in this report when costs on a firm basis are estimated (see Section Four). The 4,241 domestic manufacturing firms are distributed using Census information and Small Business Administration (SBA) data into NAICS and employment size categories as shown in Table 3-7.

[15] Later in Section Four, this double count is removed from analyses using assumptions about the percentage of firms affected at each size. The number of double counted firms resulting from using percentages is 210. For simplicity, this number, 210, is used as an approximation of the 209 double counted firms.

Table 3-5. Number of Domestic Medical Device Establishments, Distributed Using 2007 Census Data on NAICS and Establishment Size Class

Establishment Size Class	325413	334510	334517	339112	339113	339114	339115	Total
1 to 4	36	164	43	299	612	267	209	1,630
5 to 9	30	58	20	156	301	153	76	794
10 to 19	27	61	25	151	277	85	70	695
20 to 49	44	90	21	161	251	59	73	698
Total with fewer than 50 employees	**138**	**373**	**107**	**766**	**1,440**	**565**	**428**	**3,817**
Percent of estab. with fewer than 50 emp.	**65%**	**69%**	**73%**	**71%**	**80%**	**91%**	**84%**	**78%**
50 to 99	23	49	20	104	155	30	39	419
Total with 50-99 employees	**23**	**49**	**20**	**104**	**155**	**30**	**39**	**419**
Percent of estab. with 50-99 employees	**11%**	**9%**	**13%**	**10%**	**9%**	**5%**	**8%**	**9%**
100 to 249	23	57	8	119	119	18	26	369
Total with 100-249 employees	**23**	**57**	**8**	**119**	**119**	**18**	**26**	**369**
Percent of estab. with 100-249 employees	**11%**	**11%**	**6%**	**11%**	**7%**	**3%**	**5%**	**8%**
250 to 499	17	36	6	51	60	7	8	185
500 to 999	5	15	3	22	16	2	5	68
1,000 or more	5	8	2	12	12	0	3	42
Total with 250+ employees	**28**	**59**	**11**	**85**	**88**	**9**	**15**	**295**
Percent of estab. with 250+ employees	**13%**	**11%**	**8%**	**8%**	**5%**	**1%**	**3%**	**6%**
Total	**211**	**538**	**147**	**1,073**	**1,802**	**622**	**507**	**4,901**

Source: U,S. Census Bureau, 2010b and FDA's Registration & Listing Database, 2010a.

Table 3-6. Number of Firms with Labeling Establishments in FDA's Registration and Listing Database

Firms	Manufacturers	Reprocessors	Repackagers/ Relabelers	Specification Developers	All Labelers
Domestic	4,241	19	1,212	1,306	6,569
Foreign	5,440	4	330	242	5,915
Total Firms	**9,681**	**23**	**1,542**	**1,548**	**12,484**

Note: Sum of firms by specific establishment types will not add to all labelers because some firms own more than one type of establishment. A total of 209 firms have been double counted. Six firms listed two contact IDs, leading to double-counting when domestic and foreign firms are counted separately. The counts for these six firms were removed from the foreign count but not the domestic count. Additionally, one firm with two establishments was added to the count of reprocessors; FDA's online database did not reflect the same information as the online web search, which did identify the establishments as reprocessing a number of different devices.

Source: FDA Registration & Listing Database, online version, March 4, 2010 (FDA, 2010a). See Appendix A.

3.2.2 Reprocessors of Medical Devices

Another group that would be affected by potential UDI regulations is medical device reprocessors. This is a small group of establishments that reprocess single-use devices (SUDs) for further use by hospitals and other health care entities. The relevant NAICS for this type of operation is judged to be 811219, which according to the Census Bureau includes medical and surgical instrument repair and maintenance. Therefore, the establishments identified as reprocessors are not covered in the count of manufacturers discussed above. Census Bureau data are not provided at this level of product identification (medical and surgical instrument repair and maintenance is not disaggregated because it is a very small portion of the total establishments in this NAICS). Thus, the Census count of such establishments is unknown. ERG used FDA's registration database to determine the current number of medical device reprocessors, whether third party or hospital (see Table 3-4).

ERG had previously prepared a report on reprocessors in 2002 (ERG, 2002), but the review of FDA's database indicates that there have been a number of changes in the industry since that time. The number of firms involved has not changed significantly (although two of the firms listed in the 2002 report have merged to become the dominant firm) and names have changed, either due to entrance and exit or corporate name changes. At the time of that report, hospitals performing in house reprocessing were just beginning to register with FDA. A survey performed by ERG for FDA just after the deadline requiring reprocessing facilities to register noted that at that time about 14 percent of hospitals reprocessed devices in-house. The report noted a trend towards third party reprocessing, which was

Table 3-7. Distribution of Domestic Registrant (Establishment) Owner Firms of Manufacturing Establishments by NAICS and Employment Size Categories

Industry	Companies	Employment Size Categories						
		1-4	5-19	20-99	100-199	200-499	500-999	1000+
NACIS 325413, In vitro diagnostic substances manufacturing	160	38	41	34	13	13	3	18
NAICS 334510, Electromedical and electrotherapeutic apparatus manufacturing	452	141	114	111	23	15	14	34
NAICS 334517, Irradiation apparatus manufacturing	132	45	40	25	7	4	-	12
NAICS 339112 Surgical and medical instrument manufacturing	935	282	270	220	49	44	12	57
NAICS 339113 Surgical appliance and supplies manufacturing	1,562	519	489	340	71	57	25	61
NAICS 339114, Dental equipment and supplies manufacturing	585	244	238	73	12	9	5	4
NAICS 339115, Ophthalmic goods manufacturing	413	186	120	71	14	3	4	15
Total	**4,241**	**1,455**	**1,312**	**873**	**190**	**145**	**63**	**202**

Source: FDA 2010a; U.S. Census Bureau, 2010a (NAICS distribution); SBA, 2006 (employment size categories).

probably due to requirements for hospitals to meet registration and premarket requirements. Only one hospital currently appears in the FDA registry; whether this is due to non-compliance or nearly complete reliance on third party reprocessing is not certain.

According to FDA's registration and listing database, the large majority of establishments that register and list as reprocessors are also manufacturers of medical devices. These facilities, which might be reprocessing their own devices, are assumed to be captured in the count of manufacturers used in this analysis.

Some of the reprocessors repackage and relabel, but as explained in Appendix A, these are counted as reprocessors and are excluded from the R/R counts. Only 21 facilities are registered as domestic reprocessors (and are not manufacturers). There are 19 domestic U.S. firms with reprocessing establishments.

Of these 21 facilities, one is owned by a large not-for-profit hospital chain (which lists only one device). Another seven are third party reprocessors (reprocessing is their main line of business). The remaining facilities appear to reprocess only incidentally. ERG investigated all but the hospital online. Only two do not have a web site. Table 3-8 presents the distribution of reprocessors into employment size classes, using the assumptions indicated in the table. ERG analyzes all initial labelers together in Section Four, applying the estimated per-facility compliance costs for manufacturing establishments to the reprocessing establishments because these initial labeler operations (reprocessing) are considered similar to those for manufacturing establishments.

These 21 domestic facilities are owned by 19 domestic firms. These firms have also been distributed by size class. All but two firms are single facility firms, so their size generally depends on the size of the facility. One firm with two facilities is placed in the 500-999 employment size group. The other firm is assumed to own two establishments in the 20-49 size, creating one fewer firm than the number of establishments in the 20-99 employees firm size (see Table 3-9).

3.2.3 Specification Developers

Specification developers are defined as those that design specifications for medical devices but do not themselves manufacture the devices. Contract manufacturers handle the manufacturing of the devices to those specifications. The ultimate responsibility for the devices, however, rests with the specification

Table 3-8. Distribution of Domestic Reprocessors and Specification Developers (Establishments) by Size

Code	Industry Code Description	Total Establishments	1-4	5-9 (a)	10-19	20-49 (b)	50-99 (c)	100-249 (d)	250-499 (e)	500-999	1000 or more
NA	Single-Use Device Reprocessors	21	0	11	0	2	2	2	4	0	0
	Engineering Services Estabs.	57,726	30,966	9,006	7,897	6,241	2,182	1,060	243	79	52
541330	Percent of Total		54%	16%	14%	11%	4%	2%	0%	0%	0%
NA	Specification Developers (f)	1,346	722	210	184	146	51	25	6	2	1

(a) Eleven reprocessing establishments (those reprocessing incidentally, including the hospital, or with no website) are placed in the 5-9 employee group. Although the hospital is a large establishment, it is assumed that very little of the facility and its employees are engaged in this process, so assignment to this small category is more appropriate in terms of cost estimation.

(b) Two reprocessing establishments primarily engaged in kit assembly are placed in the 20-49 employment size group.

(c) Two reprocessing establishments that characterize themselves as 3rd party reprocessors list approximately half as many devices as those placed in the 100-249 group, so these are placed in the 50-99 employment size group.

(d) Two establishments list approximately half the number of devices as establishments placed in the 250-499 group, so are placed in the 100-249 group.

(e) One reprocessing firm with two establishments indicated 800 persons employed (when the website was reviewed in 2008) and is clearly one of the dominant firms in the group. These two establishments list 52 and 39 devices, respectively, as reprocessed. Each of these establishments is assumed to be in the 250-499 employment group. Two additional establishments (not owned by this firm) list more than 40 device types that they reprocess. Because these two establishments have a similar number of listings as the establishments owned by the large firm, they are considered likely to be of approximately the same size; thus, these two establishments are also placed in the 250-499 employment group.

(f) Specification developers are distributed based on the distribution of establishments among employee size classes in NAICS 541330, Engineering Services as reported in County Business Patterns.

Source: U.S. Census Bureau, 2010b; FDA, 2010a; ERG estimates (see notes above).

Table 3-9. Distribution of Reprocessor and Specification Developer Firms with Total Firms Analyzed as Domestic Initial Labelers

Code	Industry Code Description	Total Firms	1-4	5-19	20-99	100-199	200-499	500-999	1000+
NA	Single-Use Device Reprocessors	19	0	11	3	2	2	1	0
	Engineering Services Estabs.	46,761	27,530	12,562	5,109	664	407	160	329
541330	Percent of Total		59%	27%	11%	1%	1%	0%	1%
NA	Specification Developers	1,306	769	351	143	19	11	4	9
NA	Total Manufacturers	4,241	1,455	1,312	873	190	145	63	202
NA	**All Initial Labelers**	**5,566**	**2,224**	**1,674**	**1,019**	**210**	**159**	**68**	**212**

Source: FDA, 2010a; U.S. Census Bureau, 2010b.

developer. It is these establishments that are required to keep the device records, including labeling records. Some specification development is done under the specification developer's brand; other times, specification developers are contracted by private label distributors to provide the specifications and coordinate the manufacturing of the device to those specifications. Distributors are not allowed to list devices in FDA's database, however, and do not keep the device records. In the first case, where the specification developer and the contract manufacturer are the only parties involved, we assume that the costs of labeling are ultimately borne by the specification developer. In the second case, where a third party private labeler is involved, it is still assumed that the specification developer is the UDI labeler of record and incurs the immediate costs of any UDI requirements. Some of these costs might be passed to the third-party private labeler or the labeler might handle the actual label application and thereby incur costs. Nevertheless, we assume that the specification developers bear the costs and impacts because there is no way to clearly determine the extent of third-party interactions.

FDA's database indicates that there are 1,346 domestic specification development establishments and 1,306 U.S. firms with specification development establishments. (These counts do not include manufacturers or reprocessors, which might also be classified as specification developers).

The specification developers appear to be classified in NAICS 541330, Engineering Services. The 1,346 domestic specification developer establishments are distributed into employment size classes based on the distributions in this NAICS in County Business Patterns (U.S. Census Bureau, 2010). These establishments, as initial labelers, will be analyzed with manufacturers because it is assumed specification developers would have similar complexities of labeling and recordkeeping as manufacturers. The distribution of these establishments can be seen in Table 3-8. Domestic firms owning specification developers are also distributed on the basis of employment size, as shown in Table 3-9.

3.2.4 Repackagers and Relabelers of Medical Devices

A UDI requirement would also apply to R/Rs of medical devices, many of which also manufacture medical devices. Many relabeling establishments are also involved in initial labeling and are captured in the count of manufacturers shown in Table 3-5 or in counts of reprocessors or specification developers. Nevertheless, some R/Rs do no manufacturing, reprocessing, or specification development and are additional to the count of affected establishments estimated above. As Table 3-4 showed, ERG identified 1,310 domestic establishments that were not captured as manufacturing, reprocessing, or

specification development establishments and are included in the estimates of those affected by the proposed UDI rulemaking.

To develop additional information on these R/R establishments, using a previously generated list of registrants (from 2008), ERG randomly selected 16 R/Rs and investigated their Internet websites to determine if they had company websites and/or product catalogs. ERG also contacted several of these establishments, as discussed below. For the most part, the R/R establishments appeared to be medical device distributors (wholesalers), although some distributed medical devices as an adjunct to manufacturing operations. Additionally, a few were contract packager/labelers in addition to repackaging or relabeling at least one device.

Of the 16 establishments investigated online, 6 indicated they were very small or handled very few products (fewer than about 20 different devices; in one case one of the establishments appeared to handle only one product with only a few SKUs). Three establishments apparently had no websites, thus were likely to be very small establishments as well. Four were establishments associated with large or very large firms, or handled a large number of different devices. The websites associated with the firm names indicated that they handled hundreds to thousands of different medical devices. One establishment contacted by ERG indicated the establishment actually did no repackaging/relabeling. The remaining two included a turnkey packaging/labeling firm and an establishment with a one-page website that simply stated that they were a medical device distributor and indicated what types of devices they carried.

On the basis of the information gathered in this search, as well as observations about the establishments listed in FDA's database, ERG categorized R/Rs into several major groups:

- Establishments affiliated with manufacturers, where the establishment appears to be a distribution center/warehouse for the manufacturer. For example, four establishments in four locations are listed with the name BD Distribution Center. These establishments, registered as R/Rs only, are assumed to be owned by the manufacturer Becton Dickinson.

- Establishments that import and repackage and/or relabel devices. Johnson & Johnson lists an establishment in Puerto Rico, for example, that is registered in this category.

- Establishments listed as specification developers/importers/relabelers or repackagers, one of which was contacted by ERG. This establishment contracts out to foreign manufacturing establishments and imports the devices. These are delivered labeled, but sometimes require relabeling due to transportation damage (not "true" relabeling) or in order to be packaged as kits. For the analysis in Section Four, however, this establishment would be counted as a specification developer.

- Wholesale distributors handling a variety of manufacturers' products who prepare kits compiled from several different devices or who repackage and/or relabel a device under their own brand. For example, ERG contacted one such distributor who creates kits on order using various orthodontic components from several manufacturers to complete an entire set of orthodontic braces for delivery to orthodontists (this distributor would meet an exception as a custom operation, however).

- Wholesale distributors handling a variety of manufacturer's products who repackage and relabel bulk manufacturing lots into smaller lots for sale to hospitals, pharmacies, or others (possibly with their own label).

- Custom packaging and labeling establishments who handle packaging and labeling services for medical device manufacturers as an outside service, among many other types of customers. ERG contacted one of these establishments, which has in the past packaged and labeled medical devices on custom order, but was not currently doing so (such relabeling is also not considered "true" relabeling).

The registration database could generate an over-count of establishments that repackage and relabel. As noted above, ERG contacted one distributor of medical supplies (including infection control supplies and syringes), who indicated that they did not relabel or repackage medical supplies and had no idea why they were registered. Additionally, some R/Rs (such as the one relabeling due to damage and contract R/Rs) might not actually be changing the information on the label or are applying a label under direction from another party, but they think they need to register and list because they physically apply or reapply a label. Conversely, it is also possible that not all R/Rs register with FDA, even though they are required to register.

To develop the distribution of R/R establishments by size, ERG assumed that the size distribution would be similar to those in U.S. Census Bureau (2010b) County Business Patterns with data from 2007, under NAICS 42345 (Medical, Dental, and Hospital Equipment Supplies Merchant Wholesalers), and under NAICS 42346 (Ophthalmic Goods Merchant Wholesalers). ERG distributed the 1,310 domestic R/Rs into employment size categories as shown in Table 3-10. There are also a total of 1,212 domestic firms owning R/Rs. These firms were distributed on the basis of employment size as shown in Table 3-11.

Table 3-10. Industry Size Distributions for Domestic R/Rs Based on 2007 Census Data

Type of Industry (a)	Numbers of Establishments							
	Total	**1-4**	**5-9**	**10-49**	**50-99**	**100-249**	**250-499**	**>500**
Hospital Equipment & Supplies	8,578	4,856	1,365	1,779	310	177	60	31
Ophthalmic Goods	1,319	708	240	278	46	32	13	2
Total	9,897	5,564	1,605	2,057	356	209	73	33
Percent of Total	-	56.2%	16.2%	20.8%	3.6%	2.1%	0.7%	0.3%
Distribution	1,310	736	212	272	47	28	10	4

(a) The industries that are used to distribute the R/Rs identified in FDA's registration database are the Medical, Dental and Hospital Supplies Merchant Wholesalers Industry (NAICS 42345) and the Ophthalmic Goods Merchant Wholesalers Industry (NAICS 42346).

Source: U.S. Census Bureau, 2010b; FDA, 2010a.

Table 3-11. Distribution of Domestic R/R Firms by Employment Size

Type of Industry (a)	Numbers of Firms by Employment Size				
	Total	**1-4**	**5-19**	**20-499**	**>500**
Hospital Equipment & Supplies	7,031	4,282	1,811	795	143
Ophthalmic Goods	1,075	579	313	165	18
Total	8,106	4,861	2,124	960	161
Percent of Total	-	60.0%	26.2%	11.8%	2.0%
Distribution	1,212	727	318	144	24

(a) The industries that are used to distribute the R/R firms identified in FDA's registration database are the Medical, Dental and Hospital Supplies Merchant Wholesalers Industry (NAICS 42345) and the Ophthalmic Goods Merchant Wholesalers Industry (NAICS 42346).

Source: U.S. Census Bureau, 2010b; FDA, 2010a, SBA, 2006.

SECTION FOUR

DIRECT REGULATORY COSTS

4.1 INTRODUCTION

This section presents the estimated costs to implement UDI under the proposed rule. Section Five discusses economic impacts, Section Six discusses the costs associated with several regulatory alternatives that FDA also considered, Section Seven presents costs and impacts to small businesses, and Section Eight discusses the uncertainty analysis.

4.2 KEY COSTING ASSUMPTIONS

4.2.1 Assumptions—UDI Structure

The proposed rule endeavors to incorporate current practices into regulatory requirements, where possible. For example, the proposed rule incorporates current industry practices for assigning production identifiers, such as lot and batch numbers. Thus, medical device labelers will not need to change how they identify their devices or groups of devices (e.g., those who use lot numbers would not be required to switch to serial numbers). However, for those labelers using a date identifier as their production identifier, format changes to production identifiers resulting from the date format change requirement could have some impact on the assignment of those production identifiers. The number of establishments that might be affected and the extent to which this affects operations is unknown; this issue is considered in the uncertainty analysis in Section Eight.

At this time it is expected that GS1 and the Health Industries Business Communication Council (HIBCC) are likely to apply to become accredited issuing agencies for the UDI. Other agencies also might apply, but no other agencies at the present time are known to have the ability to provide such a service. These two organizations assign establishment identification numbers and have allocation rules for device product codes, and these are the basis for the static portion of the UDI. Both numbering systems also allow for the variable production information to be included in the numbering system, and both use existing barcoding standards (including those for both linear and 2-D barcoding). The two organizations coordinate data for trading partners for the efficient operation of the entire goods supply chain (from manufacturer, through distributor, to end user). GS1 covers all types of trade items (and is the issuer of retail UPCs), while HIBCC covers health-related trade items.

Given the above, ERG assumes that the assignment of HIBCC Health Industry Bar Code (HIBC) numbering and GS1 Global Trade Identification Numbers (GTIN) would remain as currently practiced and all allocation rules currently in use would be the basis for determining the appropriate UDI for a particular device or device package. The HIBCC numbering system is flexible, so the proposed rule's requirements are compatible with that system. Additionally, the proposed rule's requirements concerning when a new UDI must be or must not be issued is generally consistent with number allocation rules currently mandated by GS1. The proposed requirements are also consistent with DOD's Universal Product Numbers (UPNs), which are a combination of either the GTIN or the HIBC number (i.e., UPN is consistent with the static portion of the UDI). The assumptions discussed below build on the assumption that these two organizations would become accredited issuing agencies.

4.2.2 Assumptions—Baseline Compliance and Exceptions from the Proposed Rule

The following assumptions are used in assessing who would be incrementally affected by the proposed rule:

- The proposed rule accommodates the voluntary placement of UDI on labels and submission of data to the GUDID prior to the proposed implementation dates. To avoid understating costs, however, ERG assumes that no labelers voluntarily apply UDIs to labels and submit data to the GUDID before they are required to (although many labelers might choose to do so).

- FDA has made exceptions for certain types of devices. Therefore, ERG excludes custom device manufacturers and R&D establishments from the analysis of the proposed rule. These establishments are further assumed to be among the smallest establishments (those with 1 to 4 employees or 5 to 9 employees). ERG assumes that 70 percent of establishments with 1 to 4 employees and 30 percent of establishments with 5 to 9 employees would not be required to create UDIs or display barcodes on labels because they manufacture custom devices or are R&D establishments. Additionally, any item not required to be listed by FDA is not considered to be a device and, therefore, is assumed not to be subject to the proposed rule (e.g., raw materials and components of devices that are used only to make those devices and are not separately marketed).

- Some small labelers are assumed to exclusively label devices with UPCs and distribute to retail outlets only. Therefore, they would be in compliance with the proposed rule requirements already. This number is not known. Thus, only 10 percent of manufacturers in the 1-4 and 5-9 employment size groups (among those not already assumed to meet an exception as custom manufacturers and R&D establishments) are assumed to meet the UDI requirement because all their products have UPCs and are only sold at retail. Larger labelers, even if they label some devices for retail, are assumed to label a mix of retail and wholesale devices. Therefore, none of these larger labelers is estimated to meet UDI requirements by labeling with UPCs on all products.

- ERG assumes that 99 percent of large manufacturing firms[16] (500 or more employees), 95 percent of medium labeling establishments (20 to 499 employees) and 85 percent of small labeling firms (those with less than 20 employees)[17] already have GTIN or HIBC numbers and therefore do not need to apply to GS1 or HIBCC to number their current products . Even though fewer than these are assumed to barcode this information on their labels, the lack of current barcoding is not assumed to indicate a lack of registration with HIBCC and GS1. This estimate is based on conversations with representatives of MediCal, who found, in the course of a trial program involving the identification of medical devices, that virtually all of their suppliers had a UPN (which requires registration), but did not place a barcode on their labels and did not necessarily even know that they had a UPN (Rivera, 2009). ERG also spoke with an AdvaMed representative, who indicated that most manufacturers are generally holding off on any labeling changes such as adding barcodes, awaiting a UDI rule (Secunda, 2010), so they might have registered with GS1 or HIBCC but do not plan to add barcodes until they know more about FDA's course of action. Furthermore, ERG spoke with a HIBCC representative (Hankin, 2010), who indicated that he thought nearly all large firms and most small firms were registered with either HIBCC or GS1.

- It would be possible under the proposed regulation for one specific device to have several UDIs from the same issuing agency, due to requirements to distinguish devices only for trade purposes or because of FDA requirements. ERG is assuming that labelers would make the decision of how to define a device model relative to their usual practices for trade purposes. Labelers must often make distinctions among models that are necessary for trade purposes but are inconsequential for medical purposes and for which FDA does not require notification. For example, a minor appearance variation such as color could necessitate a different GTIN or HIBC appearing on the same device for trade purposes. Also, FDA would require and, in nearly all cases, labelers use different identifiers on different packaging configurations of the same device, and FDA allows two or more UDIs from two different issuing agencies (or a UDI and a UPC) to appear on one label. Links to the original device UDI are assumed to be set up using required data within the GUDID, so labelers could continue their current practices if they label with GTINs or HIBCs. Therefore, no costs for overcoming inconsistencies with current practices are assumed.

4.2.3 Assumptions—Display of UDI on Label

Medical devices can have multiple levels of labeling and packaging. A label can be directly applied to a device (for example, a monitor) or identification information can be marked directly onto a device. A label might appear on packaging surrounding the device (e.g., a package containing a catheter, which is not itself directly marked). Packaging that contains multiples of the same Class I device (e.g., a package of 25 examining gloves contained in a shelf pack that are not individually labeled) might be labeled. Additionally, the package of 25 examining gloves might also be grouped into packages

[16] Firms apply for registrations, so all registration assumptions are made on a firm basis.

[17] Excluding those who meet exceptions as custom manufacturers or who are assumed to use only UPCs for retail trade.

containing 10 packages of 25-glove packages, which would also be labeled. There are also packages containing different groups of devices or a device and a drug (a kit or a combination product). Labels are also applied to various levels of shipping containers, crates, and pallets.

FDA has specified three levels of labeling or packaging on which a label containing a UDI might appear. These are:

- The device itself (permanently affixed label or directly marked).
- The device label, which is the label on the package containing the individual device or a group of Class I devices (a shelf pack with unlabeled devices within).
- The device package, which contains one or more labeled devices (for example a shelf pack of individually packaged and labeled devices). (Note that if the label on the immediate device package contains the UDI, that device package is considered to have a UDI on the label and on the device package.)

FDA would not require shipping containers to be labeled with a UDI. Shipping containers are those collections of device packages that are not identified as a unit for sale, but are grouped together for transportation purposes and which could contain variable numbers of devices or even different types of devices every time a shipment is made.

ERG notes the following key concepts or makes the following assumptions about UDI placement:

- Except for items requiring direct marking and three other possible exceptions, no new levels of labeling would be required. For example, because FDA would allow shelf packs to contain multiple identical Class I devices that are not labeled with a UDI, ERG assumes that a UDI can be added to existing labeling on the shelf pack and the items within the shelf pack would not require a new label with a UDI. The following exceptions to a no new level of labeling assumption might apply, however. These exceptions are discussed within ERG's uncertainty analysis (Section Eight):
    - There might be some Class II devices that are currently included within shelf packs without individual labeling. The number of such occurrences is unknown.
    - There might be devices within a combination product that are not integral to the combination product. If a device is physically separable from a combination product that is regulated as a device, a UDI would be required on the device label. It is not certain how many such devices exist and whether there are any such separable devices that are not currently labeled separately within a combination product.
    - Kits are assumed to contain some items with a UDI and some without. The kit would require a UDI on the level at which the kit or combination product is

labeled, but some items (e.g., components labeled for individual use as well) might also have a UDI below the level of the label identifying the kit or combination product. Items intended only for one use (bandage, cottonball, examining gloves, etc.) would not need to be individually labeled, thus when unlabeled shelf pack items are removed from the shelf pack, in most cases, they would require no additional labeling. However, devices packaged in a kit that are intended to be used more than once would be required to be labeled with a UDI. Other than for multiple-use devices packaged within a kit (which must be directly marked with the UDI on the device by the initial labeler, if they are intended for sterilization), the proposed rule would not require additional labeling if a label is not currently present. The extent to which multiple-use devices that are not directly marked or that are not already separately labeled is not known.

- If each individual device within a device package is individually labeled, the manufacturer would place the UDI on this label, and the device package containing multiples of the individually labeled devices would also require another, different UDI. This device package containing multiple device packages is likely not to have a production identifier associated with it, so a static barcode is assumed to be used at this level of packaging (the label would need only a one-time redesign).

- ERG estimates that 80 percent of implant manufacturers and 75 percent of manufacturers of multi- use devices intended to be sterilized currently mark their devices in some manner. Of those who do not mark, 15 percent of implant manufacturers and 5 percent of multi-use manufacturers are assumed to be unable to mark the device or to claim health and safety issues. These labelers would need to file an exception and notify FDA. Those simply needing to file an exception in the design history file (e.g., relabelers of devices already directly marked) are assumed to do so at a negligible cost.

- ERG assumes that when FDA specifies that a UDI must be directly marked on certain devices either in an easily read plain-text or a machine-readable format, if the size of the device makes it technologically infeasible to provide a machine-readable format, any plain-text UDI applied in that same space would not be easily readable. Therefore, the labeler of such a device would not be required to mark such a device with either a machine-readable or a plain-text UDI. This labeler would notify FDA and insert this reason (technologically infeasible due to size of device) in the device history record.

- ERG assumes that FDA would not require packaging already on shelves prior to the implementation date to be relabeled.

4.2.4 Assumptions—Barcoding Used to Represent UDI

The overall implication of the assumptions above is that FDA would allow the issuing agencies and labelers to maintain nearly all of their current practices (with the exception of reusing UDIs after a device has been discontinued), including barcoding. ERG makes the following assumptions about barcoding used to represent UDI:

- ERG assumes that the symbologies used to represent the UDI on labels are those that are currently used for trade purposes (standard linear or 2-D barcodes). These barcode systems also allow for the representation of human readable numbers below or above the barcode itself.

- The barcode standards used would be GS1-128 (formerly EAN-128), Code 39, or another standard accepted by GS1 or HIBCC, using either GS1 or HIBCC numbering systems (the GTIN or HIBC); proprietary standards would not be permitted. Additionally, manufacturers could freely choose either numbering system (GS1, HIBCC, or both), depending on their choice of UDI issuing agency. Virtually all manufacturers currently barcoding their devices use either the GS1 or HIBCC systems. Thus, these assumptions imply that the vast majority of manufacturers that already have barcodes in place would not need to change their current manufacturer code, product codes, or the manner in which they assign lot numbers or serial numbers. They would also not need to change their method of encoding the barcode.

- ERG assumes that the use of primary and secondary barcodes would be acceptable. FDA does not specify the placement of the barcode and does not specifically prohibit in the proposed rule the use of primary and secondary barcodes to provide static and variable information separately on the label. Therefore, two barcodes, one representing the static information and one representing the variable information are assumed able to be placed separately on a label. This allows labelers to facilitate preprinted labeling of static information with an additional, changeable label for variable information or to keep existing package configurations where length of a barcode might be problematic.

- A small number of labelers are assumed to currently meet some of the requirements of a UDI (i.e., they include their establishment and product identifier in a GTIN or HIBC barcode on at least one level of labeling). An AdvaMed representative (Secunda, 2010) indicated that most manufacturers are generally holding off on any labeling changes awaiting a UDI rule. Estimates based on an older AdvaMed survey of barcoding practices (AdvaMed, 2004) were used to determine prevalence of any barcoding of GTIN or HIBC information. This survey indicated that approximately two-thirds of larger establishments currently barcode. However, ERG contacts with industry (see Appendix B) indicated that most of these firms do not barcode their variable information. ERG has assumed that of the two-thirds of larger manufacturers who do some form of barcoding, only 15 percent barcode with variable information and smaller manufacturers do no variable barcoding. These assumptions result in an assumption that only 3 percent of all manufacturers use variable barcoding on their labels, and these are larger manufacturers.

- ERG assumes that radio frequency identification (RFID) would be chosen voluntarily for reasons other than those imposed by FDA. Therefore, no incremental costs are included to reflect the greater costs of placing RFID data rather than barcodes on labeling.

- ERG assumes the date formats required to appear on labels refer only to dates imprinted separately from the UDI; date formats for the UDI barcode and numbering system are assumed to be allowed to remain as specified by the issuing agencies.

4.2.5 Assumptions—Incremental Costs Due to the Proposed Rule

The following assumptions affect how incremental costs of the proposed rule are estimated:

- Only one number and barcode are assumed to be required for both trade and UDI purposes on each device package or label.

- Although some manufacturers are assumed to fully meet the UDI requirements (that is, they also include production identifiers such as lot or serial number on their labeling using the GS1 or HIBCC barcoding conventions or label with UPCs for retail only), the new requirements for standardizing human readable dates on labeling means that all current device labels would need revision for one reason or another relating to the proposed rule.

- Because the date format requirement would need to be met within 90 days, all label redesign changes and any material costs associated with increase label sizes or packaging changes, are assumed, for simplicity, to be done during this time. That is, in addition to redoing the dates on the label or package, the space required for the UDI presentation would also be designed, although the UDI itself would not be printed. The assumption that all establishments would need to change their labels due to the date format change is very conservative and is discussed in the uncertainty analysis (Section Eight).

- Other provisions requiring certain records and reports to contain the UDI, even though they are required to be implemented in 90 days, would not have any practical application until UDIs are available. Thus, this provision is assumed not to force assignment of UDIs before labeling requirements must be met. ERG also assumes that placeholders for UDI do not have to be contained in these records and reports until UDIs must appear on labels. That is, the records and reports do not need to be redesigned until the UDI is available.

- Because GS1 and HIBCC currently allow for reuse of product codes after a period of time, but FDA would not, labelers would need to apply for more product codes (incurring a greater cost under the GS1 system) than is currently the case over the 10-year period used in this costing analysis. ERG assumes that there could be incremental costs associated with product codes that cannot be reused. GS1 allows product codes to be reused for a different product after a certain number of years and GS1 registers the majority of health care labelers currently using barcodes. The number of such incremental UDIs required cannot be estimated. Furthermore, HIBCC does not charge a fee for additional product numbers, so in some instances there will be no incremental costs. ERG assumes such incremental costs are small and does not estimate a cost for product codes that cannot be reused.

- ERG assumes that labelers would not have to file a supplement when adding a UDI to their labels or changing the date format of their labels, assuming no other label changes are made, because a supplement is only needed when the label change has some effect on the health or safety of the device (e.g., a change to indications for use).

4.3 COSTS TO AFFECTED ENTITIES

This section presents costs to the four major groups of labelers: manufacturers, reprocessors, specification developers, and relabelers/repackagers, as well as to UDI issuing agencies. The costs in the following subsections are estimated under an assumption that UDI requirements must be implemented immediately. Costs to initial labelers (manufacturers, reprocessors, and specification developers) are discussed first (Section 4.3.1). Costs to R/Rs, because they are assumed to have somewhat less complex processes than initial labelers, are presented separately in Section 4.3.2. Total costs to all domestic labelers are presented in Section 4.3.3, and Section 4.3.4 discusses the costs to UDI issuing agencies. Section 4.3.5 presents the total costs to all domestic entities under the immediate implementation scenario, and Section 4.3.6 adds in costs to foreign firms and establishments.

4.3.1 Cost Estimate for Manufacturers, Reprocessors, and Specification Developers

The exceptions to and current compliance with the proposed rulemaking affect cost assumptions throughout the rest of this section. As a first step in estimating costs for manufacturers, reprocessors, and specification developers, ERG needed to remove an estimated number of establishments believed to be handling custom devices (which meet an exception from the proposed rule). As noted earlier, ERG assumes that 70 percent of establishments with 1 to 4 employees and 30 percent of establishments with 5 to 9 employees would not be required to create UDIs or display barcodes on labels because they manufacture devices subject to the general exceptions to the proposed rule, such as for custom devices. Reprocessors and specification developers, however, are assumed not to be handling only custom (i.e., excepted) devices.[18] Based on the above assumptions, ERG calculates that 1,379 of these very small establishments with fewer than 10 employees are involved in manufacturing custom devices and therefore would not be subject to the proposed rule. As noted earlier, ERG also assumes that 10 percent of the remaining 1,045 very small establishments are supplying medical devices only to retail establishments, are exclusively using UPCs on their labels, and, thus, are meeting UDI labeling requirements already (105 establishments).

Additionally, ERG judges that there is some baseline compliance with the proposed rule. Based on assumptions discussed earlier and information discussed below, baseline compliance with the proposed rulemaking is judged to be relatively small. About 3 percent of all manufacturers are currently

[18] Custom devices are expected to be the major group of excepted devices. When custom device exceptions are noted, ERG intends that the discussion refers to all excepted devices.

estimated to have installed appropriate equipment to fully implement the UDI concept as defined by the proposed rulemaking (discussed more fully in Section 4.3.1.1). These manufacturers might need to make minor modifications to their administrative systems but are assumed to essentially have absorbed the costs for complying with the regulation. Reprocessors and specification developers are assumed not to have implemented any portion of UDI requirements.

To determine the appropriate assumptions to define the current baseline, ERG's first step was to determine the extent to which medical device manufacturers have already implemented a system that incorporates both static and variable device identifiers. ERG contacted a number of medical device facilities and participated in industry meetings regarding unique device identification systems. ERG also reviewed the most common industry practices with a variety of industry consultants and with vendors of label printing equipment.

ERG also obtained input by considering the experiences of manufacturers who are subject to the DOD purchasing requirements for uniquely identified equipment. However, most of these manufacturers are not making medical devices, and the DOD requirement is limited to equipment with a unit acquisition cost of $5,000 or more. Thus, while the DOD experiences are of interest, they must be considered in the more limited context of their use.

Most information gained from the manufacturer interviews relates to the capital investments required to comply with a UDI requirement. See Appendix B for details of these manufacturer interviews. ERG concluded that most medical device manufacturers have little experience with the UDI concept as envisioned under the proposed rule (dynamic barcodes linked to manufacturer, product, and variable production data) and have not studied or invested in the internal infrastructure needed to implement such systems. Some of the larger device manufacturers, however, have considered, and some have even implemented the UDI concept as currently proposed. The breakdown of the percentages by size of establishment is discussed in more detail in Section 4.3.1.1.

The unit costs of developing and installing a UDI capability cover the costs for manufacturers to go from the lowest level of compliance (no static or dynamic barcoding) to meeting the requirements of the proposed rule. Based on the conversations with medical device manufacturers, ERG expects that in order to develop UDI capability, manufacturers that do not currently barcode either static or dynamic information must undertake the following steps:

- **UDI Plan Development—**Develop a facility plan for implementing UDI and prepare new or modified Standard Operating Procedures (SOPs) to meet FDA's Quality System regulation defining the medical device good manufacturing practices (GMPs);

- **Register Barcode—**Apply for registration with GS1 or HIBCC.

- **Purchase Equipment**—Select and purchase equipment to print or place the UDI on product labels and packages and verify the quality of the UDI marking.

- **Direct Mark**—Select and purchase equipment to etch or otherwise permanently mark selected devices or apply for an exception, if applicable.

- **Relabel**—Redesign and print labels (or add a supplementary label) to replace or add to labels that do not contain

    - Any barcodes,
    - Variable barcodes, or
    - Correct date formats.

- **Data Integration**—Integrate the UDI data into information systems, including all device records required by FDA to be kept.

- **Recordkeeping and Reporting**—Provide initial information and ongoing updates to the GUDID.

The costs associated with these elements are described in the sections below. Note that in *all* tables that present numbers of firms or establishments, these numbers have been calculated based on percentage distributions by industry and size. These numbers of entities have *not* been rounded even though they are shown as whole numbers. For this reason, total costs that are calculated manually might not exactly match the totals shown in the tables. Additionally, all costs presented up to Section 4.3.6 are for domestic establishments only.

4.3.1.1 UDI Planning Costs

ERG modeled the administrative and planning costs that might be incurred in developing the basic UDI capability. Although the estimates provided during manufacturer interviews are useful, the estimates of administrative costs provided were generally mixed with various other company initiatives; therefore, potential regulatory costs were difficult to isolate using manufacturers' estimates of such costs.

ERG's goal for the modeling effort is to express the possible magnitude of costs incurred for any mandatory regulatory action requiring UDI for medical devices. There appear to be a variety of possible

modes of response for manufacturers and, thus, the costs to implement these systems are problematic to forecast.

Taking into account our discussions with manufacturers, combined with our assessment of which tasks comprise potential regulatory costs, ERG developed an estimate of the hours needed for smaller establishments to comply with the UDI requirement. As noted in Table 4-1, ERG assumed that small establishments (i.e., those with 10 to 99 employees) would require approximately 120 hours for planning UDI implementation. These hours include the time needed for basic planning activities, such as those for understanding the UDI requirements as they might affect the establishment (10 hours), preparing a basic plan for implementation (80 hours), and preparing new or modified Standard Operating Procedures (SOPs) governing new labeling practices (30 hours). ERG assumed that the administrative costs would vary with the size of the establishment. Thus, ERG used the hours estimated for this size class of establishment as the basis for estimating hours for all other employment size groups.

For establishments with 5 to 9 employees, ERG allotted one-half of the basic planning hours estimated for the 10 to 99 employment size group, or 60 hours. For most of these establishments, ERG judged that their production activities were sufficiently limited as to simplify the UDI compliance requirements. Those in the 1 to 4 employee size range were considered to have even simpler planning requirements and were assumed to need 30 hours to plan for UDI.

ERG judged that medium and large establishments would require more planning time than the 120 hours allocated to the 10 to 99 employee size group. As a result, ERG multiplied the small establishment allotment by 2, 4 and 6 to represent costs for the larger establishments, respectively. The larger establishments are likely to manufacture more products on multiple production lines and would need to revise or write additional SOPs. The larger establishments also generate some further organizational complexity requiring additional internal communication and organization costs. Using management occupations from the Bureau of Labor Statistics and identifying representative wage rates for the affected industries, ERG estimated that the cost per hour for planning and administrative tasks was about $75/hour (including a fringe benefit rate of 29 percent). ERG applied this figure to the hours estimated for these tasks to produce costs ranging from approximately $2,250 for the smallest establishments (1 to 4 employees) to $54,000 for the largest medical device establishments (500+ employees) (BLS, 2009; BLS 2010).

Table 4-1. First Year Administrative and Planning Costs per Establishment by Employee Size Class

Hours for Small Estab. (a)	Hourly Wage Rate with Benefits	Establishment First Year Cost by Size Class						
		1-4 (c)	5-9 (c)	10-49	50-99	100-249	250-499	500+
		(0.25 Times)	(0.50 Times)	(1 Times)	(1 Times)	(2 Times)	(4 Times)	(6 Times)
120	$75	$2,250	$4,500	$9,000	$9,000	$18,000	$36,000	$54,000

(a) Hours applicable to smallest size medical device establishment (10-99 employees).

(b) Based on the median hourly wage rate for management occupations in NAICS 3391 (BLS, 2009). Benefits are calculated at 29% of wages (BLS, 2010). Hourly wage rates do not vary substantially among the relevant NAICS; the wage rate for NAICS 3391 has been used for simplicity.

(c) The smallest establishments are judged to require one-half of the planning hours for compliance in the 5-9 employees group and one-quarter of the compliance time at the 1-4 employees group. Compliance would be largely manual for such firms and compliance actions would involve fewer technological and equipment decisions.

Source: BLS, 2010, Employer Costs for Employee Compensation; BLS, 2009; ERG estimates.

Even labelers whose devices meet exceptions would, at a minimum, however, need to read and understand the rule to the point that they can determine that they are not covered by the rule. Therefore, ERG assumes that these smallest establishments whose devices meet exceptions would incur costs associated with 2.5 hours for a manager to understand the rule (which is half the 5 hours assumed for the smallest affected establishments to read and understand the rule). Therefore, the costs shown in Table 4-2 for the 1 to 4 and 5 to 9 employee groups reflect the addition of 2.5 hours at $75 per hour for all establishments that are assumed not to be further affected by any of the rule requirements (1,379 establishments). The estimated 105 UPC labelers are also assumed to incur the 2.5 hours to read and understand the rule given the minimal effect the proposed rule would have on them (their date formats might need changing and they would need to upload their device information into the GUDID). Also incorporated into the costs calculated in Table 4-2 is the assumption that a small share of affected manufacturers currently barcode using variable information. ERG made several judgments about the level of current compliance by size of establishment. Specifically, ERG estimated that virtually none of the 2,333 affected manufacturers with fewer than 50 employees currently barcode with variable information. For the 1,084 larger firms with 50 or more employees, ERG relied on AdvaMed information (AdvaMed, 2004) that two-thirds of larger manufacturers (i.e., 723) currently barcode identification information using either static or variable formats.

ERG further assumes that 15 percent of these two-thirds barcode with variable information. When 15 percent of two-thirds of establishments are assumed to barcode with variable information, the overall percentage assumed to be barcoding variable information among all establishments in the 50+ employee size group is 10 percent. ERG distributed this 10 percent among the larger establishments, while assuming variable barcoding is more common as establishment size increases, by assuming 5 percent of those with 50 to 99 employees, 10 percent of those with 100 to 249 employees, 15 percent of those with 250 to 499 employees, and 20 percent of those with 500 or more employees are currently barcode using variable information.[19] These assumptions result in an estimated 108 manufacturing establishments out of 3,417 establishments (3 percent) that do not meet exceptions to or are not already meeting the proposed rule due to use of UPCs (4,901 total manufacturers minus 1,379 establishments with custom devices minus 105 establishments using only UPCs equals 3,417 establishments). The overall percentage (3 percent) is small because of the assumption that none of the establishments with fewer than 50

[19] No specification developers or reprocessors are assumed to be using variable barcodes currently.

Table 4-2. Aggregate Cost of UDI Plan Development

Establishment Type	Number of Establishments, by Size Class								Establishment First-Year Costs, by Size Class							Aggregate Costs
	1-4	5-9	10-49	50-99	100-249	250-499	500+	Total	1-4	5-9	10-49	50-99	100-249	250-499	500+	
325413	10	19	71	23	23	17	10	174	$27,076	$88,035	$639,136	$200,363	$366,464	$533,913	$453,631	$2,308,618
334510	44	37	151	49	57	36	23	397	$121,789	$169,711	$1,359,239	$423,667	$921,734	$1,108,427	$1,020,239	$5,124,806
334517	12	12	45	20	8	6	6	108	$31,757	$57,189	$406,118	$168,723	$133,527	$177,030	$250,685	$1,225,029
339112	81	98	311	104	119	51	34	797	$222,363	$452,134	$2,802,121	$886,881	$1,931,002	$1,582,252	$1,469,220	$9,345,973
339113	165	189	527	155	119	60	28	1,244	$455,607	$873,164	$4,745,444	$1,327,675	$1,944,603	$1,853,429	$1,211,337	$12,411,259
339114	72	97	145	30	18	7	2	370	$199,103	$445,581	$1,301,236	$254,660	$287,597	$222,837	$70,122	$2,781,136
339115	56	48	143	39	26	8	8	327	$155,730	$219,622	$1,285,500	$331,174	$423,900	$233,091	$330,071	$2,979,087
All Mfgs.	**440**	**500**	**1,393**	**419**	**369**	**185**	**110**	**3,417**								
Spec. Dev.	722	210	330	51	25	6	3	1,346	$1,624,580	$944,970	$2,966,908	$457,900	$444,889	$203,978	$164,945	$6,808,170
Reproc.	-	11	2	2	2	4	-	21	$0	$49,500	$18,000	$18,000	$36,000	$144,000	$0	$265,500
Total, All NAICS	1,162	721	1,725	472	396	195	113	4,784	$2,838,005	$3,299,906	$15,523,702	$4,069,043	$6,489,716	$6,058,957	$4,970,250	$43,249,579

Source: ERG estimates based on Tables 3-5 and 3-8.

Note: The numbers of establishments columns exclude 1,379 labelers that satisfy exceptions for all their devices (i.e., ERG assumes that 70 percent of establishments in the 1-4 size class and 30 percent of the 5-9 size class meet exceptions because they manufacture custom devices only). Additionally, 10 percent of the remaining manufacturers, 105 establishments, in these size groups are assumed to use UPCs and are considered already in compliance and are also excluded from the number of establishments. The costs for these establishments to read and understand the rule, however, are included in the aggregate costs.

employees currently barcodes variable information and these make up the majority of establishments. Thus, 3 percent of affected manufacturers are expected to incur only the costs of initially reading and understanding of the rule (and possibly relabeling due to date format requirements; see Section Two). The labelers already barcoding variable information would need to read and understand the rule only to the point that they realized they were currently meeting the proposed UDI requirements, so one-half of the time needed to read and understand the rule that is allotted to manufacturers that do not meet the proposed UDI requirements is allotted to this group (ranging from 5 hours to 30 hours, depending on size).

Because of the large number of affected establishments, the per-establishment compliance costs become quite substantial when aggregated over all establishments. Using the assumptions described here, the UDI requirement is estimated to generate total one-time administrative costs of approximately $43.2 million (see Table 4-2).

4.3.1.2 Barcode Registration Costs

Barcode registration costs are incurred at the level of the firm. Because these are firm rather than establishment costs, ERG used the count of owner-operators from FDA's database (Section Three, Table 3-9) to estimate the number of firms affected by the proposed rule. The total count of manufacturing firms (i.e., 4,241) is distributed by the same NAICS shown in Table 4-2 using data provided by the Small Business Administration (SBA, 2006). Table 4-3 shows the number of affected firms distributed across NAICS using Census data distributions and by firm sizes by NAICS using SBA firm size data.

These estimated numbers of firms by size are then adjusted for exceptions and baseline compliance (i.e., custom operations and UPC-only labelers) among the very smallest firms. It is assumed that the percentages of firms meeting these same criteria are the same as percentages of such establishments in this size group (fewer than 20 employees) under an assumption that one establishment equals one firm at this size. Therefore, a total of 70 percent of firms with 1-4 employees, 30 percent of firms with 5-9 employees, and no firms with 10-19 employees are assumed to label custom devices. Additionally, of the group of firms not assumed to be labeling custom devices, another 10 percent of the firms in the 1-9 employee size group are assumed to use UPCs only.

Adjustments are also made to account for existing registrations. ERG determined that although most manufacturers do not print variable (or static) barcodes on their labels, most firms are likely to be registered with either GS1 or HIBCC (Secunda, 2010; Hankin, 2010). ERG assumes that 85 percent of

Table 4-3. Numbers of Firms Assumed Needing to Register for Barcodes

	Total Number of Firms in FDA's Database (a)				Number of Firms Estimated Needing to Register (b)			
NAICS	**Total**	**Small**	**Medium**	**Large**	**Total**	**Small**	**Medium**	**Large**
325413	160	79	60	21	9	6	3	0
334510	452	255	149	48	28	20	7	0
334517	132	85	35	12	9	7	2	0
339112	935	552	314	70	60	43	16	1
339113	1,562	1,008	468	86	104	79	23	1
339114	585	483	94	9	43	38	5	0
339115	413	306	89	19	29	24	4	0
Spec. Dev.	1,306	1,120	173	14	177	168	9	0
Reproc. (c)	19	11	7	1	19	11	7	1
Total	5,566	3,898	1,388	280	**476**	**397**	**76**	**4**

(a) FDA owner operator firms were distributed by NAICS and size using SBA data on firm sizes. Small firms have fewer than 20 employees, medium firms have 20 to 499 employees and large firms have more than 500 employees. Given the small number of affected firms estimated, no adjustment was made to account for double counted firms (see Table 3-6 in Section Three).
(b) Numbers of small manufacturing firms were adjusted to account for exceptions (such as for custom operations) and existing registrations, including UPC-only firms. This adjustment was based on the percentage of small establishments assumed to meet exceptions for custom device labeling or for UPC labeling. Of the 3,119 establishments with less than 20 employees, 1,484 establishments would meet the exceptions, equaling 48 percent of small establishments (see Section 4.2.2); 52 percent of small establishments and consequently small firms are assumed to be subject to the rule. An example of this calculation is as follows: Of the 79 small firms estimated to be within NAICS 325413, 52 percent are assumed to be affected by the proposed rule (eliminating those assumed to be using UPCs only and those assumed to be labeling custom devices), and of these, 85 percent would already be registered. Therefore, 15 percent of these firms are assumed not already registered ($0.52 \times 79 \times 0.15 = 6$). Thus 6 firms are assumed to need to register incrementally in this NAICS and size group.
(c) Reprocessing firms were assumed to fall in the same employment size groups as their establishments except for two firms with two establishments each (see Section 3.2.2).
Source: FDA, 2010a, Tables 3-7 and 3-9, and SBA, 2006.

labeling firms subject to proposed UDI requirements that have fewer than 20 employees (small firms), 95 percent of manufacturing firms with 20-499 employees (medium firms) and 99 percent of firms with more than 500 employees (large firms) are registered. Specification developers are also assumed to be registered at about these same percentages. No reprocessors are assumed registered, however. In all, ERG expects that 476 initial labeler firms would need to register.

The cost of bar code registration at GS1 varies with the gross sales revenue of the establishment and the extent of the establishment's product line. The registration fees charged by GS1 are based on a sliding scale, depending on firm revenues and number of unique products requiring GTINs. GS1 believes

that under a UDI plan, registration fees might change (the fees, both initial and annual, that are charged depend on the number of subscribers and the costs incurred to maintain the system at this not-for-profit entity). We contacted GS1, but they were hesitant to discuss fees due to the complexity of their fee structure. Because we could not get an estimate from GS1 (GS1, 2008), we used information from HIBCC, which we have assumed would become an issuing agency.

The HIBCC licensing fee also varies with gross sales revenues. Based on the firm sizes set up for analysis (<20 employees, 20-499, and 500+ employees), and average revenues for those sizes based on 2002 data for U.S. manufacturers, we assume that the applicable sales ranges for small, medium and larger firms would be under $2 million for small, under $30 million for medium and over $500 million for large. These sales ranges equate to fees in the HIBCC schedule of $500, $4,000, and $20,000, respectively (HIBCC, 2010). HIBCC charges $100 for each additional license if more than one license is needed for an individual establishment, but HIBCC indicates that this rarely occurs. Thus, it is assumed that only one license per firm is needed (see Table 4-4). HIBCC does not charge additional fees by numbers of unique products requiring barcodes, nor do they charge an annual fee. Since labelers are free to choose an issuing agency, ERG assumes that if HIBCC fees are less expensive than GS1 fees, the labeler would be choosing GS1 for reasons other than those relating to meeting basic UDI requirements. Furthermore, should FDA become the issuing agency, ERG assumes that the current HIBCC fees would be representative of fees that FDA might impose, if allowed by law. The total cost for firms to register a barcode is estimated to be $0.6 million (see Table 4-4).

Because HIBC does not charge an annual fee, because the large majority of registrants in future years (start-up firms) are assumed to have registered even if the proposed rule were not promulgated, and because of the very modest cost that would apply to very small start-up firms, ERG assumes recurring registration costs are negligible and only includes this cost component as a first-year cost.

Table 4-4. Costs for Barcode Registration

Firm Size	Adjusted Number of Firms	Cost per Firm To Register	Aggregate Costs to Register
Small	397	$500	$198,300
Medium	76	$4,000	$304,153
Large	4	$20,000	$75,794
Total	476		$578,246

Source: Hankin, 2010; HIBCC, 2010; Table 4-3; and ERG estimates.

4.3.1.3 Equipment Costs

4.3.1.3.1 Regulatory Baseline and Compliance Strategies

To estimate equipment costs for the proposed rule, ERG forecast manufacturers' incremental investment and operating costs to modify and/or supplement their existing product labels given their existing labeling systems and their likely compliance strategies. The estimates were prepared in stages to reflect the variety of possible compliance approaches. It should be noted, however, that the exact compliance strategy would vary substantially among firms, reflecting, among other things, wide variations in production and/or packaging line speed, labeling requirements, and the existing labeling systems in place. These estimates only approximate these complexities and cannot address the much wider variety of specific changes and equipment installations likely to be made. The assumptions are applied to all establishments that are not already assumed to use variable barcodes on their labels.

The relatively simple approach to cost estimation described here is justified partly because of the need to consider only the potential regulation-induced cost of the FDA action under consideration. FDA would not require extensive label changes, only the addition of the UDI. The effect of this change on some relatively complex labeling systems, some of which carry considerable marketing content, encompasses both compliance and marketing-driven considerations. Thus a measure of the response to a UDI requirement would involve extra measures that are not strictly part of the regulatory impact.

In preparing the estimates, ERG worked with project consultants and discussed label printing costs with manufacturers, consultants, and a subcontractor specializing in industrial installations of UDI and other process enhancements. The subcontractor, Mass Group, Inc., of Chatsworth, CA (2007), helped to estimate the expected hardware and software costs for manufacturers to add the required barcoded UDI number containing variable information to their labeling. In addition to Mass Group, ERG contacted consultants in the label printing area to help consider the range of possible responses. In the estimates below, the Mass Group hardware and software costs are not shown separately. The final estimates reflect a combination of inputs and should be considered to represent ERG's best judgment.

Manufacturer costs to implement the proposed rule would vary widely depending on their current labeling capabilities and the potential labeling capabilities of their equipment. ERG compiled manufacturer data (presented in Appendix B), but, while helpful, these data do not provide a clear consensus on the equipment costs for meeting the proposed rule requirements. To develop a basic model of equipment costs, ERG considered the collected manufacturer data, but also reviewed additional

references from the trade literature and made contacts with equipment vendors to derive some representative costs.

ERG's review of current labeling practices indicated that there are a variety of current labeling systems employed in medical device manufacturing reflecting the needs of manual and automated systems; low- and high-speed production lines; simple or complex label designs; institutional and consumer-friendly packaging; in-house and contractor supplied labels; and low- and high-consumption rates for ink, toner, and label stock. To consider the incremental costs that UDI would create for these systems, we have focused on the most common baseline scenarios combined with the likely manufacturer responses to the proposed requirements. Current baseline and manufacturer response to the proposed rule are differentiated primarily by the size and complexity of the operation. Large establishments with automated production lines have different baseline conditions and responses to the proposed rule than very small establishments with manual production lines. The primary basis for the difference in manufacturer response is the difference in prevalence of baseline digital printing technology.

A UDI requirement under the proposed rule creates a challenge for label requirements because a portion of the label information referred to as the *variable* component, changes frequently. Thus, lot numbers or serial numbers for devices change with each lot or each device while the rest of the label is unchanged. Many printing technologies, such as printing press technology, are not geared to presenting variable information, but rather are designed to produce large numbers of static labels or other printed materials very cheaply.

ERG reviewed methods that manufacturers have used to comply with similar initiatives requiring printing of variable information. As noted earlier, DOD operates a program (the Unique Identification [UID] program) in which manufacturers are required to place unique identifiers on high-value (over $5,000) assets. While more restrictive in its requirements than FDA proposes, the DOD requirement is of some interest as an indicator of how industry might comply with this type of regulation, since manufacturers would be able to choose from several possible techniques for placing UDI barcodes on their devices or packaging.

A White Paper prepared by Zebra Technologies Corporation (2005) stated that the majority of defense contractors can comply with the DOD UID requirements by using fairly inexpensive thermal transfer label printing machines. (Zebra Technologies Corporation manufactures these and other types of printers.) A relatively small share of manufacturers uses data plate systems or DM techniques that imprint

the identifier directly onto the item.[20] Thermal transfer printers generate highly readable output and can accommodate digital technologies. These printers are also relatively durable for production line applications. For these reasons, ERG bases the cost of meeting the basic barcode printing requirements on the use of thermal transfer printers, rather than on more costly technologies that are less commonly used to meet the DOD UID requirements.

Digital printing is likely to be the method of choice for any manufacturer needing to serialize medical device UDI labeling because of the relative ease of connecting digital printing and information technology (IT) systems. Digital printing is also extremely versatile, and can accommodate changes quickly (Medical Device Manufacturer A, 2006; Medical Device Manufacturer D, 2006; Batesko, 2006). Thus, the proposed UDI requirement can significantly modify the economics of labeling depending on the relative prevalence of digital printing technology among manufacturers.

The prevalence of digital printing varies depending on size and complexity of production lines, particularly whether the production line or lines are manual or automated (which tends to correspond to size of establishment). Therefore, ERG first discusses the larger manufacturers, which are assumed to use automated lines predominantly, then the very small manufacturers (fewer than 10 employees), who are assumed to use manual production lines predominantly.

Large Manufacturers: Baseline Labeling and Likely Responses to the Proposed Rule

Large manufacturers, which are assumed to operate automated lines, indicated that the two most commonly used labeling methods are (1) use of preprinted labels (including labels produced by outside contractors) and (2) use of online printing systems, such as flexographic printers (i.e., printing plates) (Pitts, 2006; Morin, 2006; Zitella, 2006). Digital printing systems have been coming into use but are still only used at a modest share of facilities (i.e., probably no more than 15 percent) based on estimates collected from a number of printing machine vendors.

To model how larger manufacturers would respond to the proposed rule requirements, manufacturers were placed into three principal groups: (1) those using outside printing contractors to prepare their labeling, (2) those printing labels in-house using systems poorly suited to print variable information (e.g., flexographic printers), and (3) those printing in-house using thermal transfer or other printing systems that can readily accommodate variable information. Table 4-5 below summarizes the principal choices forecast for the larger medical device manufacturers who use automated lines and

[20] Data plate systems produce a plastic or metal plate that is then affixed to the item.

indicates the percentage in each group that are expected to choose a particular compliance strategy. (The table also applies to choices smaller manufacturers might make with minor modifications to account for manual lines; smaller manufacturers are discussed later in this section.) The table reflects a simplified view of the diverse labeling environment. Nevertheless, it captures the essential requirements of the potential FDA proposal. The discussions below detail the assumptions used to model the compliance strategies for each of the three principal groups: those using outside printers, those using thermographic printers in-house, and those using digital printing systems in-house.

Table 4-5. Characteristics of Manufacturer Baselines and of Expected Compliance Responses (b)

Beginning Manufacturer Characteristics	Current Use of Barcodes/Standard Numbering	Estimated Share of Establish-ments (a)	Response to Proposed UDI Labeling Requirement	Probable Impacts	Investments
Using outside label printer	None	10% of those using outside printers	With existing or new outside printer, implement number & barcode	Modest increment in per label cost	None
	Presenting basic product identifying number & barcode (no lot numbers or serial numbers)	88% of those using outside printers	With existing or new outside printer, implement number & barcode	Modest increment in per label cost	None
	Either using or not using barcodes or other product identifiers at this time	2% of those using outside printers	Regardless of current labeling, change to in-house printing operation; install thermal transfer printers	Significant increase for in-house printing costs	Depends on number of production lines
Using in-house flexographic printing (printing plates)	None or presenting basic product SKU & barcode only (no lot or serial numbers presented in HIBCC or GS1 format)	60% of those with flexographic printing	Modify labeling system to accommodate variable information	Substantial cost to retool in-house printing	Depends on number of production lines
	Same	40% of those with flexographic printing	Modify labels so main part is printed by flexographic printers and variable component by thermal transfer	Significant increase for thermal transfer but do not completely retool	Depends on number of production lines
Using in-house thermal transfer printers	Present basic product identifying number and barcode (HIBCC or GS1), static only, at most	100% of those with adequate in-house printing capabilities	Modify labels and add software to increment lot numbers	Modest incremental costs (none equipment-related)	None

(a) Estimated by ERG based on discussions with project consultants.
(b) For establishments with manual lines, the same percentage is assumed to use outside printers now (40%) as those with automated lines, but the remainder are assumed to have adequate printing in place (60%). Additionally, establishments with manual lines that switch outside printers are assumed to be the same percentage (10%), but we assume all manual lines that do not switch printers add a supplemental label printed in house (90%).

Compliance Strategies for Larger Manufacturers Using Outside Printers

Although two-thirds of larger medical device establishments are estimated to be using barcodes on their packaging (AdvaMed, 2004),[21] not all of these establishments have the printing equipment in-house to print variable information in-line. Larger manufacturers that use outside label printers can (1) ask their outside labeling printers to provide revised labels that incorporate the lot numbers (i.e., to have the variable information printed by an outside contractor), (2) keep their existing labeling arrangements but also produce a separate (presumably small) label in-house with the barcoded information (supplemental labels), or (3) move the entire labeling function in-house. Among these strategies, we judge that the first two would be much more commonly chosen. The last option would require a much larger investment in new printing and labeling equipment and this would generally not become cost-effective for a company that heretofore has not been printing labels in-house. The first strategy requires that manufacturers request that their outside printing contractor print the variable information needed on the labels. This strategy requires essentially no initial investment by device manufacturers. However, the manufacturer might need to adapt a portion of their information technology (IT) system around lot numbers produced by an outside contractor.

Although most label printing contractors do not now print variable information on device labels, some barcodes on medical devices are pre-printed by contract printers (Hohberger, 2006). There are no technical limitations preventing contractors from providing the revised labels, but many would need to purchase new equipment. These purchases are considered a voluntary response to the potential regulation by a group that is not directly regulated and are not included as part of the regulatory impact. However, label printing prices offered by outside contractors are likely to rise because they will need to use different, higher-cost technologies and they are offering an enhanced service, so much of this additional cost to printers is assumed passed through to device manufacturers (the size of this increase is considered further below). Manufacturers who choose to continue to use outside printers will have to adjust to a new framework in which lot numbers are either (1) assigned outside the facility or (2) assigned by the manufacturer but then communicated frequently to an outside printer. We make no judgment as to where lot numbers would originate. Virtually any configuration of printing arrangements appears possible.

[21] Secunda (2010) believes that this number has not changed dramatically, because manufacturers are waiting to see what FDA does in terms of requiring UDI before making changes.

Certain identifiers, such as those assigned as a date of manufacture (which often occurs with capital equipment) or lot/batch numbers that are associated with one day's production, would require little coordination between manufacturer and printer. The manufacturer can most likely estimate with some confidence how many labels would be required for each day's production, and the printer can be instructed to prepare that number of labels each day with the date or other number assigned for each day's lot. For other manufacturers, assignment of lot numbers by the printing contractor might prove awkward unless lot numbers or other variable identification information are not meaningful or important to tracking operations or unless the manufacturer can determine ahead of time how many devices are likely to be manufactured within a given lot (such as in the example provided above). ERG judged, therefore, that some manufacturers will continue to use their current outside printers, but others might contract with a new printing establishment able to print variable information, or bring all (or part of) their printing operations in house.

The second strategy requires the purchase of one or more thermal transfer or other printers that can print barcode information, both static and variable. Many manufacturers would be able to use a single printer to prepare supplemental labels for displaying the barcode, leaving the original label and/or package printing unchanged or with very minor modifications to allow placement of the barcode. For example, a printer industry executive indicated that electrical medical devices (a category which includes many capital assets, such as laboratory equipment and many monitors and measurement devices) currently must carry an Underwriters' Laboratory (UL) label throughout their useful life (Hohberger, 2006). A UDI number could be added to this label at a relatively minimal cost. This change would not require any investment in new equipment for manufacturers now placing UL labels. For this possibility, FDA would need to accept placement of the UDI on a stick-on label as opposed to the basic packaging. As noted earlier, ERG assumes FDA would allow placement of supplementary labels displaying the barcoded UDI.

The third strategy requires moving the entire label production operation in-house. Only a small percentage of manufacturers are expected to do this because it entails significant costs and may not be cost-effective for many manufacturers. This choice would be made by firms that cannot accommodate lot numbers produced by outside vendors, for example if meaningful lot numbers cannot be specified in advance, or if numbers of devices within a lot cannot be specified with enough certainty. These firms would presumably also not be able to accommodate a supplemental label for the barcode. Some firms, however, might opt for this approach for business reasons unrelated to such issues. For example, the

literature notes that medical device manufacturers have shown an increasing interest in in-line printing of labeling (Vaczek, 2006; Allen, 2004; Hackett, 2002).

Compliance Strategies for Larger Manufacturers Using In-House Non-Digital Printing Technologies

Many larger manufacturers printing in-house are using flexographic (printing plate) technology, which is poorly suited to incorporating barcodes containing variable information. (This generalization might not hold where lot sizes are so large that preparation of a printing plate with variable information is economic, but few production lines meet that criterion.) These manufacturers have the option of revising their entire label printing methods by switching out their flexographic printers for thermal transfer or other digital equipment, or by preparing supplemental labels to affix to their existing labels. The complexity of their compliance methods would vary with the demands of their labeling. A number of medical device manufacturers are known to be using thermal transfer in-line printing to print variable information (e.g., lot and expiration dates) on demand (Summit Publishing Company, 2000, Hackett, 2002; Medical Device Manufacturer A, 2006).

Compliance Strategies for Larger Manufacturers Using In-House Digital Printing Technologies

A small share of large manufacturers has equipment that can accommodate the proposed UDI requirements for some or all of their production lines. Among those companies that are not now presenting lot number information in a form that satisfies the proposed FDA requirement, all should be able to accommodate the requirement without major equipment changes on lines where their digital equipment is in place.

Very Small Manufacturers: Baseline Labeling and Likely Responses to the Proposed Rule

In contrast to larger manufacturers, very small manufacturers (i.e., those with approximately 1 to 9 employees) are expected to commonly use digital printing, using a laser printer to print manually applied labels. Their labeling operations are probably similar to those of the small R/Rs contacted (see Section 4.3.2). Consequently, very small manufacturers would likely have fewer responses to the proposed rule than larger manufacturers.

ERG contacted one very small manufacturer who printed labels in-house using a laser printer. This manufacturer did place barcoding on the label of at least one product line (Small Manufacturer A,

2008). ERG also contacted an additional very small manufacturer with special printing needs (washable labels; labels that can withstand interiors of battery boxes). This manufacturer uses an outside printer. The manufacturer indicated that the outside printer would not have a problem dealing with either variable or static barcoding (although labels were not currently barcoded); their contract printer already prints serial numbers on their device labels (Small Manufacturer B, 2008). This latter manufacturer also noted that they would continue to use their outside printer if they were required to barcode, but with enough lead time, might bring the printing process in-house. Neither of these very small manufacturers would have to make major changes to their equipment or their current practices, although both noted that per-label costs would increase sharply with a variable barcode among their low-volume products.[22]

ERG assumes that 60 percent of very small manufacturers currently use digital printing equipment and 40 percent currently use outside printers (the same breakout that was assumed for larger manufacturers). Of those assumed to be using outside printers, 75 percent (or 30 percent of all very small manufacturers) are assumed to bring labeling in-house (using an existing laser printer) and 20 percent (or 8 percent of all very small manufacturers) are assumed to continue to use an outside printer (their current printer or a new printer, if necessary). ERG assumes that many very small operations with straightforward printing needs will opt to bring printing in-house, given that the incremental cost of using laser printers on manual lines is very small. In-house printing also offers simpler implementation of variable information in the printing process. Only 10 percent of very small establishments (or 2 percent of all very small manufacturers) currently using outside printers are assumed to use a supplemental labeling approach (produce a separate label in-house with the barcoded information), due to the expense of manually applying a second label. Only a few establishments with more elaborate labels who do not wish to coordinate variable information with an outside printer are assumed to use this approach.

4.3.1.3.2 Equipment Costs for Compliance Strategies

ERG determined that there are several categories of equipment that might be needed by manufacturers that currently do not barcode variable information on medical device labels, should they opt to print labels in house (software needs are discussed later in Section 4.3.1.6). These categories include:

- Label printing and scanning equipment

[22] The increase would be generated by either the time to apply a supplementary label or by an increase in price charged by the printer

- Barcode verifiers
- New label applicator equipment
- Engineering/installation costs

Not all equipment would be needed by all manufacturers and these equipment needs would vary depending on whether the establishment operates manual, low-speed automated, or high-speed automated packaging and labeling lines.

Label Printing and Scanning Equipment

ERG obtained several estimates of the costs to install a new label printing and scanning capability in manufacturing facilities. For example, a large medical device manufacturer estimated that the investments per printer would average $5,000 to $10,000 (Medical Device Manufacturer A, 2006). ERG's subcontractor estimated printing and scanning costs at approximately $5,000 per application.[23] Because these estimates were prepared several years ago, ERG allowed for some increase in costs over time and judged that an average cost of $6,000 per label printer per production line would suffice. ERG judged that each production line would need its own label printer in all but the smallest manufacturing establishments. The establishments with fewer than 20 employees were assumed to rely on their existing label printing capabilities and to make no purchases. This estimate was based on the judgment that these facilities are producing labels at low to moderate production rates that can be satisfied by their existing printing capacity.

It will be possible for medical device manufacturers to comply by printing supplemental labels for their devices. Thus, the establishment would simply print a new label with the barcode data. One printer vendor (Hohberger, 2006), a printer manufacturer executive, estimated that a basic equipment set would cost roughly $3,000, with higher speed or higher quality equipment costing approximately $6,000. We have included the possibility of supplemental labeling because it represents a legally adequate means of complying with the regulation. This option might allow some firms to continue to use outside label printing contractors for their main label (which would not carry UDI barcodes), while adding an in-house on-line printing capability for their UDI label. We have forecast that relatively few establishments would make this selection, primarily when there is some chance of confusion in their labeling or to avoid two labeling functions. Nevertheless, this choice might make economic sense for firms that have some

[23] Scanners are assumed necessary to meet presumed basic barcode readability requirements (that is, it is not enough that a barcode appear on a label—it must be readable; use of scanners ensures that printed barcodes can be read by a scanner).

restrictions in their other labeling choices. Firms might not want to perform the main labeling task while also not wanting to share variable production information with an outside contractor.

Label Applicator Equipment

A minority of establishments would also need label applicators. Applicators might be needed in higher speed production operations. ERG calculated a weighted average cost for an applicator based on a unit cost of $2,500 (Mass Group, 2007), assuming 25 percent of larger establishments installing either a new label system or a supplemental label system would require an applicator, resulting in a weighted average cost of $625 per facility.

Barcode Verifiers

The proposed UDI regulation does not specify a standard of readability for the barcoded information, but there is a presumption of readability. Therefore, we assume that labelers would need to verify the quality of their printed barcodes (a scanner simply indicates that a barcode can be read, not the quality of the barcode). This verification step is part of the quality system and would help to ensure that manufacturers have affixed the correct UDI.

Verifiers are generally too slow for production line use (requiring 15 seconds or more to ascertain the quality of the barcode), but it is not generally necessary to verify 100 percent of the production. Thus, we do not forecast that verifiers would be placed on the production line, but would be used instead as part of the quality program, with barcoded labels sampled from the production lots. Verifiers are small units and can be brought to the production line, as needed. Our estimates assume that manufacturers with multiple production lines would purchase more than one verifier.

Barcode verification equipment is sold by a number of vendors. We have identified prices ranging from approximately $2,000 to $15,000 from various contacts. We have used estimates of $5,000 and $12,000 to represent the lower and upper end averages for this equipment. For manual production lines, we judged that handheld scanners would suffice to determine whether barcodes are readable. Lower speed printing needed on manual lines is expected to contribute to fewer potential quality issues.

Additionally, verifiers require labor time to operate. It is assumed that the labor requirement to operate verifiers as a part of the quality system would add 0.15 FTEs at establishments with one automated line to 1.0 FTEs at establishments with 6+ lines.

Engineering/Installation Costs

ERG next judged that establishments would incur engineering costs to select, install, and test the equipment to be added to their production lines. Based on input from a medical device manufacturer, ERG allotted engineering costs that were roughly equal to 75 percent of the costs of the production line investments themselves where a new label printing system is being installed (Medical Device Manufacturer A, 2006).

ERG has included additional costs to integrate the UDI investments into the production line. Most manufacturers would have some flexibility about the location of the printers and applicator equipment. The printed labels can be brought to the production line, although some integration of new labeling operations would be needed. New label applicators, where used, would need to be integrated into the production or packaging line in some fashion. The cost of integrating the new applicator equipment would vary widely with the production circumstances.

To capture potential integration costs, ERG added 50 percent to the engineering overhead costs to bring the total engineering overhead expenses to 125 percent of equipment costs.

Equipment Costs for Smaller Manufacturers with Manual Lines

Manual lines at the smallest manufacturing firms are expected to be associated with significantly less equipment and lower costs. Discussions with very small manufacturers indicated that they routinely have access to digital printers, such as laser printers, and currently print labels using this equipment or their outside contract printers have access to the necessary equipment. Additionally, manual lines do not need label applicator equipment, nor, given their smaller, slower label throughput, would verifiers be necessary. Although some very small manufacturers might obtain scanners for their own use, they are assumed unnecessary in such an environment with only a very few product types with low-speed printing (barcode readability issues are reduced and any printing problems could be caught by eye during a manual label application process). ERG assumes that no additional equipment is needed for very small establishments with manual production lines that do not outsource their label printing.

Equipment Costs for All Affected Establishments

Table 4-6 presents the estimated range of costs for both small establishments with manual lines and the larger manufacturing establishments with automated lines. The table describes investment costs for modifying all label printing or for supplementing the existing label with a new label printer specifically for the UDI information for automated lines and for making minor modifications at manual

Table 4-6. First-Year Investments per Production Line and Establishment for Barcode, Printer, Verifier, and Overhead Costs

Investment	New Label Printing System	Supplemental Label Printing	Manual Production Lines	Sources/Assumptions
Printer/scanner set or hand scanner	$6,750	$3,750	$200	For full label: Weighted average based on 75 percent of establishments using the minimum printer/scanner pairing costing $5,000 (Mass Group, 2007) and 25 percent of establishments using the high end printer/scanner combination costing roughly $10,000 (Medical Device Manufacturer Contact A, 2006); for supplemental label, costs are $3,000 and $6,000 (Hohberger, 2006 and Sherman, 2006). Manual lines, with small throughput, are assumed to use existing general purpose, office digital printers based on discussions with very small manufacturers (see text); hand-held scanners are assumed sufficient for verification on manual lines. Such scanners, with USB port connection capabilities, can be purchased for less than $200 (barcodesinc.com, 2008).
Applicator	$625	$625	$0	New applicator not needed in all cases. Unit cost of $2,500 (MassGroup, 2007) per applicator was assumed to apply to 25 percent of those adding supplemental labeling system. Manual lines are assumed not to require an applicator.
Verifier	$12,000	$5,000	$0	Various industrial consultants (including Villotti, 2010, and Mara, 2010) estimate verifier costs as ranging from $4,000 to $15,000. Unit costs of $12,000 and $5,000 were used to represent the high-end and lower end averages. Manual lines are assumed to use scanners in lieu of verifier (see text).
Engineering overhead for equipment	$24,219	$11,719	$250	Estimated at 75 percent of equipment costs (Medical Device Manufacturer A, 2006). An additional 50 percent overhead allotted to allow for integration of equipment into production line.
Totals				
1 production line	$43,594	$21,094	$450	Includes printer/scanner, applicator (as necessary), verifier and overhead for automated systems; manual systems assumed to need only a verifier.
2-3 production lines	$46,813	$21,094	NA	New system includes 1 verifier and 2 printer/scanners and applicators (as necessary), with overhead; supplemental assumed to need only one of each.
4-5 production lines	$93,625	$24,063	NA	New system includes 2 verifiers and 4 printer/scanners and applicators (as necessary), with overhead; supplemental increases by one printer/scanner.
6+ production lines	$119,438	$31,719	NA	New system includes 2 verifiers and 6 printer/scanners and applicators (as necessary), with overhead; supplemental increases by one more printer/scanner.

Source: As presented.

lines. Automated lines have different costs associated with each approach; manual lines have the same cost regardless of whether they supplement or replace their entire label. Among automated lines, as will be noted, some of the possible investments would not be needed in all establishments. The unit cost of these items is, therefore, a weighted average of establishments that require or do not require the equipment. Although data are limited, ERG projects that the majority of automated establishments do not operate high-speed production lines, which are associated with higher cost equipment.

The equipment costs that were estimated in Table 4-6 are applied to the estimated distribution of baseline characteristics of medical device manufacturers described Table 4-5. These distributions are spelled out in detail in Table 4-7, which shows the distribution in percentage terms of manual vs. automated lines, baseline printing capabilities, and likely compliance strategies. Table 4-7 further presents the aggregate costs calculated using the per-establishment costs by number of production lines and the assumed percentage of establishments in each category of baseline and compliance strategy characteristics. The numbers of establishments reflect the removal of those establishments assumed already to be printing variable barcodes.

In distributing the establishment costs across the industry, ERG made two other important assumptions. First, ERG estimated the number of production lines in relationship to the distribution of employment in the industry. Thus, establishments with 1-9 employees (1,183) were assumed to have one manual production line, establishments with 10-99 employees (2,176 establishments) were assumed to have one automated production line, and establishments with 100-249 employees (359 establishments) were assumed to have two automated production lines. Second, ERG judged that ¾ of establishments with over 250 employees (194 establishments) were assumed to have 4-5 production lines and ¼ were assumed to have 6 or more production lines (65 establishments).

With this format, ERG calculated the costs for manufacturers to modify their label printing systems. The aggregate costs indicate investments totaling $71.5 million. Operating costs are estimated at 10 percent of investment costs and total $7.2 million per year. With labor to operate verifiers added in, annual costs are $36.5 million per year.

4.3.1.4 Direct Marking Costs

FDA would require manufacturers of permanently implanted devices and devices intended for multiple uses that require sterilization between uses (e.g., surgical instruments; called multi-use devices for this discussion) to be permanently marked. Software developers would need to add a UDI to a new or already-developed

Table 4-7. Equipment Investments for UDI Requirements

Establishments, by Baseline Label Printing System	Manual Lines (% Establish-ments)	Automated Lines (% Establish-ments) (b)	Equipment Costs, by Number of Production Lines (a)					Total
			Manual	Automated				
			1 line	1 line	2-3 lines	4-5 lines	6+ lines	
Number of establishments, by assumed number of prod. Lines			1,883	2,176	359	148	110	4,677
Per establishment costs to install full on-line label printing system			NA	$43,594	$46,813	$93,625	$119,438	
Per establishment cost to install supplemental label system			NA	$21,094	$21,094	$24,063	$31,719	
Per establishment FTEs to operate verifiers			$0	0.15	0.30	0.60	1.00	
Per establishment cost to operate verifiers (c)			$0	$6,947	$13,894	$27,787	$46,312	
Per establishment costs to print labels--manual lines			$450	NA	NA	NA	NA	
Establishments using outside label printers	**40%**	**40%**						
Switch to new outside label printer, add lot #s (10% of 40%) (d)	NA	4%	NA	NA	NA	NA	NA	NA
Move entire label operation in-house (2% of 40%)	NA	1%	NA	$758,914	$134,446	$110,958	$105,229	$1,109,547
Add small supplemental label, applied in-house (88% of 40%)	NA	35%	NA	$16,157,528	$2,665,586	$1,254,753	$1,229,599	$21,307,466
Man. line: switch to new outside label printer, add lot#s (20% of 40%)	8%	NA	NA(d)	NA	NA	NA	NA	NA
Man. line: move entire label operation in-house (75% of 40%)	30%	NA	$254,238	NA	NA	NA	NA	$254,238
Man. line: add small supplemental label, applied in-house (5% of 40%)	2%	NA	$16,949	NA	NA	NA	NA	$16,949
Establishments printing labels in-house with printing systems that do not accommodate variable information	**0%**	**45%**						
Modify entire label printing operation (60% of 45%)	0%	27%	$0	$25,613,354	$4,537,554	$3,744,816	$3,551,480	$37,447,204
Add small supplemental label, applied in-house (40% of 45%)	0%	18%	$0	$8,262,372	$1,363,084	$641,635	$628,772	$10,895,863
Establishments w/label printing systems accommodating var. data	**60%**	**15%**						
Modify label with existing printing equipment (100% of 15%)	NA	15%	$0	NA	NA	NA	NA	NA
Man. line: modify label w/existing equipment (100% of 60%)	60%	NA	$508,476	NA	NA	NA	NA	$508,476
Total Investment								$71,539,744
Total labor for operating verifiers			$0	$15,116,928	$4,987,826	$4,116,423	$5,100,335	$29,321,512
Total O&M (10 percent of equipment cost) plus Labor								$36,475,487

(a) From Table 4-6. Numbers of establishments are from Table 4-2, adjusted for the 3 percent of manufacturers who are assumed to be printing variable barcodes at the present time. These counts exclude small manufacturers assumed to be manufacturing custom devices or who are assumed to be using UPCs exclusively

(b) From Table 4-5 and ERG assumptions (see text).

(c) Assumes a wage rate plus 29 percent fringe of $22.27 per hour (BLS, 2009) for inspectors in NAICS 339 for the number of FTEs noted in the line above.

(d) Incremental costs for outside printer labels assumed primarily costs of coordination, which is passed through to labelers. This cost is captured in Table 4-12.

startup screen or "about" screen for standalone software. Section 4.3.1.4.1 discusses the requirements and costs for direct marking for implants and multi-use devices. Section 4.3.1.4.2 discusses requirements and costs for standalone software.

4.3.1.4.1 Requirements and Costs for Implants and Multi-Use Devices

Implants and multi-use devices would need to be marked directly using either a barcode or easily read plain text. However, FDA has allowed for exceptions. Firms can obtain exceptions when their device materials are not suitable for marking, or when marking poses safety and health issues, when the device is too small to mark, or where the curvature of the device surface makes mark impractical (it is difficult to read marks on curved surfaces). The majority of exceptions to multi-use devices are expected to be based on size and curvature issues.

The types of devices covered by the DM requirements would generally be manufactured by establishments in NAICS 339112 and 339113. According to the NAICS descriptions, implants are primarily captured in 339113, but that product type is only one of very many product types captured in that NAICS. Multi-use devices are likely to include most surgical instruments plus additional components of equipment that are used during surgery, such as bronchoscopes or endoscopes that are assumed already marked because the label is affixed directly to the device (where a label can be permanently affixed to the device, no additional marking is required). Surgical instruments and other multi-use equipment comprise a major portion of the products listed in NAICS 339112.

ERG received lists of product codes from FDA that were judged likely to meet the definition of implant or multi-use equipment. Using FDA's registration and listing database (FDA, 2010a), ERG identified the manufacturers and specification developers that list a device with a product code indicating either an implant or a multi-use device.[24] Table 4-8 presents the counts of establishments with listed devices meeting implant or multi-use device definitions (according to FDA). These counts have been distributed using Census data on the distribution of establishments by employment size class for NAICS 391112 (multi-use devices), 391113 (implants), and 541330 (specification developers) (U.S. Census Bureau, 2010b). As the table shows, 1,222 establishments (517 with multi-use items and 705 with implants) might need to do direct marking on at least one implantable or multi-use product out of the 4,784 labelers estimated to be affected by the proposed rule (26 percent).

[24] There are no establishments that are counted twice, having both a device coded as an implant and one coded as a multi-use device; the count of establishments, therefore, can be compared to the total number of device labeling establishments.

Discussions with vendors of DM equipment seemed to indicate that the use of DM among medical device manufacturers was widespread and growing. Surgical instruments, such as scalpels and retractors are readily marked and many are already marked with brand names and logos. One contact indicated that most implants are marked, and the concerns with the remaining devices arise because the devices are too small or surfaces are too curved for the mark to be read (Villotti, 2010). ERG (as discussed in Section 4.2.3) assumes that 75 percent of multi-use devices and 80 percent of implants are currently directly marked.

Some manufacturers noted that certain types of marking equipment are unsuitable for implants due to health and safety issues, or that certain locations on a device cannot be safely marked, but no one indicated global health and safety issues that would prevent marking a device that was practical to be marked. Size or surface issues could also be problematic among multi-use items. Therefore, ERG assumes that some manufacturers (and specification developers) of devices that currently are not marked would need to file an exception for their device products, primarily due to size, material markability issues, or lack of appropriate markable surfaces.[25] Table 4-8 shows the assumed number of affected products for each establishment size category. Among all implant establishments, 15 percent are expected to label some devices requiring exceptions (primarily due to size or surface curvature), and among all multi-use device establishments, only 5 percent of establishments are expected to label devices requiring exceptions. All others not currently marking are assumed to go forward with installing and purchasing marking equipment and, thus, would not file for exceptions. ERG further assumes that it will take about 10 hours per product to (1) document the need for an exception in the design history file and (2) notify FDA of the need for an exception. ERG estimates that the exceptions process would take relatively little time to document the issue and notify FDA because the exceptions are assumed to be for size or markability reasons, rather than for health and safety reasons, which appear rare under circumstances when device marking is possible from a size, material, or other practicality standpoint. A management wage rate of $75/hour is also assumed. The time needed for an exception could vary widely. An establishment might require very little time to document an exception for a device based on size limitations; providing documentation supporting a health or safety issue might be more time-intensive, although, as noted, this situation is expected to be rare.

[25] Note that ERG has assumed that if no technologically feasible machine-readable mark can be applied, no easily readable plain-text UDI could be applied either; such a device would be considered to be one for which direct marking is not technologically feasible. FDA has indicated in the preamble to the proposed rule that current technologies would limit the size of a machine-readable mark, but is silent on “easily readable.” We are assuming easily readable does not mean “with magnification.”

Table 4-8. Costs for Establishments to Document Exceptions to the Direct Marking Requirements

Establish-ment Size	Estimated Estab. with Multi-Use Items	Estimated Estab. with Implants	Number of Implant Estab. Document-ing Exception	Number of Multi-Use Estab. Document-ing Exception	Assumed Products per Estabs. Affected	Cost per Estab. (a)	First Year Costs for Multi-Use Estabs.	First Year Costs for Implant Estabs.	Total Cost	New Products	Recurring Costs per Estab. (a)	Recurring Costs Multi-Use Estabs.	Recurring Costs Implant Estabs.	Aggregate Recurring Costs
1-4	94	155	23	5	1	$750	$3,528	$17,436	$20,964	0.3	$188	$882	$4,359	$5,241
5-9	67	108	16	3	1	$750	$2,504	$12,138	$14,642	0.3	$188	$626	$3,034	$3,660
10-49	188	272	41	9	2	$1,500	$14,095	$61,104	$75,199	1	$375	$3,524	$15,276	$18,800
50-99	58	75	11	3	4	$3,000	$8,743	$33,575	$42,318	1	$750	$2,186	$8,394	$10,579
100-249	64	56	8	3	10	$7,500	$24,157	$62,883	$87,040	3	$1,875	$6,039	$15,721	$21,760
250-499	28	27	4	1	30	$22,500	$30,950	$92,352	$123,301	8	$5,625	$7,737	$23,088	$30,825
500+	18	13	2	1	50	$37,500	$33,737	$71,319	$105,055	13	$9,375	$8,434	$17,830	$26,264
Total	517	705	106	26			$117,714	$350,805	$468,519			$29,428	$87,701	$117,130

(a) Assuming 10 hours per exception at a fully loaded wage rate of $75.

Source: ERG estimates.

Additionally, ERG assumes that new products might require exceptions in ongoing years. We assume that the count of such products would be one-quarter of the original number of products needing exceptions in each year.

Table 4-8 shows that, under these assumptions, applying for an exception from direct marking for every establishment involved in DM for at least a few of their devices could cost about $0.5 million initially and about $0.1 million each following year.

Based on discussions with vendors and manufacturers, ERG assumes that many affected establishments already do some form of part marking, even if barcodes are not yet widely used. One vendor noted about 20 percent of their customers who do direct marking use barcodes (Vendor B, 2010). ERG assumes, therefore, that 80 percent of establishments currently marking do not barcode in their direct marking. Although FDA would allow the affected devices to be marked with either a barcode or plain text, device size and configuration in some instances might require the use of a reduced size 2D barcode, where plain text might not fit. However, it is not difficult to add a software module to existing software to handle barcodes. A software module designed to create barcodes for direct marking is sometimes provided at no cost, although perhaps ranges from about $600 to as high as $2,000 (Villotti, 2010; Vendor A, 2010). ERG uses the lower end of the add-on cost range of $600 to represent an average upgrade cost for the software to print a variable 2D barcode on devices. Because of the relatively modest cost of adding a barcoding capability, ERG did not attempt to determine the frequency with which labelers might need to use 2D barcodes in lieu of plain text and assumed that all labelers currently marking might need to add barcoding software for their marking systems as a worst-case assumption.

Additionally, among those establishments with devices that must be directly marked and that are currently using some form of direct marking technology (75 percent of multi-use device manufacturers and 80 percent of implant manufacturers), ERG assumes that the markings must be redesigned among the 80 percent of these establishments because they are not currently barcoding (the redesign is needed to accommodate a 2D barcode within the logo design or other information currently marked). The cost of this redesign is assumed the same as that to redesign the main packaging label, which will be discussed below in Section 4.3.1.5.1 in detail. Table 4-9 presents the assumptions concerning current ownership of direct marking equipment among multi-use and implantable devices and the assumptions regarding costs incurred among all those with equipment that do not barcode at this time. As the table shows, establishments that currently do some DM (without barcoding) will incur software upgrade costs of about $0.5 million and redesign costs of about $7.3 million, for a total of $7.8 million.

Table 4-9. Costs for Software Upgrades and Redesign Costs for Establishments Already Marking Devices

Estab. Size	Total Number of Multi-Use Item Estabs.	Total Number of Implant Estabs.	Assumed Baseline Comp-liance Multi-Use Items	Assumed Baseline Comp-liance Implants	Aggregate Cost of Software Upgrade (a)	Per Estab. Cost of Redesign to Include Barcode (b)	Aggregate Cost of Redesign	Total Costs for Multi-Use Estabs. Already Marking	Total Costs for Implant Estabs. Already Marking	Total Cost for Estabs. Already Marking
1-4	94	155	75%	80%	$93,387	$1,250	$194,557	$104,441	$183,504	$287,944
5-9	67	108	75%	80%	$65,468	$2,500	$272,783	$124,190	$214,060	$338,251
10-49	188	272	75%	80%	$171,939	$5,000	$1,432,823	$631,446	$973,316	$1,604,761
50-99	58	75	75%	80%	$49,634	$10,000	$827,225	$370,704	$506,155	$876,859
100-249	64	56	75%	80%	$44,655	$20,000	$1,488,499	$796,226	$736,929	$1,533,154
250-499	28	27	75%	80%	$20,411	$50,000	$1,700,958	$835,232	$886,137	$1,721,369
500+	18	13	75%	80%	$11,346	$75,000	$1,418,264	$816,154	$613,456	$1,429,610
Total	517	705			$456,840		$7,335,109	$3,678,392	$4,113,556	$7,791,949

(a) Design changes and software upgrades to allow barcodes to be printed are assumed to cost $600 among the 80 percent of establishments with DM equipment not currently barcoding.

(b) Redesign costs are assumed the same as redesign costs for main label (see Section 4.3.1.4).

Source: Table 4-8 and ERG estimates.

Costs for equipment among establishments assumed not to have DM equipment are estimated as follows and are based on various information from vendors (Villotti, 2010; Vendor A, 2010; Vendor B, 2010; Vendor C, 2010).

Before per-establishment costs are discussed, ERG calculates the number of establishments that would need to install equipment. Those establishments that do not mark are identified (25 percent of multi-use device establishments and 20 percent of implant establishments). These counts do not include the numbers of establishments expected to file exceptions (see Table 4-8). The total numbers of establishments estimated to purchase equipment are shown in Table 4-10.

Next, ERG reviewed the type of equipment that might be needed. The two likeliest DM marking systems for use with medical devices are CO_2 lasers and yttrium aluminum garnet (YAG) lasers. CO_2 lasers are relatively inexpensive, but require inks when used to engrave metal (although not when engraving plastics). YAG lasers are more expensive but have very low maintenance costs and do not require consumables. ERG assumes, based on information provided by vendors, that a CO_2 laser would cost about $12,000 to purchase, while a YAG laser would cost about $55,000 to purchase. An engineering cost of 75 percent for installation of DM equipment into the production lines is also assumed. Because of the need to add inks to be able to read engraving when using a CO_2 laser (Vendor C, 2010) and questions about whether the inks would be compatible with implanted devices, ERG assumes the more expensive YAG lasers would be used for all implantables. At high product volumes, the consumables cost of a CO_2 laser tends to make the YAG laser more cost-effective, so YAG lasers are assumed for larger establishments. O&M costs are calculated at 10 percent of all one-time costs. Furthermore at the very largest establishments, highly automated, high-speed integrated laser systems are assumed to be used on at least some of the product lines. These laser systems can cost from $150,000 to over $1 million, although usually these types of lasers are found only in special applications, such as semiconductor manufacturing (Vendor B, 2010). ERG assumes that the highest speed lines at some of the large establishments would be fitted with such a laser system at $150,000 per laser (one laser out of four at establishments with 4-5 lines and two lasers out of six at establishments with six or more lines).

Validation that the health and safety aspects of the devices would not be compromised by the direct marking is assumed to involve a minimum effort in most cases because ERG did not find any issues with marking devices that would entail a health and safety issue. Most operations are assumed able to show that no health and safety issues would arise without performing extensive product testing. A total of 40 hours at a wage rate of $75 (for managerial wage and fringe) is assumed, generating a cost of

Table 4-10. Costs to Install and Operate Direct Marking Equipment among Establishments Not Currently Marking

Estab. Size	Total Number of Multi-Use Item Estabs.	Total Number of Implant Estabs.	Multi-Use Item Estab. Needing Equip-ment (a)	Implant Estab. Needing Equip-ment (a)	Assumed No. of Lines (b)	Capital Cost plus Installation for YAGs/High Speed Lasers per Estab. by Size (c)	Process Redesign Costs for Implant Manuf. (d)	Capital Cost plus Installation Assuming CO_2 Lasers	One Time Costs for Multi-Use Items (e)	One-Time Costs for Implants (e)	Total-One Time Costs	Total O&M Costs (f)
1-4	94	155	19	8	1	$96,250	$25,000	$21,000	$451,635	$962,852	$1,414,487	$141,449
5-9	67	108	13	5	1	$96,250	$25,000	$21,000	$320,491	$670,287	$990,778	$99,078
10-49	188	272	38	14	1	$96,250	$75,000	$21,000	$902,065	$2,366,075	$3,268,140	$326,814
50-99	58	75	12	4	1	$96,250	$100,000	$21,000	$279,776	$743,303	$1,023,080	$102,308
100-249	64	56	13	3	2	$192,500	$150,000	NA	$2,557,456	$973,982	$3,531,438	$353,144
250-499	28	27	6	1	4-6+	$640,938	$200,000	NA	$3,600,837	$1,169,017	$4,769,855	$476,985
500+	18	13	4	1	4-6+	$820,313	$250,000	NA	$3,011,323	$688,979	$3,700,303	$370,030
Total	517	705	103	35					$11,123,585	$7,574,495	$18,698,080	$1,869,808

(a) Subtracts those applying for exceptions as calculated in Table 4-8 and assuming a 75 percent baseline compliance rate among multi-use device establishments and 80 percent among implant establishments.

(b) Assumptions about numbers of lines are the same as those used in Table 4-7.

(c) Includes engineering costs assumed at 75% of capital expenditures. Also assumes that two largest sizes install 1-2 fully automated lasers at $150,000 per laser. Only smaller operations producing multi-use items are assumed to use CO_2 lasers due to high cost of materials. Only YAGs or high speed lasers are assumed for implants.

(d) Process redesign costs would vary widely. ERG judged that costs would increase with establishment size, from $25,000 to $250,000 per establishment.

(e) One time costs include 40 hours per line at $75/hour to validate operations showing no health and safety issues based on similar devices with markings currently in use.

(f) O&M assumed at 10 percent of one-time costs.

Source: ERG estimates and discussions with vendors (see text).

$3,000 per production line. If extensive product testing is required for some products, validation costs could be substantially greater. Such a possibility is discussed in the uncertainty analysis in Section Eight.

Costs to establishments that manufacture or specify implants and multi-use devices are estimated to be about $18.7 million, with recurring costs of about $1.9 million per year (see Table 4-10).

4.3.1.4.2 Standalone Software

Standalone software would be required to have the UDI present on the startup page or in a menu, such as in the help menu under an "About…" selection. Because FDA has provided, at a minimum, 3 years between promulgation and implementation, and because software revisions are made frequently, ERG assumes that the work to add the UDI in these locations within the software would be integrated into regular revision and update cycles. Most of the time needed to meet this requirement is for planning the implementation of UDI in general, and this has been accounted for in Section 4.3.1.1. Time needed to add the UDI within the software itself (while the startup page is being edited to contain a new version identifier and/or revision date) is considered to be a negligible increment to the 30 to 720 hours allotted to the various size establishments to plan for UDI implementation. Additionally, future software revisions would require new UDIs, but again these changes would be incorporated while other revisions were being made to the software. Furthermore, some software is not packaged nor labeled in the traditional sense (e.g., it might be sold via the Internet as a downloadable electronic file). Thus, it is likely that general labeling costs (e.g., for printing and materials) assigned to such software establishments and firms are overstated. Therefore, it is assumed that the cost of including a UDI in standalone software is negligible.

4.3.1.5 Costs Related to Changes to Device Labels

ERG identified several additional label-related cost elements that will also affect the costs of implementing UDI labeling systems at medical device companies. The cost elements include:

- Cost to modify label content
- Inventory loss; and
- Cost of new or incremental label materials.

The first two cost items are one-time costs, while the last cost item is a recurring incremental cost of meeting the UDI requirements. The following sections present the one-time costs, then the recurring costs of relabeling.

4.3.1.5.1 Label Redesign Costs

ERG determined that incremental relabeling costs associated with the potential need to modify product labels and/or stickers would be incurred by manufacturers in meeting proposed rule requirements. ERG previously developed a model to estimate medical device relabeling costs (ERG, 2002). The model was based on a shelf-keeping-unit (SKU)-based paradigm for revising labeling. Thus, ERG judged that manufacturers consider most labeling changes on a SKU-by-SKU basis. With a much-expanded use of online printing, however, the potentially universal applicability of UDI requirements, and the possibility that some establishments would add supplemental labels to all devices, the SKU-by-SKU model was judged to be much less relevant. Several elements of the changing relabeling circumstances are:

- With digital on-line printing technologies (as opposed to traditional SKU-based relabeling needs), several traditional elements of relabeling costs are of reduced or negligible significance. For example, with on-line labeling, labels can be generated on an as-needed basis and small or no labeling inventories are discarded for each label change. In ERG's previous model, loss of label inventories was a significant cost factor.

- Because UDI does not require changes to label text other than to include the UDI barcode, there is little need for a SKU-by-SKU labeling review, such as that which might involve marketing, legal, medical and other departments. Further, if UDI is to be applied comprehensively, manufacturers are likely to identify methods to accomplish the relabeling using techniques applicable to all device models, rather than by revising all labels in a SKU-specific fashion.

- With UDI, a key cost element is integration/coordination of a UDI program into the company information technology (IT) infrastructure. This cost element is generally not SKU-based, and would vary with the extent of IT development among manufacturers.

ERG received one set of estimates from an IT manager of a large medical device company that recently moved from linear barcoding to a two-dimensional barcode system that supports UDI as defined in the proposed rule (static and variable information displayed in a barcode). This executive estimated that his company spent approximately $50,000 converting their current barcode numbers for 27,000 products (Manufacturer A, 2006). He also noted that there are considerable economies of scale to such an undertaking, as the cost would have been the same whether they had done 5 products or 27,000. This estimate also includes the costs of integrating the UDI into operations and notifying customers of the change in numbering. This company already had thermal transfer printers on their production lines and was previously barcoding products (using traditional, static, product identification bar codes). Overall, ERG considered this estimate to be extremely low for average labeling experiences, although it potentially reflects relabeling costs at companies with high levels of technical integration.

Although the fixed component to the relabeling exercise appears to predominate, ERG assumed that smaller companies would spend less than other companies to redesign their labels. ERG noted that many medical device establishments are extremely small, i.e., 4 or fewer employees. Such establishments, even if affected by the proposed rule, would spend very little on a relabeling exercise. ERG estimated that the very small establishments (most of which are presumed to have very-small-scale production operations) are allocated $1,250 for the one-time relabeling design effort. This allocation increases across the size range. ERG assumed the $50,000 cost reported by the large firm would apply to the 250-499 employees category of establishments. This figure was increased to $75,000 for the largest establishments. These costs are also assumed to cover the cost of label inventory losses. Note, however, that inventory losses and redesign costs would be substantially minimized given FDA's proposed implementation period. An implementation period such as the one offered for Class I devices of 5 years would likely result in few incremental costs for label redesign and inventory loss (if date format changes are not needed), since manufacturers redesign labels periodically for marketing purposes and with enough warning could draw down label inventories prior to needing to implement a barcoding requirement. ERG has not assumed that these incremental costs would be reduced by the extended implementation period, however. Additionally, ERG assumes that even those establishments that are assumed to be labeling with variable barcodes or UPCs would be affected by relabeling costs because of the date format requirements.

With these assumptions, as shown in Table 4-11, aggregate first-year costs for label redesign total about $43.0 million. These estimates, however, are considered very approximate and a wide range of uncertainty is assigned to these costs in the uncertainty analysis in Section Eight.

Table 4-11. Derivation of Incremental Device Labeling Redesign Cost, per Establishment and Total

Employment Size	Number of Establishments	Costs Per Establishment	Aggregate Costs
1-4	1,211	$1,250	$1,513,842
5-9	777	$2,500	$1,941,599
10-49	1,725	$5,000	$8,624,279
50-99	472	$10,000	$4,722,088
100-249	396	$20,000	$7,918,441
250-499	195	$50,000	$9,746,853
500+	113	$75,000	$8,485,628
Total	4,889	-	$42,952,729

Source: Estimated by ERG. No establishments are assumed to be presenting label information in the precise format required by the proposed rule. Although some manufacturers might print variable barcodes, the new date format requirement is assumed to require some of these to need to redo labels. The number affected is not known, so all establishments except custom manufacturers are assumed affected (those labeling UPCs are also assumed to be affected by the date format change).

4.3.1.5.2 Additional Time and Materials Costs

ERG also considered the increase in labeling costs due to use of slightly larger labels, new labeling technologies (with a higher rate of use for consumables), or additional supplemental labels. These costs would be incremental costs incurred in every year going forward.[26] There are numerous influences on the share of total manufacturing costs represented by the immediate product label. We lack data that isolate the average contribution of incremental label costs as a share of manufacturing costs.

Based on discussions with consultants, however, ERG judged that the incremental label costs would represent a very small share of manufacturing costs and used an estimate of 0.2 percent of all material costs in medical device manufacturing, or $2 in $1,000 of materials costs, to represent this cost element. Table 4-12 summarizes the assumptions and calculations used. Using the distribution of the total costs of materials for NAICS 339112, Surgical and Medical Instrument Manufacturing, ERG developed an estimate of the distribution of total material costs by size of establishment. This distribution was then applied to the total cost of materials for all medical device NAICS. Using this method, we calculated that, as a baseline figure, labeling costs represent $58.1 million out of $29.1 billion in materials, parts, containers, and packaging costs.

ERG next assumed that labeling material costs would increase by 10 percent under the proposed regulation and that all establishments would need to do at least some relabeling (although some establishments might already be printing variable barcodes, the new date format requirement is expected to trigger additional relabeling needs). As noted, the increase is the result of several factors, including an increase in label size, an increase in the rate at which consumable materials, such as ink or toner, are used, or the addition of a supplemental label with the UDI information. This estimate is also speculative but is intended to be conservatively large.

Additionally, ERG accounts for very small manufacturers who are assumed to print labels in-house for a manual production line (60 percent of the 1-9 employment group; see Table 4-7). ERG does not assume the use of sophisticated software to integrate UDI information and automate labeling changes to accommodate variable information in the very smallest establishments (see Section 4.3.1.6 below).

[26] The potential for additional packaging or labeling needs among a few types of device packages, such as shelf packs containing unlabeled Class II devices, is discussed in Section Eight (Uncertainty Analysis).

Table 4-12. Derivation of Incremental Device Labeling Materials Cost, per Establishment and in Aggregate

Employ-ment Size	Number of Estabs. (a)	Estimated Materials, Parts Container Costs by Estab. Size	Assumed Cost Share for Labels	Baseline Label Material Cost	Incremental Annual Label Cost (Materials)					Coordination with Outside Printer (b)			Aggregate Cost (Time & Materials) (c)
					Percent	Amount	Per Estab.	Aff. Estabs.	Total Cost	Hrs.	Cost	Aff. Estabs.	
1-9	1,883	$382,075,687	0.2%	$764,151	10%	$76,415	$41	1,883	$76,415	50	$3,750	151	$740,259
10-49	1,725	$1,904,053,769	0.2%	$3,808,108	10%	$380,811	$221	1,725	$380,811	100	$7,500	86	$1,027,632
50-99	451	$1,961,135,780	0.2%	$3,922,272	10%	$392,227	$869	451	$392,227	200	$15,000	18	$662,973
100-249	359	$5,656,194,889	0.2%	$11,312,390	10%	$1,131,239	$3,151	359	$1,131,239	800	$60,000	11	$1,777,442
250-499	167	$4,279,955,277	0.2%	$8,559,911	10%	$855,991	$5,121	167	$855,991	1,200	$90,000	5	$1,307,286
Over 500	91	$14,888,853,597	0.2%	$29,777,707	10%	$2,977,771	$32,678	91	$2,977,771	2,400	$180,000	0	$2,977,771
Total	4,677	$29,072,269,000	-	$58,144,538	-	-	-	4,677	$5,814,454	-	-	271	$8,493,362

(a) Includes all establishments except those currently assumed to be using variable barcodes, those with custom devices only, and those labeling only with UPCs for retail in the 1-9 employment size category.

(b) Assumes a wage rate of $75/hour for a print shop manager and a medical device manager to coordinate (each require the same number of hours for coordination, so hours of coordination time are multiplied by two). Hours are multiplied by two to account for outside label price increases due to an assumed cost pass-through from printers to account for coordination at the printing shop.

(c) Includes costs for 2 percent of establishments with 1-9 employees (38 estabs.–not including UPC estabs.) to add a supplemental label at a cost of $2,625 per year (see text).

Source: For establishment and materials, parts, and container costs, U.S. Census Bureau, 2010a. For distributions by establishment size, see Table 4-2. All other estimates and calculations prepared by ERG.

Using these assumptions, the incremental labeling costs for materials are estimated at $5.8 million per year. Although this result is quite sensitive to the assumptions used, it suggests that it is unlikely that the increased annual costs for incremental consumption of labeling materials are a major regulatory impact.

Certain establishments would also incur some additional costs associated with time to add supplemental labels manually (only the smallest establishments are assumed to incur these costs), or to coordinate with outside printers to ensure proper lot, batch, or serial numbers are printed and to ensure that numbers of labels with a lot or batch number are printed for the lot/batch group to be produced.

For the very smallest manufacturers, ERG assumes all label applications are manual, thus use of a supplemental label would require additional time, effectively doubling the labeling process time. Based on the assumptions shown previously in Table 4-7, ERG has estimated that 2 percent of establishments in the 1-9 employment group (38 establishments) would decide to use supplemental labels for reasons related to difficulties coordinating variable numbers with outside printers. The average employment at establishments with 1-9 employees is estimated to be approximately 4 employees, of which 3 employees are expected to be involved in production, including labeling. Labeling is estimated to entail about 2 percent of these 3 employees' time, with the vast majority of time directed towards the device production itself. Doubling this time means that 3 employees (assuming a 2,080 hour work year) are estimated to spend an additional 125 hours per year applying a supplemental label. BLS (2009) indicates that in NAICS 339100 (Medical Equipment and Supplies Manufacturing), the average production operator earns $16.04/hr., including a 29 percent fringe (BLS, 2010), this is $21/hr., or $2,625 per year per establishment. In Table 4-12, this cost to the 38 establishments assumed to use supplemental labels is not shown as a separate activity, but is incorporated into the total costs for time and materials among the establishments in the 1-9 employment group.

Another group of establishments is also assumed to need additional time for labeling purposes. All establishments that continue to use an outside printer are assumed to require some coordination time with their printing contractors to implement variable labels. ERG assumes that for the 8 percent of smallest establishments estimated to retain an outside printer (see Table 4-7), this coordination would entail about 25 hours per year (approximately ½ hour per week per line). At larger establishments, ERG assumed that the hours per week would increase as a function of numbers of product lines. It is further assumed that as the size of the establishment increases, the complexity of coordination increases as well,

so that numbers of hours per week per line also increases somewhat as the size of the establishment increases.

Additionally, some increase in prices charged by outside printers to cover the costs of their time to coordinate with the device establishments is also assumed. This price increase, assumed to fall on labelers, is estimated to be approximately the same as the cost to the labelers to coordinate with the printer (e.g., the outside printer for the smallest establishment would also incur 25 hours per year coordination time) for a total of 50 hours. Therefore, hours per establishment for coordination are doubled at each size of establishment. Thus, coordination takes 1 hour per week per line at establishments with 10-49 employees (with 1 automated line) for two persons (device manufacturer and printer) for a total of 50 × 2 or 100 hours; 2 hours per week per line at establishments with 50-99 employees and 1 automated line (100 × 2 or 200 hours); and so on.

These estimates are applied to a diminishing percentage of establishments expected to be using outside printers in the baseline. A total of 4 percent of all larger manufacturers are assumed to be using outside printers, but the percentage is judged to decline with establishment size. That is, 5 percent of the 10-49 employees group, 4 percent of the 50-99 group, 3 percent of the 100-499 employees group, and 0 percent of the 500+ employees group are assumed to be using outside printers. These percentages produce an overall 4 percent of total larger manufacturers switching to outside printers, consistent with the percentage shown in Table 4-7 for manufacturers using automated lines that are assumed to switch to outside printers. Total costs for materials and the time for coordination and applying supplemental labels are shown in Table 4-12. The total is $8.5 million, which is incurred annually.

4.3.1.6 Software and Information Technology Integration Costs

The next cost area covers the purchase or development of software to manage the UDI compliance and to incorporate the UDI information into the firms' information technology (IT) system. These costs are assumed to apply at the firm level, since firms would need to coordinate their software changes across their establishments. The first-year cost items include the software packages needed to print barcodes; costs to install, test and integrate the software into existing IT systems (where necessary); costs to validate the software to meet FDA software validation requirements; and costs to train employees in the use of the software.

The extent of the validation activity is substantial. First, there is a test of the software to ensure that it is configured correctly for the purposes it is used for and that it works properly. FDA validation requirements also require a full paper trail of the validation process at each step in that process, including the establishment of procedures to use the software, the actual testing of the software both in the test environment and then in the production environment, records of output from the software tests, records of any fixes needed and made, etc. Based on FDA guidelines (FDA, 2002), ERG estimates that the costs of validating barcoding software would range from modest (at the smallest firms) to substantial at firms with complex enterprise resource planning (ERP) systems (e.g., SAP or Oracle systems) and many facilities. At firms running ERP systems where barcoding software must be integrated into the system, FDA validation procedures become extensive.

ERG assumes two levels of baseline IT sophistication through the range of medical device manufacturing operations. At the lower end, ERG assumes that relatively simple management software is in place and that relatively little integration of barcoding software would be needed, which means that validation efforts are relatively simple as well. At the higher end, at larger operations with many establishments, ERG assumes that sophisticated IT environments exist, such as those using complex ERP software. In these environments, ERG assumes that some significant integration tasks must be performed in order to maintain the traceability of medical device processing.

The inclusion of a system-wide software integration and validation effort in such ERP systems adds substantially to the compliance costs. It would be possible for medical device firms to add the UDI software and a traceability capability without integrating into their entire software system or generating a need for a full validation (and re-validation) effort throughout all systems (beyond the labeling system). For certain firms, however, this limited software introduction might conflict with normal modes of software introduction or cause other, unforeseen difficulties. Thus, ERG included sufficient costs to represent large software integration and complex validation efforts for the largest strata of firms, reflecting the potential costs for complex software system enhancements and integrations of changes.

No firms with fewer than 200 employees are assumed to require the more-elaborate software integration and validation tasks. All firms with 200 or more employees, are, however, assumed to require significant integration/validation efforts. Firms with fewer than 100 employees are assumed to be managing the efforts at only one facility. Firms in the 100 to 199 employee size range are assumed to have one to two establishments, requiring slightly more complex validation, but generally to lack the highly complex ERP-type systems. Those with more than 200 employees are assumed to face

increasingly complex validation tasks among multiple establishments. Firms in the 200-499 employees group are split. In this group, 75 percent of firms are assumed to have simpler integration efforts and 25 percent are assumed to have more intensive integration/validation efforts). The following sections discuss the costs at larger firms with complex ERP systems, followed by a discussion of costs at smaller firms with simpler systems.

4.3.1.6.1 IT Costs at Larger Firms with ERP Systems

ERG made calls to a number of large manufacturers. These firms stated that they will spend substantially on software solutions and IT integration tasks. Medical Device Manufacturer C indicated that they had spent $130,000 for software allowing them to print variable barcoded information on their secondary packaging (they had not yet applied barcoding to their primary packaging). ERG used this figure for barcoding software with sufficient quality assurance and validation tools for the largest manufacturers, scaling this cost downward for large and very large manufacturers. For the 25 percent of larger manufacturers (those with 200-499 employees) assumed to be operating complex ERP systems, and at very large firms (with 500 or more employees), ERG estimates that software at these firms might cost $75,000. With the weighting assumptions for larger manufacturers and using the costs estimated for this size group for those without ERP systems (see Section 4.3.1.6.2), the overall cost per firm in this size group is estimated at about $52,500 (see Table 4-13).

ERG assumes a systems integration task must be added to the installation, verification, and testing tasks at the larger firms. For example, Medical Device Manufacturer C indicated that system integration would cost $200,000 to $250,000. This cost also includes hardware integration, which is an issue for the high speed production lines found at larger facilities and has not been fully captured elsewhere. ERG estimated that the largest firms would incur costs of $250,000 for installation, verification, testing, and integration. This cost has been adjusted downward to $150,000 for firms with 500-999 employees and to $100,000 for the 25 percent of larger firms (200-499 employees) assumed to have ERP systems. This produces a weighted average of about $45,000 for all firms in the 200-499 employment size group when the lower costs for the remaining firms in this size group that are assumed not to have ERP systems are included.

ERG assumes that the larger facilities with ERP systems would encounter complex and time consuming validation procedures. Medical Device Manufacturer C estimated that they would undertake software validation, employing approximately five people over the period of a year (i.e., up to 5 FTEs),

Table 4-13. Software and Associated Costs for UDI Compliance

Cost Element	Employment Size by Firm							Total
	Smallest (1-4) (a)	Small (5-19)	Medium (20-99) (b)	Large (100-199) (c)	Larger (200-499) (d)	V. Large (500-999) (e)	Largest (1000+) (e)	
Initial Investment Costs								
Software	$200	$7,500	$15,000	$30,000	$52,500	$75,000	$130,000	
Installation, Integration, Verif. & Testing	$600	$1,000	$5,000	$25,000	$45,000	$150,000	$250,000	
Validation	$0	$1,000	$2,000	$3,500	$55,000	$250,000	$400,000	
Total software investment	$800	$9,500	$22,000	$58,500	$152,500	$475,000	$780,000	
No. of employees assumed needing training	1	10	50	175	375	750	1,250	
Training-first year (@$100/employee)	$100	$1,000	$5,000	$17,500	$37,500	$75,000	$125,000	
Number of firms	1,162	1,403	1,019	210	159	68	212	4,232
Reduction for double-counted firms (f)	0%	0%	3%	10%	30%	35%	41%	210
Exclusion for firms with UDI software (f)	0%	0%	1%	9%	14%	18%	29%	85
Aggregate First-Year Investment	$1,045,585	$14,727,378	$26,457,592	$13,080,740	$18,197,537	$19,960,279	$80,539,846	$174,008,958
Recurring Annual Costs								
Recurring training costs (25% 1st yr.)	$25	$250	$1,250	$4,375	$9,375	$18,750	$31,250	
Recurring validation costs (10% 1st yr.)	$0	$100	$200	$350	$5,500	$25,000	$40,000	
Annual maintenance contract (18%)	$36	$1,350	$2,700	$5,400	$9,450	$13,500	$23,400	
Total recurring annual costs	$61	$1,700	$4,150	$10,125	$24,325	$57,250	$94,650	
Aggregate Recurring Costs	$70,867	$2,384,433	$4,066,630	$1,742,664	$2,329,764	$2,077,684	$8,423,311	$21,095,353

(a) The smallest firms (1-4 employees) are assumed to perform limited production and to purchase simpler software, with simple testing and no validation.
(b) Assumes compliance can be achieved with use of single UDI server (only one establishment and line assumed).
(c) Same software costs as for medium firm although greater testing costs are assumed to be required and two software licenses are needed.
(d) Assumes 75 percent of firms use two software licenses and 25 percent of firms have complex ERP systems that require more expensive software and more time-consuming integration.
(e) Assumes much more complex installation requirements associated with ERP systems, with more establishments to consider for the very largest firms.
(f) All firm counts are adjusted to account for 3 percent of manufacturers who are assumed to be printing variable barcodes at this time (adjustments for exceptions for custom operations among the smaller firms and for use of UPCs only were made as shown in Table 4-3). Specification developers and reprocessors are assumed not to use variable barcodes currently. Additionally, firms are double counted when broken out by establishment types owned (see Section Three), primarily large firms. A percentage reduction is calculated assuming most of such firms are the largest firms. This percentage reduction results in the removal of 210 firms. The actual number of double counted firms is 209 (see Table 3-6).
Source: Estimated by ERG based on discussions with software providers and as discussed in the text. Firm counts use total registered firms in Table 4-3 distributed with data on firms in the affected NAICS by employment size in SBA, 2006, and adjusted as discussed in footnote (f).

which suggests costs exceeding $500,000. Another manufacturer reported even higher costs. Nevertheless, other sources suggested that validation costs would not be nearly as high as these forecasts. Vendors of device identification and traceability software reported that validation costs would be unlikely to exceed $100,000. These contacts also noted that spending on enhancements for some enterprise software could be virtually unbounded, depending upon the extent of integration with existing software being sought. Still other contacts, including large manufacturers, were unable to even estimate their costs, although they expressed concern that the validation costs could be quite high.

ERG judged that the validation cost estimates of the software vendors might underestimate the full complexity of integrating costs in the FDA-regulated medical device setting. We also were concerned that the manufacturer estimates of validation costs might overstate the actions strictly mandated by the UDI regulation, and might incorporate costs to integrate device identification-type systems of various company components that are incompletely integrated at the present time. Thus, while we accepted that large firms would spend extensively to bring UDI into their enterprise software, we did not accept the full share of costs for the largest of firms as entirely due to regulatory costs. Nevertheless, the largest two size classes of firms were estimated to spend $250,000 and $400,000 on UDI software validation. For the 25 percent of larger firms (200-499 employees), we assumed that they might spend as much as $200,000 per firm. With weighting, the overall average per firm in this group was estimated at about $55,000 when the lower costs per firm at those without ERP systems are included.

Training costs are calculated in the same way as those for the smaller firms (at $100 per employee) using the midpoint of the employment range as the number of employees requiring training. For the largest size category, however, where the number of employees is unbounded, we estimated training for 1,250 persons.

For recurring costs, ERG makes the same assumptions as those used for calculating recurring costs to smaller firms: 18 percent of initial software costs for ongoing maintenance, 25 percent of validation costs for addressing patches and upgrades, and 25 percent of first year training costs for recurring training costs.

4.3.1.6.2 IT Costs at Smaller Firms without ERP Systems

For smaller firms, ERG obtained an estimate of software costs at the lower level of software integration needs from a subcontractor, Mass Group, Inc. (Chatsworth, CA), and from other software

vendors. Because ERG combined the various estimates and generated some supplemental information, only a combined set of estimates is provided and these estimates are the responsibility of ERG. Table 4-13 summarizes the components of the IT costs. Mass Group provided forecasts of the representative software purchases needed to generate and record lot or serial number information for a medium and a large manufacturer without complex software integration issues. This company sells a moderately priced software package for traceability (called "Traceability Made Easy") and used that package as a benchmark for the costs for a basic software package. This software provides lot or serial number generation, scanner input-output, traceability data organization, and compilation of verification data. This software is priced at $15,000 per site license. This package of software is forecast to address the requirements for most small to medium firms in the industry. It addresses the needs for firms that might lack such software at the present time. All firms with fewer than 100 employees are assumed to operate one production line with one establishment.

ERG made two adjustments to the figures provided by Mass Group, Inc. Based on discussions with other vendors and device manufacturers, ERG judged that somewhat larger firms might use two or more software site licenses to drive different servers where more than one production line is operated or where they operate more than one establishment. ERG thus multiplied the software costs by two at large firms (with 100 to 199 employees), which are assumed to operate two production lines. For the 200-499 group, as noted, a portion of this size group (25 percent) is assumed to be using complex ERP systems; their costs were discussed previously. Thus, only 75 percent of the large size group is assigned $45,000, representing three software licenses for firms in this group, which are assumed to average two establishments per firm, with some lines sharing servers, others not. The other 25 percent are assumed to incur a cost of $75,000 for an ERP module. As discussed previously, costs shown in Table 4-13 for this employment size group reflects an approximate weighted average of costs estimated for the two levels of IT complexity assumed present in this group of firms.

For small manufacturers (5 to 19 employees), software needs are expected to be more modest, since traceability can be more easily handled manually and the only necessary item is software to create and print barcodes. Each printer will need barcoding software capable of creating, for example, GS1-128 barcodes (formerly EAN-128). Because of FDA software validation requirements, however, a simple barcoding software package could be insufficient for medical device manufacturing uses, and all but the very smallest operations might obtain software that provides FDA validation tools. ERG estimates that a package half as expensive as for medium size operations estimated above ($7,500) would provide sufficient validation software for use in the FDA-required validation procedures. This software provides

the tools necessary for creating the necessary paper trail showing the software is operating properly for its intended use. The very smallest operations (1 to 4 employees), however, are assumed to have so little complexity that a basic barcoding software package, with limited installation and testing requirements, is considered sufficient.

Following software acquisition, the software must be installed, verified, and tested. Installation, verification, and testing tasks at firms that are not expected to fully integrate their software with existing IT systems are estimated to cost from $600 at the smallest firms, up to $25,000 at 75 percent of large firms (200-499) that are assumed not to use complex ERP systems. Mass Group provided a cost of $5,000 for a medium size firm and about $25,000 at a large firm (100-250 employees). Once the basic testing is complete, FDA validation procedures are assumed to be undertaken at all but the very smallest firms, which use manual lines to produce relatively little throughput. Software validation costs at smaller firms are expected to range from $1,000 to $2,000 per label printing operation. ERG has assumed the small firms (5 to 19 employees) incur $1,000 to validate their software, rising gradually to $2,000 at facilities with 20-99 employees. At large firms, where ERG assumes two production lines operate, validation costs do not quite double, since the procedures established for validating one system can be applied to the other system, but the labor time to actually test each system remains. ERG assumes validation at firms in the 100-199 employee size group will incur $3,500 to validate barcode software on two production lines, while the 75 percent of those in the 200-499 employee size group will incur $6,000 to validate four lines each.

Training costs are assumed to be required to make employees aware of the UDI numbering process and how to use the software, as might be necessary for job functions. First-year training costs were estimated for all sizes of firms on the basis of $100 per employee over, roughly, the midpoint of employment for the range in that employment classification (e.g., 30 employees would need training at the typical 20-49 employee firm). Firms with 1 to 4 employees are assumed to require training for only one employee.

Ongoing costs are also incurred. Software maintenance costs are estimated at 18 percent of the software package, based on discussions with the software vendor. Validation is also an ongoing effort. Since new software releases and patches must also be validated, ERG assumes that 25 percent of the first-year validation costs are incurred in subsequent years to deal with software upgrades and patches. Recurring training costs are estimated at 25 percent of the first-year costs.

4.3.1.6.3 IT Costs for All Firms

Table 4-13 presents the software purchase, integration and related training costs described above for all firms considered affected by such requirements. The table accounts for the firms that are double-counted when firms are counted by the establishment types they own (see Table 3-6 in Section Three). Only the largest firms are considered likely to be double-counted with any frequency because these are the likeliest firms to own both a manufacturing establishment and a specification developer or R/R. The percentages used to reduce the firm count in this table approximate the 209 firms (shown as 210 firms in the table), and all double-counted firms are assumed to own at least one manufacturing establishment, so the double-counts are corrected in this table only. Furthermore, counts of firms are reduced to account for custom operations, small firms using UPCs only, and larger firms that are assumed to be using variable barcodes at this time.

Accepting the idea of some fairly significant integration requirements for the largest strata of firm, costs for the software component of UDI are substantial. Under ERG's assumptions, first-year costs are estimated at $174.0 million, and recurring costs at $21.1 million. All costs presented in Table 4-13 are highly speculative, however. Costs could be substantially larger or smaller, given variations in data integration needs and the complexity of the underlying IT systems in place (see Section Eight).

4.3.1.7 Costs of Recordkeeping and Recording including Costs for the GUDID

To meet the various revisions to recordkeeping and reporting requirements (the conforming amendments) firms would need to make changes throughout their records to include the UDI of the device in records and reports firms must keep or submit to FDA.. For larger firms, integrating UDI into all software systems as noted in Section 4.3.1.6 would automate virtually all recordkeeping and reporting requirements associated with the conforming amendments, resulting in no measurable additional costs for meeting these requirements. Additionally, costs for the smaller firms, who would handle UDI in a more manual fashion are also considered minimal. Incrementally these costs would be minimal because the incremental effort to provide a UDI during a process when many other pieces of information are being gathered and recorded would be small, and in many cases, the UDI replaces other, multiple pieces of data necessary for identifying the device, resulting in a potential time savings.

ERG also considered the cost for recordkeeping changes and the costs to submit UDI and UPC data to FDA's GUDID. All device labelers required to have UDIs (including those labeling with UPCs only) would need to submit these data to FDA.

It is assumed that FDA would create a website that would be designed to accept either web-entered data or would have an upload button for ensuring ease of database uploads, similar to the FURLS system currently in place for registering establishments and listing devices.

The costs to submit UDI data to FDA is separate from these other recordkeeping and reporting costs. As noted previously in Section Two, the following data will be required for submission to the GUDID. For most devices, the following information will be needed:

- Labeler name and contact information.
- The issuing agency name.
- The device identifier portion of the UDI (i.e., the static information).
- The device identifier previously associated with a device (if any) (manufacturer's original UDI).
- If the device is permanently marked, the device identifier used on the device (if different from that on the label).
- The brand or trade name of the device.
- The model number, version number, or similar reference that appears on the label of the device.
- Whether the device is sterile or contains natural latex.
- The size of the device (if produced in more than one size; for example, catheters are available in several diameters) and unit of measure.
- Type of production identifiers (e.g., batch or serial number).
- Premarket submission number or note of exemption.
- Listing number.
- The Global Medical Device Nomenclature Code (GMDN), which specifies the type of device.[27]
- The number of devices contained within the device package.

[27] Access to the GMDN is assumed free of charge because FDA does not intend to ask for this information if it is not freely available at the time UDI data must be submitted (see Section Two).

Although not specified in the list of GUDID requirements, ERG assumes that the UDI of the package selected by the labeler as the initial UDI to be entered into the system would also be required. This assumption is made because FDA intends for the detailed information on a device to be input only once, with the information other device packages containing the same device to comprise just the additional UDIs for other device packages and the number of devices they contain. ERG also assumes that the labeler would enter one or more additional HIBC, GTIN or UPC, if more than one identifier is presented on the label for similar reasons. Inputting additional and alternative UDIs for what is technically the same device also allows such UDIs to be linked. UDI linking would allow FDA (and other users) to know all UDIs that apply to a specific device. This additional information that is assumed to be included in the GUDID has been considered in this cost analysis.

ERG assumed that smaller establishments with only one or a few products would have the option of entering the information by hand on a web page provided by FDA. Labelers may also choose to upload an SPL file with the UDI data, which would likely be the option chosen by the medium and large establishments that label many products. Costs incurred for submission of the UDI data include:

- Gathering, preparing, and organizing files,
- Validation of the data submission process
- Conversion to SPL
- Accessing and uploading to GUDID
- Changes to data

These are described in greater detail below.

A regulatory affairs manager would need to spend time gathering, preparing and organizing the files that are needed for the web page entry of the data or for creating an SPL file. ERG assumes that medium and large establishments would have already done this during their IT reconfiguration task and no additional costs are incurred. For smaller facilities, this should be a relatively simple effort to collect the data on a few products. ERG estimates that small establishments will spend 1 to 2 hours to organize the UDI data for entry or upload.

The UDI submission process would also need to be validated to ensure that the correct data has been provided to FDA. ERG estimated the time spent validating procedures might require 2 to 3 hours for a small establishment and approximately 4 hours for larger establishments with more products.

Data entry would also be a very straightforward task given the number of items that are required. ERG estimates that small establishments would spend approximately one hour to enter the required data. The amount of time needed to upload an SPL data set is also expected to be small; ERG estimates that it would require roughly 1 hour to upload an SPL file to the GUDID.

Based on conversations with an SPL conversion provider, many manufacturers are currently using free software from FDA (Xforms) to create SPL files (SPL Conversion Service Provider A, 2010). Many manufacturers are expected to use this software or a conversion service provider to create their SPL documents containing the UDI data. The SPL conversion service provider that ERG consulted currently charges $100 for converting registration and listing data to SPL. The customer provides the conversion service provider with spreadsheet that contains the data to be converted in fields. The service provider converts the spreadsheet into SPL for $100. The $100 is a flat fee so customers pay the same amount, regardless of whether they manufacture 1 product or 10,000. If a facility can convert data into SPL using Xforms at a lower cost, they might do so. Thus ERG assumes that $100 per establishment is a conservative estimate of the cost to convert UDI data into SPL format.

Assuming hourly wages based on the median hourly wage rate for management occupations in NAICS 3391 (BLS, 2009), with benefits calculated at 29% of wages (BLS, 2010), total costs per establishment for uploading UDI data to the GUDID range from $450 and $750 for the smallest establishments to $338 for larger establishment (see Table 4-14). The aggregate first-year investment across all facilities is $2.7 million.

Furthermore, ERG is assuming that labelers would only need to submit the data once, unless changes need to be made to the information in the database. It is also assumed that any changes would not be costly. UDI data submitted on web pages can be easily retrieved and modified. SPL documents, once created, can be modified while keeping any unchanged information and resubmitted. ERG expects that each establishment would make one minor change annually that would require 1 hour of a manager's time. The total cost for these changes is $75 per establishment and the total recurring cost for all establishments is $0.4 million per year.

Table 4-14. Per Establishment and Total Cost to Upload UDI Data to the GUDID

Cost Element	Employment Size							Total
	1-4	5-9	10-49	50-99	100-249	250-500	500+	
Initial Investment Costs per Establishment								
Hours to gather, prepare and organize files	3	3	6	NA (a)	NA (a)	NA (a)	NA (a)	
Hours to validate submission process	2	2	3	4	4	4	4	
Hours to access and upload to GUDID	1	1	1	0.5	0.5	0.5	0.5	
Hourly wage with benefits	$75	$75	$75	$75	$75	$75	$75	
Subtotal cost per establishment	$450	$450	$750	$338	$338	$338	$338	
Conversion to SPL	$0 (c)	$0 (c)	$0 (c)	$100	$100	$100	$100	
Total costs per establishment	$450	$450	$750	$438	$438	$438	$438	
Total establishments (mfgs., reprocessors & spec. dev.) (d)	1,211	777	1,725	472	396	195	113	4,889
Aggregate First-Year Investment	**$544,983**	**$349,488**	**$1,293,642**	**$206,591**	**$173,216**	**$85,285**	**$49,499**	**$2,702,704**
Recurring Costs per Establishment								
Hours to access and upload to FURLS	1.0	1.0	1.0	1.0	1.0	1.0	1.0	
Hourly wage with benefits	$75	$75	$75	$75	$75	$75	$75	
Total costs per establishment	$75	$75	$75	$75	$75	$75	$75	
Aggregate Recurring Costs	**$90,830**	**$58,248**	**$129,364**	**$35,416**	**$29,694**	**$14,620**	**$8,486**	**$366,658**

(a) Costed in MIS software reconfiguration costs. See Table 4-13.
(b) Based on the median hourly wage rate for management occupations in NAICS 3391 (BLS, 2009). Benefits are calculated at 29% of wages (BLS, 2010).
(c) Web entry.
(d) From Table 4-2; adds in establishments assumed to use UPCs only (10 percent of non-exempt establishments in the 1-9 employment size groups).

4.3.1.8 Total and Recurring Year Costs for Initial Labelers

Table 4-15 presents the total first-year and the annualized first-year and recurring costs of the UDI requirements for medical device manufacturers, reprocessors, and specification writers. The investment total is approximately $362.0 million. For comparison purposes with other costs discussed later in this report (e.g., costs of alternatives to the proposed rule), the annualized costs of the proposed rule to initial labelers are calculated assuming immediate implementation would be required. However, FDA has proposed implementation periods of up to 5 years for Class I devices, and implementation periods ranging from 3 to 7 years for devices that would be required to be marked directly. ERG uses these implementation periods to calculate the actual costs over time in Section 4.4.

Assuming immediate implementation, and including both recurring costs and annualized investment costs, the total yearly cost is estimated at $120.0 million. The investment costs are annualized over 10 years at a 7 percent discount rate.

Table 4-15. Total Investment and Annual Recurring Costs for UDI Implementation for Medical Device Manufacturers, Reprocessors and Specification Developers

Cost Element	First-Year	Annualized and Recurring
Labeling and Database Requirements		
Administration and planning	$43,249,579	NA
Barcode registration costs	$578,246	NA
Equipment and other investments	$71,539,744	$36,475,487
Incremental label cost and time	NA	$8,493,362
Label redesign cost	$42,952,729	NA
Software (with training)	$174,008,958	$21,095,353
Recordkeeping and Reporting (GUDID)	$2,702,704	$366,658
Total Labeling and Database Requirements	$335,031,960	$66,430,859
Direct Marking		
Implants (a)	$12,038,857	$845,151
Multi-use devices (a)	$14,919,691	$1,141,787
Total Direct Marking	$26,958,548	$1,986,938
Total--All Cost Items	**$361,990,508**	**$68,417,797**
Annualized Investment Total (a)		**$51,539,305**
Total Annualized Costs		**$119,957,102**

Source: See previous tables.

(a) Includes annualized first-year costs and O&M costs estimated at 10 percent of one-time cost totals for implants and multi-use devices (Table 4-10) and recurring costs for exceptions (Table 4-8).

(b) First-year costs are annualized at 7 percent over 10 years.

4.3.2 Costs for Repackagers and Relabelers

R/Rs would also be subject to the proposed rule because they must affix their own UDI to their label. ERG estimates, using the database of R/Rs compiled from FDA's establishment registration database, that there are 1,310 R/Rs of medical devices that might be affected by a UDI requirement, as discussed in Section Three. Given the predominance of what appears to be medical device wholesale establishments or distribution centers associated with medical device manufacturers, most of these establishments are assumed to be wholesale establishments.

ERG also assumes that the size distribution of the 1,310 establishments would be similar to those in U.S. Census Bureau (2010b) County Business Patterns under NAICS 42345 (Medical, Dental, and Hospital Equipment Supply Merchant Wholesalers) and NAICS 42346 (Ophthalmic Goods Merchant Wholesalers). This distribution was shown in Table 3-10 in Section Three and is repeated here in Table 4-16 to show the number of R/R establishments by employment class size assumed in this costing analysis. Although some R/Rs might be preparing custom kits or other custom operations or using UPCs only, ERG made no assumptions about the number of R/Rs that might meet exceptions from proposed UDI requirements or that might already be in compliance with the proposed requirements.

Table 4-16. First Year Administrative and Planning Costs for R/Rs

Relabeler Size	Percentage of Establishments (a)	Distribution of R/Rs	Assumed Cost/Facility (b)	Aggregate Cost
1-4	56%	736	$1,125	$828,528
5-9	16%	212	$2,250	$477,997
10-49	21%	272	$4,500	$1,225,221
50-99	4%	47	$4,500	$212,046
100-249	2%	28	$9,000	$248,975
250-499	1%	10	$18,000	$173,925
>500	0%	4	$27,000	$117,936
Total		1,310		$3,284,629

(a) Percentage of establishments is from Table 3-10 in Section Three.

(a) Half the planning time is assumed to be needed for R/Rs as for manufacturers; see Table 4-1 for per-establishment costs for manufacturers.

Under the proposed rule, the costs to R/Rs are incurred in similar categories to those incurred by manufacturers:

- UDI planning costs.
- Barcode registration costs.
- Direct marking costs (limited to costs of noting exceptions).
- Equipment investments.
- Relabeling costs.
- Integration costs (software).
- GUDID costs.

4.3.2.1 UDI Planning Costs

ERG assumes that the facility planning costs associated with a UDI requirement under the proposed rule would be less than that for similar-sized manufacturing establishments. In our discussion with several of the distributors, relabeling/repackaging appeared to be a minor portion of their overall business. Furthermore, repackaging and relabeling generally does not involve high speed, complex manufacturing processes. ERG assumed that costs for administration and planning would be half of that for manufacturers of a similar size. Table 4-16 presents the initial planning costs estimated for R/Rs, which are estimated at $3.3 million (first-year cost).

4.3.2.2 Barcode Registration Costs

As with initial labelers, the barcode registration costs are assumed to be incurred by the firm. ERG distributed the 1,212 firms identified as R/R firms in Section Three using the same NAICS used to distribute establishments (see Table 4-17). No R/Rs are assumed currently to have registered barcodes.

The costs of registration per firm are exactly the same costs as those used to compute the costs of registering for manufacturers, reprocessors, and specification developers and were obtained from HIBCC. Registration costs for R/Rs are estimated to be a one-time cost of $1.6 million (see Table 4-18).

Table 4-17. Distribution of R/R Firms Using SBA Firm Data for Two Key NAICS

Industry	Total Firms	Small Firms (<20)	Medium Firms (20-499)	Large Firms (500+)
Hospital Equipment & Supplies	7,031	6,093	795	143
Ophthalmic Goods	1,075	892	165	18
Total Firms	8,106	6,985	960	161
Percent of Total Firms		86%	12%	2%
Number of R/R Firms	1,212	1,044	144	24

Source: SBA, 2006; FDA, 2010a.

Table 4-18. Costs for Barcode Registration for R/Rs

Firm Size	Number of Firms	Initial Cost per Firm To Register UDI	Aggregate Costs to Register UDI
Small	1,044	$500	$522,195
Medium	144	$4,000	$574,152
Large	24	$20,000	$481,451
Total	1,212		$1,577,798

Source: Hankin, 2010; HIBCC, 2010; Table 4-17; and ERG estimates.

4.3.2.3 Direct Marking Costs

Although R/Rs generally would not be responsible for the initial direct marking of medical devices, certain R/Rs may handle the repackaging and relabeling of devices that have been previously marked. The proposed rule would require them note exceptions on the basis that the devices they are handling have been previously marked in their design history files. ERG assumes that noting that a device has been previously marked when recording other required design history items is a negligible incremental task that generates no measurable costs to R/Rs.

4.3.2.4 Equipment Costs

Although it is known that at least some R/Rs have in-house barcoding capabilities for printing UPCs using equipment suitable for variable barcode printing, the percentage of such establishments is not known. However, all of the R/Rs contacted (or their contract printers) did have the capability of barcoding variable information, although one of these would have to obtain the barcoding software for their laser printer. The R/Rs contacted stated that they expected their largest costs to come from label redesign costs or for acquiring barcoding software. However, ERG assumes that R/Rs have labeling profiles similar to those of manufacturers, and that 40 percent of R/Rs outsource their label printing (as did one of the R/Rs contacted), regardless of whether they use manual or automated labeling lines. Additionally, 45 percent of those using automated lines are assumed to print static labels in house (although use of flexographic technologies was not noted, the sample of R/Rs contacted was very small). Finally, 15 percent using automated lines are assumed able to accommodate a variable barcode on their printing equipment (and to have the barcoding software in house, as did one of the R/Rs contacted). Of these 15 percent, none are assumed to be currently printing an appropriate UDI barcode. ERG also assumes the same decisions of how to meet the UDI requirements are made in the same proportions as for manufacturers. Table 4-19 presents these calculations. The printing enhancements add $11.3 million to the investment

Table 4-19. Equipment Investments for UDI Requirements for R/Rs

Establishments, by Baseline Label Printing System	Manual Lines (% Estabs.)	Auto-mated Lines (% Estabs.)	Equipment Costs, by Number of Production Lines (a)					Investment Total
			Manual	Automated				
			1 line	1 line	2-3 lines	4-5 lines	6+ lines	
Number of establishments, by assumed number of prod. lines			949	319	28	8	6	1,310
Per estab. costs to install full on-line label printing system			NA	$43,594	$46,813	$93,625	$119,438	
Per estab. cost to install supplemental label system			NA	$21,094	$21,094	$24,063	$31,719	
Per establishment FTEs to operate verifiers			$0	0.15	0.30	0.60	1.00	
Per establishment cost to operate verifiers (b)			$0	$6,947	$13,894	$27,787	$46,312	
Per estab. costs to print labels--manual lines			$0	NA	NA	NA	NA	
Establishments using outside label printers	**40%**	**40%**						
Switch to outside new label printer, add lot #s (10% of 40%) (c)	NA	4%	NA	NA	NA	NA	NA	NA
Move entire label operation in-house (2% of 40%)	NA	1%	NA	$111,388	$10,360	$6,246	$5,438	$133,433
Add small supplemental label, applied in-house (88% of 40%)	NA	35%	NA	$4,901,082	$205,405	$70,630	$63,547	$5,240,664
Man. line: switch to new outside label printer, add lot#s (20% of 40%)	8%	NA	NA(c)	NA	NA	NA	NA	NA
Man. line: move entire label operation in-house (75% of 40%)	30%	NA	$0	NA	NA	NA	NA	$0
Man. line: add small supplemental label, applied in-house (5% of 40%)	2%	NA	$0	NA	NA	NA	NA	$0
Establishments printing labels in-house with printing systems that do not accommodate variable information	**0%**	**45%**						
Modify entire label printing operation (60% of 45%)	NA	27%	$0	$3,759,352	$349,655	$210,797	$183,544	$4,503,348
Add small supplemental label, applied in-house (40% of 45%)	NA	18%	$0	$1,212,694	$105,037	$36,118	$32,496	$1,386,344
Establishments w/label printing systems accommodating variable data	**60%**	**15%**						
Modify label with existing printing equipment (100% of 15%)	NA	12%	$0	NA	NA	NA	NA	NA
Man. line: modify label w/existing equipment (100% of 60%)	60%		$0	NA	NA	NA	NA	$0
Total Investment								$11,263,789
Total labor			$0	$2,218,759	$384,352	$231,715	$263,591	$3,098,416
Total O&M (10 percent of equipment cost) plus Labor								$4,224,795

(a) See Tables 4-5, 4-6, and 4-7.

(b) Assumes a wage rate plus 29 percent fringe of $22.27 per hour (BLS, 2009) for inspectors in NAICS 339.

(c) Incremental costs for outside printer labels assumed primarily costs of coordination, which is passed through to labelers. This cost is captured in Table 4-21.

total and $4.2 million to the labor and operating and maintenance requirements, assuming O&M is 10 percent of first-year costs.

4.3.2.5 Labeling Costs

Table 4-20 and Table 4-21 summarize the application of label costs to R/Rs. Although ERG collected some evidence that digital printing technologies may be more prevalent, ERG continues to use the same assumptions as those used for manufacturers, with per-establishment costs for materials and one-time redesign costs equaling those for manufacturers. The first year costs of redesign are $4.6 million and the recurring materials costs are $1.0 million under these assumptions.

4.3.2.6 Software Costs

Table 4-22 presents the estimated software costs for R/Rs. The size distribution for these firms has been aggregated over wider ranges than was done for manufacturers because ERG believes the simpler production operations in these firms make costs less sensitive to size. R/Rs might not have the same need for integration as manufacturers, therefore, ERG assumes lower costs by employment range apply at the larger sizes. Costs rise only to the level of those seen at larger manufacturing firms. Therefore, only about 25 percent of the largest R/R firms are assumed to incur costs of integrating UDI into all ERP systems. Other operations with ERP systems might opt to integrate UDI into all of their systems, but because they are not manufacturing, ERG assumes that not all such costs are required as a result of the proposed rule. Costs are estimated at $13.1 million in the first year and $1.1 million in subsequent years.

4.3.2.7 GUDID Costs

R/Rs will need to submit similar data to the GUDID as that outlined in Section 4.3.1.7 for manufacturers, reprocessors and specification developers. Although they submit the previously used UDI of the initial labeler, they would be required to input all detailed device information again (rather than being linked to the initial labelers' UDI information). Because R/Rs could look up the detailed information using the initial labeler's UDI, this could save some time. However, because the R/R is now responsible for that information and the information supplied by the initial labeler could be inaccurate or out of date, the R/Rs are assumed to at least check the information against the initial label information, which would take some additional time. Therefore, the same costs per establishment are assumed for R/Rs as for initial labelers. Table 4-23 shows these costs aggregated over the 1,310 R/R establishments

Table 4-20. Derivation of Incremental Device Labeling Redesign Cost, per Establishment and in Aggregate for R/Rs

Establishment Size	Number of Establishments	Costs Per Establishment	Percent Incurring Cost	Aggregate Cost
1-4	736	$1,250	100.0%	$920,587
5-9	212	$2,500	100.0%	$531,108
10-49	272	$5,000	100.0%	$1,361,357
50-99	47	$10,000	100.0%	$471,213
100-249	28	$20,000	100.0%	$553,279
250-499	10	$50,000	100.0%	$483,126
500+	4	$75,000	100.0%	$327,599
Total	1,310			$4,648,270

Source: Estimated by ERG. No firms are assumed to be presenting label information in the precise format required by the proposed rule.

Table 4-21. Derivation of Incremental Device Labeling Materials Cost and Time, Per Establishment, For Relabelers and Repackagers

Employ-ment Size	Number of Estab-lishments	Average Per Establish-ment Incremental Cost	Total Incremental Material Cost	Coordination with Outside Printer			Aggregate Cost (Time & Materials) (a)
				Hrs.	Cost	Aff. Estabs.	
1-9	949	$41	$38,503	50	$3,750	76	$372,995
10-49	272	$221	$60,112	100	$7,500	14	$162,213
50-99	47	$869	$40,959	200	$15,000	2	$69,231
100-249	28	$3,151	$87,171	800	$60,000	1	$136,966
250-499	10	$5,121	$49,484	1,200	$90,000	0	$75,573
500+	4	$32,678	$142,738	2,400	$180,000	0	$142,738
Total	1,310		$418,966			93	$959,716

(a) Includes costs for 2 percent of establishments with 1-9 employees (19 estabs.) to add a supplemental label at a cost of $2,625 per year (see Table 4-12). Also adds material costs to the total. Cost is multiplied by two to account for outside label price increases due to an assumed cost pass-through from printers to account for coordination at the printing shop.
Source: ERG estimates, assuming label time and material costs will equal that for manufacturers on a per-establishment basis; see Table 4-12.

Table 4-22. Software and Associated Costs for UDI Compliance for R/Rs

Cost Element	Employment Size by Firm					Total
	Smallest (1-4) (a)	Small (5-19) (a)	Medium (20-199) (b)	Large (200-499) (c)	Largest (500+ (d)	
Initial Investment Costs						
Software	$200	$7,500	$15,000	$30,000	$52,500	
Installation, Integration, Verif. & Testing	$600	$1,000	$5,000	$25,000	$45,000	
Validation	$0	$1,000	$2,000	$3,500	$55,000	
Total software investment	$800	$9,500	$22,000	$58,500	$152,500	
No. of employees assumed needing training	1	10	50	175	375	
Training-first year (@$100/employee)	$100	$1,000	$5,000	$17,500	$37,500	
Number of firms	727	318	131	13	24	1,212
Aggregate First-Year Investment	$654,130	$3,334,570	$3,524,309	$988,619	$4,573,782	$13,075,411
Recurring Annual Costs						
Recurring training costs (25 percent of first-year)	$25	$250	$1,250	$4,375	$9,375	
Recurring validation costs (10 percent of first-year)	$0	$100	$200	$350	$5,500	
Annual maintenance contract (18%)	$36	$1,350	$2,700	$5,400	$9,450	
Total recurring annual costs	$61	$1,700	$4,150	$10,125	$24,325	
Aggregate Recurring Costs	$26,165	$428,730	$352,431	$70,244	$227,485	$1,105,056

(a) The smallest firms (1-4 employees) are assumed to perform limited production and to purchase simpler software, with simpler testing and no validation.

(b) Assumes compliance can be achieved with use of single UDI server (only one establishment and line assumed).

(c) Same as for medium firm although greater testing costs are assumed to be required and two software licenses are needed.

(d) Assumes 75 percent of firms use two software licenses and 25 percent of firms have complex ERP systems that require more expensive software and more time-consuming integration.

Source: Estimated by ERG based on discussions with software providers and as discussed in the text. Firm counts use total registered firms in Table 4-17 distributed with data on firms in the affected NAICS by employment size in SBA, 2006.

Note: Most R/Rs are not assumed to require integration of information into ERP systems as a result of the proposed rule, although they might integrate information for their own purposes.

Table 4-23. Per Establishment and Total Cost for R/Rs to Upload UDI Data to the GUDID

Cost Element	Employment Size						Total
	Smallest (1-9)	Small (10-49)	Medium (50-99)	Large (100-249)	Very Large (250-500)	Largest (500+)	
Initial Investment Costs per Establishment							
Hours to gather, prepare and organize files	1	2	NA (a)	NA (a)	NA (a)	NA (a)	
Hours to validate submission process	2	3	4	4	4	4	
Hours to access and upload to GUDID	1	1	0.5	0.5	0.5	0.5	
Hourly wage with benefits	$75	$75	$75	$75	$75	$75	
Subtotal cost per establishment	$300	$450	$338	$338	$338	$338	
Conversion to SPL	$0 (c)	$0 (c)	$100	$100	$100	$100	
Total costs per establishment	$300	$450	$438	$438	$438	$438	
Total Establishments (d)	949	272	47	28	10	4	1,310
Aggregate First-Year Investment	**$284,674**	**$122,522**	**$20,616**	**$12,103**	**$4,227**	**$1,911**	**$446,053**
Recurring Training Costs (25 percent of first-year)							
Submitting changes	0.5	0.5	0.5	0.5	0.5	0.5	
Hourly wage with benefits	$75	$75	$75	$75	$75	$75	
Total costs per establishment	$38	$38	$38	$38	$38	$38	
Aggregate Recurring Costs	**$35,584**	**$10,210**	**$1,767**	**$1,037**	**$362**	**$164**	**$49,125**

(a) Costed in MIS software reconfiguration costs. See Table 4-22.

(b) Based on the median hourly wage rate for management occupations in NAICS 3391 (BLS, 2009). Benefits are calculated at 29% of wages (BLS, 2010).

(c) Web entry.

(d) From Table 4-16.

assumed to be affected by GUDID submission requirements. The costs to R/Rs are expected to be $0.4 million initially, and only about $50,000 per year thereafter for all R/Rs.

4.3.2.8 Total Costs to R/Rs

Table 4-24 presents the cost totals for R/Rs. These establishments add $34.3 million to the investment total and $10.1 million to the annualized cost total (including annualized investment costs and recurring year costs) for the proposed rule under an assumption that all costs are incurred immediately after promulgation. See Section 4.4 for total costs estimated under the proposed implementation schedule.

Table 4-24. Total Investment and Annual Recurring Costs for UDI Implementation for R/Rs

Cost Element	First-Year	Annual Recurring
Administration and planning	$3,284,629	NA
Registration Costs	$1,577,798	NA
Equipment and other investments	$11,263,789	$3,098,416
Incremental label cost	NA	$959,716
Label redesign cost	$4,648,270	NA
Software (with training)	$13,075,411	$1,105,056
Recordkeeping & Reporting (GUDID)	$446,053	$49,125
Total	$34,295,949	$5,212,314
Annualized Investment Total (a)		$4,882,972
Total Annualized Costs		$10,095,285

(a) First-year costs are annualized at 7 percent over 10 years.
Source: See previous tables.

4.3.3 Total Costs to U.S. Industry

When costs for R/Rs are combined with those for initial labelers, the proposed rule is estimated to generate total investment costs of $396.3 million (see Table 4-25). When annualized, with recurring costs considered and under an assumption of immediate implementation, the costs are $130.1 million per year. See Section 4.4 for cost estimates under the proposed implementation period.

Table 4-25. Total Investment and Annual Recurring Costs for UDI Implementation under Proposed Rule—Manufacturers, Reprocessors, Specification Developers, and R/Rs

Cost Element	First-Year	Annual Recurring
Labeling and Database Requirements		
Administration and planning	$46,534,208	NA
Registration costs	$2,156,044	NA
Equipment and other investments	$82,803,532	$39,573,903
Incremental label cost	NA	$9,453,078
Label redesign cost	$47,600,999	NA
Software (with training)	$187,084,368	$22,200,409
Recordkeeping & Reporting (GUDID)	$3,148,757	$415,783
Total Labeling and Database Requirements	$369,327,910	$71,643,173
Direct Marking		
Implants	$12,038,857	$845,151
Multi-Use Devices	$14,919,691	$1,141,787
Total Direct Marking	$26,958,548	$1,986,938
Total	**$396,286,458**	**$73,630,111**
Annualized Investment Total (a)		**$56,422,276**
Total Annualized Costs for Industry		**$130,052,387**

(a) First-year costs are annualized at 7 percent over 10 years.
Source: See previous tables.

4.3.4 Costs to the Issuing Agencies

ERG reviewed the materials and information available on the GS1 and HIBCC websites and concluded that much of the information required to be submitted to FDA is already in existence at these two potential issuing agencies. ERG also concluded that the systems in place, with very minor modifications to procedures, match FDA's requirements for UDI creation and management. Therefore, ERG has assumed that the costs of meeting FDA's requirements are primarily to gather the information to submit to FDA as part of an initial and recurring application to serve as an issuing agency, to inform their existing members of any changes, or to reassure them that the process would remain substantially the same. ERG assumes that some website work might be done, as well as the development of letters and emails to current members. Additionally, the issuing agencies would need to submit a list of labelers to FDA both initially and ongoing. ERG assumes that this work would entail modifications to data collection systems currently used for managing GTINs and HIBCs to automate such data collection to distinguish UDI number requests from other number requests. Costs for registering additional members

incremental to the numbers that might register absent the proposed rule is not a cost of the rule; providing these organizations with new members is beneficial to the organizations.

Nevertheless, ERG also judged that the assumption of significant responsibilities in the UDI program for the issuing agencies would be examined carefully by executives and by legal counsel for these organizations. The entities would want to ensure that their current membership interests are protected and that their organization's goals are not impeded by the new relationship.

ERG allotted $250,000 per entity in the first year to address any organizational and legal issues involved, a cost which dominates the overall cost for the entities. ERG estimates that the total cost to the two organizations performing functions similar to issuing agencies would be about $529,000 in the first year and $54,800 in subsequent years. Annualized over 10 years at 7 percent, the cost to these organizations is approximately $130,000 per year (see Table 4-26).

Although, at this time, ERG assumes only two agencies would become issuing agencies, ERG also considered whether such costs would be similar for any other agency that wished to become an issuing agency and concluded that such costs would be similar to those for GS1 and HIBCC. The rationale is that any basic startup costs associated with being an issuing agency are not regulatory. FDA is not requiring anyone to be an issuing agency; it is voluntary. The act of becoming an issuing agency requires that agency to track their members, provide information to their members, and other similar tasks. FDA requirements, however, impose specific tasks that might be incremental to these tasks, requiring a specific way of organizing information and informing members. Because agencies wishing to become issuing agencies would be able to assess the best way to organize themselves to meet their own internal requirements as well as FDA requirements at the time of start up, it is possible that the incremental costs estimated for HIBCC and GS1 could be reduced at new startup agencies. Therefore, the incremental costs to meet the proposed requirements should be similar to or less than those estimated for the two likeliest issuing agencies.

Table 4-26. Costs to Issuing Agencies for Meeting FDA Requirements (Assumes Two Agencies)

Cost Element	Number of Hours	Wages (a)	Total Cost
First-year Costs			
Informing labelers of requirements	80	$75	$12,000
Set up list of labelers (to automate data collection)	20	$125	$5,000
Initial application	80	$75	$12,000
Executive and legal reviews	Not est.	NA	$500,000
Aggregate First-Year Investment	**NA**	**NA**	**$529,000**
Recurring Costs			
Maintaining a list of labelers	12	$75	$1,800
Application renewal	20	$75	$3,000
Recurring executive and legal reviews (10 percent of first year)	Not est.	NA	$50,000
Aggregate Recurring Costs	**NA**	**NA**	**$54,800**

(a) Wage rate of $75 reflects management wage plus fringe; wage rate of $125 reflects software engineer wage plus fringe.
Note: These costs are estimated assuming that any costs associated with the inability to reuse numbers when a device is discontinued (as is currently done) will be negligible. Additionally, GS1 and HIBCC generally require a change in the UDI if there is a significant change to the product. It is assumed that any changes that require a UDI change by FDA would also require a change by GS1 and HIBCC.
Source: Based on data from GS1 (assuming UDI is the GTIN) and HIBCC (assuming UDI is HIBC) websites. Numbers offered by these organizations include barcoding capability (AIDC technology) and an option for production identifiers and appear to match the proposed rule requirements, assuming the organizations are in compliance with ISO/IEC 15459-4.

4.3.5 All Costs of UDI to All U.S. Entities

Based on the forgoing, ERG estimates that the total annualized cost to U.S.-based entities, including issuing agencies, under an assumption of immediate implementation, is $130.2 million per year, discounted at 7 percent over 10 years. Estimated costs calculated under FDA's proposed implementation schedule are presented in Section 4.4.

4.3.6 Costs for Foreign Entities and All Affected Entities

The number of foreign labeling entities is nearly equal to the number of domestic labeling entities. Using the assumptions that those entities are similar to domestic entities, the annualized costs to foreign entities should approximately equal those for domestic entities, or a total of $130.1 million per year. This would bring the total of all annualized costs to all entities both foreign and domestic to about $260.2 million per year (see Table 4-27).

Table 4-27. Costs of the Proposed Rule for All Affected Entities

Entity	One-Time Costs	Recurring Costs	Annualized One- Time Costs	Total Annualized Costs
Domestic Industry	$396,286,458	$73,630,111	$56,422,276	$130,052,387
Issuing Agencies	$529,000	$54,800	$75,318	$130,118
Foreign Industry (a)	$396,286,458	$73,630,111	$56,422,276	$130,052,387
Total Non-Federal Costs	**$793,101,916**	**$147,315,022**	**$112,919,870**	**$260,234,892**

(a) Assumes costs to foreign industry are the same as domestic costs, based on number of registrations with FDA.

Source: See previous tables.

4.4 TIMING OF INVESTMENTS

The costs in the previous sections are estimated assuming that all costs are incurred at promulgation. In reality, FDA has proposed granting additional time for device labelers to come into compliance with UDI requirements. Class III devices would be given a year from promulgation to be labeled and if they needed to be marked, these devices would be given an additional 2 years before direct marking would be required. Class II and Class I (and unclassified) devices would be given three years and five years, respectively, from promulgation before the labels for those devices would need to display a

UDI. An additional 2 years beyond the basic labeling requirement implementation timeframe is provided before direct marking of the device would be required (i.e., 5 years for Class II and 7 years for Class I).[28]

ERG investigated the device classification of those devices identified as implants and multi-use devices (see Section 4.3.1.4). Generally, implants are classified as Class III devices and most multi-use devices are classified as Class I devices. Therefore costs to mark implants are considered to begin two years after general Class III costs begin to be incurred and costs to mark multi-use devices are considered to begin 7 years after general Class I costs begin to be incurred.

Any extensions in implementation dates would reduce costs. First, costs for label redesign, if not required for implementing a change to a date format, would most likely be reduced. For many devices, particularly Class I and Class II devices (assuming no date format change applied), that redesign might occur during the normal cycle for redesigning labels regardless of other, regulatory requirements. Additionally, the regulatory costs of purchasing printing equipment might also be reduced if those purchases would have been made anyway or to replace worn out equipment. Even if the printer choice is upgraded to comply with UDI requirements, the incremental cost would be the difference between what the original choice might have been versus the upgraded choice, not the cost of a new printer altogether.

ERG is not speculating on the effect such compliance extensions might have on incremental costs, except to note that certain costs for some labelers could be less than those represented in this section of the report for the reasons discussed above. However, any outlay the industry makes that is delayed has an effect on the value of that outlay in the present (that is, the farther in the future an outlay is made, the less expensive that outlay is in terms of its present value). Therefore, ERG has arrayed the outlays expected to be made in the years in which the proposed rule requires compliance so that the present value of all outlays by labelers can be estimated and the present value of those outlays can be annualized for comparison to the estimate calculated in Table 4-25, which assumes an immediate outlay at promulgation.

ERG uses the first year and recurring year costs shown in Table 4-25 and assigns those costs on the basis of the proportion of establishments with Class III, Class II, or only Class I devices. The numbers of establishments by each Class of device are calculated using FDA's Registration & Listing database

[28] Unclassified devices have the same compliance date as Class I devices; these devices have been grouped with Class I devices for the purpose of this analysis. Where Class I is shown, unclassified devices are implied as well.

(FDA, 2010a), which contains the product codes of all devices labeled by each labeler. ERG then linked FDA's product code database (FDA, 2010b), which provides the Class of the device for each product code, with the registration and listing data to create a count of domestic labelers who label (1) any Class III devices, (2) Class II and Class I devices only, or (3) Class I devices only. These counts can be seen in Table 4-28. The percentages shown in the table are those used to distribute the costs of compliance by year incurred. Note that half of recurring costs are assigned, for simplicity, in the first year of implementation for each device Class because ERG assumes that some operating costs (which are captured as a portion of recurring year costs) are incurred in the first year of implementation. For example, as the table shows, 6 percent of all labeling establishments label Class III devices. Therefore, ERG assumes that 6 percent of first year costs and half of the 6 percent of recurring year costs (excluding costs for DM) are incurred by the Class III compliance date.

ERG has also made a simplifying assumption that, for example, if a labeler labels any Class III device, the entire establishment and all of its lines would come into compliance at the time the Class III device must meet UDI requirements (excluding devices requiring DM). So even if some lines are labeling Class I devices, the entire establishment's outlay is assumed to have occurred by the most restrictive compliance date (in this case, the Class III compliance date). This could overstate costs to some extent, since certain lines at an establishment might be brought into compliance later than is estimated here. As noted, DM costs are assumed to be incurred 2 years after the compliance date for the relevant type of device (implant costs are assumed incurred 2 years after the Class III compliance date and multi-use devices are assumed incurred 2 years after the Class I compliance date).

ERG also made some simplifying assumptions regarding the effect of the 90-day implementation period for date format changes. Because we assume all labelers are affected by this requirement, and that all labelers would meet the date format change and simultaneously redesign their labels to accommodate UDI, we assume they incur the costs of label redesign and label materials immediately. We have, therefore, placed the first year costs of label redesign and all recurring costs of label materials and labor time in the first year. We have not separated the time costs to apply secondary labels and to confer with outside printers from the costs of materials even though such costs would not be incurred immediately. These time costs are small, however and placing all label time and materials costs in the first year simplifies the timing calculations.

The timing assumptions for costs other than those related to labeling redesign and materials are as follows. ERG assumes that the rule would be promulgated by year end 2011, with Class III device

compliance required at the end of 2012. (The formula used to calculate present value, however, is one that calculates a beginning of year outlay because many outlays would be made in the year prior to the compliance date.) ERG then assigns 50 percent of the recurring costs in the same year in which implementation outlays begin and all recurring costs are assigned in subsequent years.

Table 4-28. Numbers and Percentages of Labeling Establishments with Class III, Class II, and Class I Devices

	Class I Only		Class I & II Only		Any Class III		
Type of Labeler	**Number of Estabs.**	**Percent**	**Number of Estabs.**	**Percent**	**Number of Estabs.**	**Percent**	**Total**
Manufacturer	1,813	24%	2,729	36%	359	5%	4,901
Reprocessor	8	0%	13	0%	0	0%	21
Spec. Developer	646	9%	636	8%	64	1%	1,346
R/R	829	11%	460	6%	21	0%	1,310
All Labelers	3,296	**43%**	3,838	**51%**	444	**6%**	7,578

Source: FDA's Registration & Listing Database, FDA, 2010a; FDA's Product Codes Database, FDA, 2010b.

The timing array is presented in Table 4-29. The table computes the present value and annualized costs under two analytical time frames and two discount rates. The first time frame is a 20-year timeframe, in which certain outlays are incurred when reinvestments in equipment and software are made 10 years after initial outlays are made. The present value calculated covers the entire 20 years of outlays and is annualized over 20 years at a 7 percent discount rate and then at a 3 percent discount rate. The second time frame is a 10-year time frame (which corresponds to the time frame used elsewhere in this report). In this analysis, the present value is calculated over 10 years and is annualized over 10 years and at the 7 percent and 3 percent discount rates.

As Table 4-29 shows, the annualized costs to labelers, which were $130.1 million per year in Table 4-25, drop to $92.6 million per year using the same 7 percent and 10-year time frame as used previously. This is $37.4 million per year less than that shown in the earlier table. At 3 percent over 10 years, the costs are $92.4 million per year, or $37.6 million less than that shown in the earlier table. Under the 20-year time frame at the 7 percent discount rate, costs are $96.8 million per year (higher than under the 10-year analysis due to the need for some reinvestment following the end of the 10-year time frame), which is $33.2 million less than that shown in the earlier table. At a 3 percent discount rate over 20 years, the cost is $97.1 million per year ($32.9 million per year less than that calculated under the immediate implementation assumption).

Table 4-29. Total Costs of the Proposed Rule to All Labelers with Timing of Outlays Occurring in Years Corresponding to Compliance Dates One Year, Three Years, and Five Years from Promulgation, Depending on Class of Device Labeled

Year	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Industry Share	5.86%	0.00%	50.65%	0.00%	43.49%															
Class III	$20,672,070	$3,643,759	$16,105,191	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909
Class II			$178,692,356	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174
Class I					$153,457,531	$27,049,162	$42,539,747	$28,190,949	$28,190,949	$28,190,949	$28,190,949	$28,190,949	$28,190,949	$28,190,949	$28,190,949	$28,190,949	$28,190,949	$28,190,949	$28,190,949	$28,190,949
Labeling	$57,054,077	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078
Reinvestment (a)											$15,812,909		$141,555,121		$117,385,923		$10,668,380			
Total	$77,726,148	$13,096,837	$204,250,625	$45,439,161	$198,896,693	$72,488,324	$87,978,909	$73,630,111	$73,630,111	$73,630,111	$89,443,020	$73,630,111	$215,185,232	$73,630,111	$191,016,033	$73,630,111	$84,298,491	$73,630,111	$73,630,111	$73,630,111
PV at 7%	$77,726,148	$12,240,034	$178,400,406	$37,091,891	$151,737,335	$51,683,173	$58,624,062	$45,853,132	$42,853,395	$40,049,902	$45,468,296	$34,981,135	$95,544,816	$30,553,878	$74,079,311	$26,686,941	$28,554,815	$23,309,407	$21,784,493	$20,359,339
PV at 3%	$77,726,148	$12,715,375	$192,525,804	$41,583,270	$176,717,135	$62,529,065	$73,680,951	$59,868,018	$58,124,289	$56,431,349	$66,554,007	$53,191,959	$150,926,592	$50,138,523	$126,284,101	$47,260,366	$52,532,032	$44,547,428	$43,249,930	$41,990,223
NPV over 20 yrs. at 7%	$1,097,581,910																			
Annualized (7%, 20 yrs.)	$96,826,138																			
NPV over 20 yrs. at 3%	$1,488,576,565																			
Annualized (3%, 20 yrs)	$97,141,483																			
NPV over 10 yrs. at 7%	$696,259,478																			
Annualized (7%,10 yrs.)	**$92,646,435**																			
NPV over 10 yrs. at 3%	$811,901,404																			
Annualized (3%, 10 yrs.)	$92,407,391																			

Source: ERG calculations. Total first-year and annual costs from Table 4-25. After 10 years, reinvestments in equipment and software are assumed. First-year costs for other items do not recur after 10 years. Half of recurring costs are assumed incurred in first year of implementation.

SECTION FIVE

ECONOMIC IMPACTS

The proposed rule, with costs as shown in Section Four, would have an impact on firms and establishments identified as medical device labelers. This section discusses these impacts in terms of compliance costs as a percentage of firm and establishment revenues. Both initial labelers (manufacturers, reprocessors, and specification developers) and R/Rs are discussed, respectively, in Sections 5.1 and 5.2 below. Section 5.3 summarizes the number of firms that are affected by the compliance costs in excess of 1 percent, 3 percent, and 5 percent of revenues. Impacts on firms with and without direct marking are presented for comparison purposes. Impacts on all establishments are presented in Section 5.4.

5.1 IMPACTS ON DEVICE MANUFACTURING, REPROCESSING, AND SPECIFICATION DEVELOPMENT FIRMS

To determine impacts on firms, ERG needed to combine costs estimated for establishments and those estimated for firms. Those costs already calculated per-firm for each size of firm needed little additional work. However, establishment costs did require some work before they could be applied to firms. Specifically, ERG defined all of these costs on a per-establishment basis by size, then made assumptions (based on firm size) about the size and numbers of establishments owned by firms.

ERG first compiled the costs estimated in Section Four that were based on establishments. These costs included planning and administrative costs, printing equipment and related costs, costs to initially redesign device labels to accept the barcodes, ongoing label labor and materials costs for supplemental labels or larger device labels, and costs for uploading information into the GUDID. Section Four did not, however, present all of these per-establishment costs by establishment size. Therefore, ERG restructured the aggregate costs for initial labelers (manufacturers, reprocessors, and specification developers) so that they could be presented on the basis of size. Additionally, a few establishments are expected to incur sizeable DM costs. Because most establishments would not incur these costs, ERG separately addresses DM costs and assigns them to a subset of affected establishments.

Table 5-1 presents the results of this distribution of aggregate first year and recurring year establishment costs by establishment size and by type of cost. (These costs are not yet annualized). Because ERG is developing “typical costs” to apply to firms, costs for some small establishments (with 1 to 9 employees) to read and understand the rule to the point where they realize they have an exception, are

Table 5-1. Total Costs by Establishment Employment Size Group for Initial Labelers (Excludes Software and Computer-Related Costs)

Estab. Size	No. of Initial Labelers	Costs of Planning, Labeling & GUDID (a)		Costs of Equipment		Additional Costs of DM, Multi-Use Items (b)		Additional Costs of DM, Implants (b)	
		First Year	Rec. Yr.	First Year	Rec. Year	First Year	Rec. Year	First Year	Rec. Year
1-4	1,162	$4,673,706	$547,652	$481,138	$48,114	$451,635	$45,163	$962,852	$96,285
5-9	721	$5,535,925	$341,685	$298,525	$29,853	$320,491	$32,049	$670,287	$67,029
10-49	1,725	$25,441,623	$1,156,996	$40,259,751	$16,008,212	$902,065	$90,207	$2,366,075	$236,607
50-99	472	$9,178,559	$698,388	$10,532,418	$4,187,934	$279,776	$27,978	$743,303	$74,330
100-249	396	$15,218,253	$1,807,136	$8,700,669	$5,857,893	$2,557,456	$255,746	$973,982	$97,398
250-499	195	$16,849,872	$1,321,907	$6,960,185	$6,114,641	$3,600,837	$360,084	$1,169,017	$116,902
500+	113	$14,644,780	$2,986,256	$4,307,057	$4,228,841	$3,011,323	$301,132	$688,979	$68,898
Total	**4,784**	**$91,542,717**	**$8,860,020**	**$71,539,744**	**$36,475,487**	**$11,123,585**	**$1,112,359**	**$7,574,495**	**$757,450**

(a) Does not include planning cost for exempt facilities to understand rule.

(b) Includes only the cost of DM (does not include costs for exemptions or software upgrades).

Source: Previous tables in Section Four.

not considered (however, costs to establishments using UPCs only are included on a weighted average basis). These costs are assumed to have a negligible impact on the firms to which they apply and are not considered sufficiently widespread or large enough to distribute across all firms that do not meet exceptions.

Additionally, DM costs reflect only the costs for DM; costs for filing exceptions and notifying FDA, if necessary, and for upgrading software are very small and affect only a small portion of those establishments required to directly mark devices. Also, DM costs should be the "typical" costs applying to the few establishments that would need to mark devices rather than "average costs" distributed across all establishments, which would understate impacts. By omitting some small costs not applicable to the majority of establishments and by separating the substantial DM costs (which apply only to a few establishments), from other costs applicable to all establishments, ERG can construct per-establishment costs that are representative of costs to the large majority of establishments. Costs to establishments and impacts on firms that would need to meet DM requirements are handled separately from other costs and impacts throughout this section.

Table 5-2 presents the costs shown in Table 5-1 on an annualized basis (using 7 percent over 10 years), then presents those costs on a per-establishment basis for the various size establishments. Total per-establishment costs applicable to all establishments are shown, along with additional costs that would apply to establishments that would need to meet various DM requirements. Note that equipment costs reflect a weighted average cost to establishments, a few of which are assumed to have variable printing capabilities already (about 3 percent of establishments overall, mostly larger establishments). The per-establishment costs calculated with this weighted average do not differ substantially from those calculated assuming that no establishments have variable printing capabilities. As a result, ERG believes that the per-establishment costs captured are representative of the equipment costs for a very large majority of establishments owned by affected firms.

As Table 5-2 indicates, total costs applicable to all establishments on a per-establishment basis range from a little over $1,000 per year for the smallest establishments up to about $88,000 per year for the largest establishments. DM costs add substantially to the costs of the few establishments that would need to meet DM requirements. The DM costs range from a low of about $6,000 per facility per year for the smallest establishments for marking multi-use equipment up to a high of over $260,000 per establishment per year for marking implants at the largest facilities. These costs are used later in Section 5.4 to investigate impacts at the establishment level.

Table 5-2. Annualized Costs and Per-Establishment Costs for Initial Labelers (Excluding Software and Computer-Related Costs)

Estab. Size	No. of Initial Labelers	No. of Affected DM Estabs.		Annualized Cost of Planning, Labeling and GUDID	Annualized Cost of Equipment	Annualized Cost of DM, Multi-Use Items (a)	Annualized Cost of DM, Implants (a)	Per-Estab. Costs of Planning, Labeling, and GUDID	Wtd. Avg. Per-Estab. Costs of Equipment (b)	Total Per-Estab. Costs Applicable to All Estabs.	Per Estab. Costs of DM, Multi-Use	Per-Estab. Costs of DM, Implants
		Multi-Use	Implants									
1-4	1,162	19	8	$1,213,082	$116,617	$109,466	$233,374	$1,044	$100	$1,144	$5,817	$30,115
5-9	721	13	5	$1,129,877	$72,356	$77,680	$162,462	$1,567	$100	$1,667	$5,817	$30,115
10-49	1,725	38	14	$4,779,311	$21,740,295	$218,640	$573,483	$2,771	$12,604	$15,375	$5,817	$42,234
50-99	472	12	4	$2,005,208	$5,687,513	$67,811	$180,160	$4,246	$12,044	$16,291	$5,817	$48,294
100-249	396	13	3	$3,973,873	$7,096,672	$619,870	$236,071	$10,037	$17,924	$27,961	$48,112	$84,469
250-499	195	6	1	$3,720,949	$7,105,615	$872,762	$283,343	$19,088	$36,451	$55,539	$158,621	$207,096
500+	113	4	1	$5,071,343	$4,842,069	$729,877	$166,993	$44,823	$42,796	$87,619	$202,825	$263,419
Total	**4,784**	**103**	**35**	**$21,893,644**	**$46,661,137**	**$2,696,107**	**$1,835,887**					

(a) Cost of DM only (does not include costs of exceptions or software upgrades to print barcodes).

(b) Cost of equipment per establishment is the weighted average of costs to those printing variable barcodes (3 percent of all establishments) and to those that are not.

Source: Table 5-1. Costs are annualized at 7 percent over 10 years.

In Table 5-3, ERG distributes the per-establishment costs among the medical device labeling firms, based on several assumptions about the number of establishments per firm. The planning, labeling, GUDID, and equipment costs for the various sizes of establishment are assigned to firms based on assumptions shown in the footnotes to Table 5-3. These assumptions are based on the fact that most firms own only one establishment and most multi-establishment firms are larger firms. These assumptions are also adjusted to keep the number of establishments by size allocated among the various firm sizes reasonably consistent with the estimated total number of establishments by size and to keep the overall aggregate annualized costs to the firms roughly equal to the overall aggregate annualized costs to all the establishments for those four cost categories.

Once all of the planning, labeling, equipment, and GUDID costs are distributed to firms based on the assumptions shown in Table 5-3 and the software costs to the firms are added in, the annualized cost per firm (not including DM) is calculated. This cost ranges from about $1,300 per year at the smallest firms to about $0.5 million per year at the largest firms. Note that it is assumed that a firm would own only one DM establishment, so the number of affected DM firms equals the number of affected DM establishments. ERG does not know the distribution of such establishments by firm. If some firms own more than one such establishment, impacts on such firms might increase, but the number of affected firms would be fewer.

To judge the impacts such costs would have on the various industries, ERG obtained a 2007 estimate of aggregate revenues and total firms by firm size and by NAICS from SBA. ERG assumes the revenues for reprocessors are similar to those for manufacturing firms in NAICS 339112 (Surgical and Medical Instrument Manufacturing). ERG also assumes that the revenues for specification developers are similar to the average revenues, by size, across all device manufacturing NAICS. ERG makes these assumptions because these firms make up a highly specialized and very small fraction of the NAICS groups to which they belong and the revenues for those NAICS groups are not considered to reflect the revenues received by firms with ultimate responsibility for the manufacture or reprocessing of medical devices. ERG then calculated the average revenues for various firm size categories, as shown in Table 5-4. Because these firm size categories are more aggregated than those used by ERG to distribute costs, Table 5-5 combines the firm sizes between 20 employees and 499 employees to produce a weighted average cost for this aggregated size group. Table 5-6 then assigns the costs that are applicable to all firms by size (not including DM) to each NAICS and compares these costs to the revenues by size and NAICS.

Table 5-3. Assignment of Establishment Costs to Initial Labeler Firms (Includes Software and Computer-Related Costs)

Cost Element	Employment Size by Firm						
	Smallest (1-4)	Small (5-19)	Medium (20-99)	Large (100-199)	Larger (200-499)	V. Large (500-999)	Largest (1000+)
No. of Firms (adjusts double counting)	1,162	1,403	980	172	96	36	89
Planning, labeling, equip. & GUDID	$1,144	$7,150	$15,741	$28,886	$56,356	$103,880	$249,826
Total excluding software and DM	$1,329,233	$10,029,140	$15,425,123	$4,971,630	$5,397,627	$3,769,941	$22,233,127
Software first year	$900	$10,500	$27,000	$76,000	$190,000	$550,000	$905,000
Software recurring	$61	$1,700	$4,150	$10,125	$24,325	$57,250	$94,650
Software annualized	$189	$3,195	$7,994	$20,946	$51,377	$135,558	$223,502
Total costs per firm annualized	$1,333	$10,345	$23,736	$49,831	$107,733	$239,437	$473,328
No. of firms with implant estabs.	8	5	7	4	6	5	1
Add DM implant cost to total	$31,449	$40,461	$65,970	$98,125	$169,038	$329,030	$736,747
No. of firms with multi-use estabs.	19	13	19	12	22	15	4
Add multi-use DM cost to total	$7,150	$16,162	$29,553	$55,648	$138,008	$301,686	$676,153

Source: See previous tables; software costs are from Table 4-13 and are on a firm basis already.

Assumptions for assigning establishment costs to firms:

Costs for planning, labeling, equipment and GUDID use the weighted average costs for facilities needing variable printing equipment and those not needing it (3 percent).

Most firms are single-facility firms (3,901 firms and 4,784 facilities are affected). Number of firms excludes those assumed using variable barcodes.

The largest numbers of facilities are in the 10-49 size; these are assumed common extra facilities among those with multiple facilities.

Small firms (5-19 employees) are assumed to incur costs for one facility weighted at 60 percent 5-9 employee size and 40 percent 10-49 employee size; approximated based on numbers of establishments in each size, assuming single facility firms only.

Medium firms (20-99 employees) are assumed to incur costs for one facility weighted at 60 percent (10-49 employees size) and 40 percent (50-99 employees size).

Large firms (100-199 employees) are assumed split between single-facility firms and firms with two establishments; 20 percent are assumed to have two establishments with 50-99 employees in each facility and 80 percent are assumed single facility firms with 100-249 employees.

Larger firms (200-499 employees) are assumed split between single-facility firms and firms with three establishments; 20 percent are assumed to have three establishments--a 10-49 employee size, a 50-99 employee size and a 100-199 employee size--and 80 percent are assumed to be single facility firms with 250-499 employees.

Very large firms (500-999 employees) are all assumed to be multi-facility firms with five facilities--two 100-249 employee, two 50-99 employee and one 10-49 employee establishments.

Largest firms (1,000+ employees) are all assumed to be multi-facility firms with eight facilities--one 500+ employee, one 250-499 employee, one 100-249 employee, two 50-99 employee and three 10-49 employee establishments.

Firms affected by DM costs are assumed to own only one such establishment.

Firms with implants and multi-use items--affected establishments are distributed so that not all medium firms (20-99 employees) own all 10-49 estabs with multi-use items and implants.

Table 5-4. Estimated Revenues by Firm Size and Industry (2007)

Industry	Firm Revenues by Employment Size			
	0-4 Employees	5-19 Employees	20-499 Employees	500+ Employees
NACIS 325413, In vitro diagnostic substances manufacturing	$890,439	$3,459,254	$28,350,919	$413,375,320
NAICS 334510, Electromedical and electrotherapeutic apparatus mfg.	$520,423	$2,093,210	$21,094,808	$328,866,579
NAICS 334517, Irradiation apparatus manufacturing	$594,135	$2,287,712	$18,572,244	$799,591,714
NAICS 339112 Surgical and medical instrument manufacturing	$443,048	$1,726,137	$15,901,566	$240,247,711
NAICS 339113 Surgical appliance and supplies manufacturing	$365,781	$1,619,236	$13,649,692	$233,294,991
NAICS 339114, Dental equipment and supplies manufacturing	$330,737	$1,042,052	$16,218,051	$167,667,417
NAICS 339115, Ophthalmic goods manufacturing	$1,643,624	$1,556,642	$8,124,152	$215,169,000
Reprocessors (a)	$443,048	$1,726,137	$15,901,566	$240,247,711
Specification Developers (b)	$568,173	$1,657,778	$15,742,070	$284,274,405

(a) Reprocessors are assumed to have revenues similar to those for surgical and medical instrument manufacturing.
(b) Specification developers are assumed to have revenues similar to the average medical device manufacturer.
Source: Based on estimated receipts reported for 2007 (SBA, 2007).

Table 5-5. Costs per Firm Consolidated to Match Firm Sizes for Which Revenue Data Are Available

Cost Element	Employment Size by Firm			
	Smallest (1-4)	Small (5-19)	Medium (20-499)	Largest (500+)
Number of firms (adjusts double counting)	1,162	1,403	1,248	125
Planning, labeling, equipment & GUDID/firm (a)	$1,144	$7,150	$20,672	$207,550
Aggregate costs excluding software and DM	$1,329,233	$10,029,140	$25,794,381	$26,003,068
Aggregate software costs, first year	$900	$10,500	$57,735,869	$100,500,125
Aggregate software costs, recurring	$61	$1,700	$8,139,058	$10,500,995
Aggregate software costs, annualized	$189	$3,195	$16,359,347	$24,809,951
Total costs per firm annualized	**$1,333**	**$10,345**	**$33,782**	**$405,577**
Number of affected firms with implant estabs.	8	5	17	5
Add DM implants (a)	$31,449	$40,461	$111,327	$376,923
Number of affected firms with multi-use estabs.	19	13	53	18
Add multi-use (a)	$7,150	$16,162	$81,147	$374,537

(a) Annualized.

Source: See Table 5-3.

Table 5-6. Impacts of the Proposed Rule on Initial Labelers (i.e., Manufacturers, Reprocessors, Specification Developers)

	No. of Affected Firms (No DM) by Size (a)				Compliance Costs as Percentage of Revenues			
NAICS	1-4	5-19	20-499	500+	1-4	5-19	20-499	500+
325413	10	32	52	10	0.15%	0.30%	0.12%	0.10%
334510	38	91	134	19	0.26%	0.49%	0.16%	0.12%
334517	12	32	31	4	0.22%	0.45%	0.18%	0.05%
339112	57	201	226	22	0.30%	0.60%	0.21%	0.17%
339113	133	382	401	29	0.36%	0.64%	0.25%	0.17%
339114	66	189	85	1	0.40%	0.99%	0.21%	0.24%
339115	50	95	81	6	0.08%	0.66%	0.42%	0.19%
Reprocessors	0	11	6	1	NA	0.60%	0.21%	0.17%
Spec. Dev.	769	351	163	8	0.23%	0.62%	0.21%	0.14%
Total	1,135	1,384	1,178	101	NA	NA	NA	NA

(a) With DM firms removed from counts. DM firms are found only in NAICS 339112 and NAICS 339113. Exempted firms (custom operations and those assumed to be using UPCs only) are also excluded from count, as are those assumed to be using variable barcodes.

Source: Tables 5-4 and 5-5.

As Table 5-6 shows, in all cases, the estimated compliance costs are less than 1 percent of revenues, before DM is considered. The highest percentage shown in the table is 0.99 percent for firms with 5-19 employees in NAICS 339114. This situation changes when DM costs are considered. Table 5-7 presents the compliance costs as a percentage of revenues for the two NAICS categories in which DM requirements would be expected to apply. As the table shows, impacts in terms of compliance costs as a percentage of revenues are higher than 1 percent for all very small firms (1-4 employees) and firms with 5-9 employees marking implants. These higher percentages range from 1.6 percent to nearly 9 percent of revenues (five firms are expected to incur this highest percentage of costs to revenues).

5.2 IMPACTS ON REPACKAGING AND RELABELING (R/R FIRMS

As for estimating impacts on initial labeling firms, ERG first organized the aggregate first-year and recurring-year cost data from Section Four by establishment size. These costs were then annualized and presented on a per-establishment basis in Table 5-8. As the table shows, these costs range from less than $1,000 per establishment per year at the smallest establishments to about $100,000 per establishment per year at the largest establishments. Again, these costs exclude software and computer-related expenses because these have been estimated on a firm basis and are added in after all other establishment-based costs are assigned to firms.

Table 5-9 allocates these establishment costs to firms based on the assumptions shown in the footnote to Table 5-9. The table then adds in software costs.[29] The table also consolidates the costs for firms in the 20-499 size group so that costs can be compared on the same basis as available revenue estimates. Total costs per firm range from about $1,000 per firm per year in the smallest size group to about $144,000 per firm per year in the largest size group. ERG obtained an estimate of aggregate revenues for the two NAICS assumed to represent the R/Rs (see Section Three). The revenues shown are the weighted average revenues between the two NAICS. These revenues are then compared to the compliance costs per year per firm and a percentage is calculated. As the table shows, for all size classes, compliance costs as a percentage of revenues are less than 1 percent.

[29] Unlike initial labelers (who are assumed only rarely to need to register barcodes), the R/Rs are all expected to register, so these costs are included in the table.

Table 5-7. Impacts of the Proposed Rule on Firms Required to Direct Mark

DM Type	Number of Affected Firms (with DM) by Size (a)				Compliance Costs as Percentage of Revenues			
	1-4	5-19	20-499	500+	1-4	5-19	20-499	500+
Multi-Use Items	19	13	53	18	1.61%	0.94%	0.51%	0.16%
Implants	8	5	17	5	8.60%	2.50%	0.82%	0.16%
Total DM	**27**	**19**	**69**	**24**				

Source: Table 5-4 and Table 5-5. Totals might not add due to rounding.

Table 5-8. Aggregate Costs and Annualized Cost per Establishment for R/Rs

Estab. Size	No. of R/Rs	Costs of Planning, Labeling & GUDID (a)		Costs of Equipment		Total Annualized Costs	Total Annualized Costs per Establishment
		First Year	Rec. Yr.	First Year	Rec. Year		
1-4	736	$1,970,056	$317,106	$0	$0	$597,598	$811
5-9	212	$1,072,838	$91,473	$0	$0	$244,221	$1,150
10-49	272	$2,709,100	$172,424	$8,511,459	$2,742,562	$4,512,541	$16,574
50-99	47	$703,875	$70,999	$1,473,058	$474,649	$855,593	$18,157
100-249	28	$814,357	$138,004	$670,456	$451,398	$800,805	$28,948
250-499	10	$661,279	$75,935	$402,360	$353,480	$580,853	$60,114
500+	4	$447,446	$142,902	$206,456	$202,707	$438,710	$100,437
Total	**1,310**	**$8,378,952**	**$1,008,841**	**$11,263,789**	**$4,224,795**	**$8,030,321**	

Source: Previous tables in Section Four. Costs are annualized using 7 percent over 10 years.

Table 5-9. Annualized Costs per R/R Firm, Revenues per Firm and Impacts of the Proposed Rule

Cost Element	Employment Size by Firm					
	Smallest (1-4)	Small (5-19)	Medium (20-199)	Large (200-499)	Medium/ Large (20-499)	Largest (500+)
Number of Firms	727	318	131	13	144	24
Cost of Planning, Labeling, GUDID & Equipment/Estab.	$811	$2,692	$17,272	$44,729	$19,760	$89,909
Aggregate Cost of Planning, Labeling, GUDID & Equip.	$589,761	$854,918	$2,254,456	$581,840	$2,836,296	$2,164,335
Per Firm Cost of Software, First Year	$900	$10,500	$27,000	$76,000	$31,441	$190,000
Per Firm Cost of Software, Recurring Year	$61	$1,700	$4,150	$10,125	$4,691	$24,325
Annualized Per Firm Cost of Software	$189	$3,195	$7,994	$20,946	$9,168	$51,377
Per Firm Cost of Registration	$500	$500	$4,000	$4,000	$4,000	$20,000
Annualized Per Firm Cost of Registration	$71	$71	$570	$570	$570	$2,848
Total Annualized Cost per Firm, including Software and Registration	$1,072	$5,958	$25,835	$66,244	$29,497	$144,133
Total Revenues per Firm	$807,452	$2,804,152	NA	NA	$25,144,926	$462,879,102
Impacts (Compliance Costs as a Percentage of Revenues)	0.13%	0.21%			0.12%	0.03%

Source: Table 5-8, Table 4-18, and Table 4-22; SBA, 2007.

Assumptions used to assign establishment costs to firms:

Small firms (5-19 employees) are assumed to own one facility; 90 percent are assumed to own establishments in the 5-9 employee size class and 10 percent are assumed to own establishments in the 10-49 size class.

Medium firms (20-199 employees) are assumed to own one facility; 90 percent are assumed to own an establishment in the 10-49 employee size class, 5 percent are assumed to own an establishment in the 50-99 employee size class and 5 percent are assumed to own an establishment in the 100-249 employee size class.

Large firms (200-499 employees) are assumed to own one or two facilities; 20 percent are assumed to own two establishments (a 10-49 employee and a 100 to 249 employee size establishment), 40 percent are assumed to own one 250-499 employee size establishment, and 40 percent are assumed to own one 100-249 employee size establishment.

The largest firms (500+ employees) are assumed to own one to four establishments; 50 percent are assumed to own one 500+ establishment; 30 percent are assumed to own two establishments: a 50-99 employee size establishment and a 250-500 employee size establishment; and 20 percent are assumed to own four establishments: three 50-99 employee size establishments and one 100-249 employee size establishment.

5.3 SUMMARY OF IMPACTS ON MEDICAL DEVICE LABELING FIRMS

Table 5-10 summarizes the count of all firms by size and type where compliance costs as a percentage of revenues exceed 1 percent, 3 percent and 5 percent. This table presents a count of such firms with and without DM considered. As the table shows, compliance costs exceed 1 percent of revenues only among firms that would need to meet DM requirements. With DM considered, 1.4 percent of the smallest firms (1-4 employees), 0.3 percent of firms with 5-19 employees, and no larger firms are expected to incur compliance costs exceeding 1 percent of revenues. Therefore, only 0.6 percent of all firms are estimated to incur costs exceeding 1 percent of revenues.

5.4 IMPACTS ON MEDICAL DEVICE LABELING ESTABLISHMENTS

The forgoing analyses investigated the potential for impacts on firms. This analysis investigates the potential for impacts on establishments, also determining whether costs as a percentage of revenues at establishments exceed 1 percent. ERG used Census data (U.S. Census, 2010a) to estimate the value of shipments or receipts at initial labeling and R/R establishments, by size of establishment.

For initial labelers, ERG calculated an estimated average value of shipments per employee at each of the industries determined to be affected by the rule. As in the firm analysis, ERG used the medical device manufacturing industry value of shipments per employee as a proxy for those revenues per employee received by reprocessors and specification developers for similar reasons. That is, ERG believes that the average revenues of establishments in those NAICS reflect primarily the much larger groups of establishments that are not responsible for the manufacture or reprocessing of highly regulated items such as medical devices; therefore, these average revenues are not representative of average revenues associated with specification developers and reprocessors.

Table 5-11 shows the value of shipments per employee calculated in this way by industry. To simplify the analysis, ERG chose the smallest value of shipments per establishment (about $230,000) for all initial labeler establishments, regardless of industry. ERG then used the approximate midpoint of employment in each size group (setting 750 employees as the estimate for employment at establishments with more than 500 employees). We multiplied the number of employees at each size of establishment by the estimated value of shipments per employee to estimate the per-establishment value of shipments at

Table 5-10. Number of Firms with Costs Exceeding 1%, 3%, and 5% of Revenues, With and Without DM Considered

	No. of Firms with Costs >1% of Revenues					No. of Firms with Costs >3% of Revenues					No. of Firms with Costs >5% of Revenues				
NAICS	**1-4**	**5-19**	**20-499**	**500+**	**Total**	**1-4**	**5-19**	**20-499**	**500+**	**Total**	**1-4**	**5-19**	**20-499**	**500+**	**Total**
325413	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
334510	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
334517	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
339112 (no DM)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
339112	19	0	0	0	19	0	0	0	0	0	0	0	0	0	0
339113 (no DM)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
339113	8	5	0	0	13	8	0	0	0	8	8	0	0	0	8
339114	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
339115	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Reprocessors	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Spec. Dev.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
R/Rs	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total with DM	27	5	0	0	32	8	0	0	0	8	8	0	0	0	8
Total without DM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
All Firms	1,889	1,720	1,432	193	5,234	1,889	1,720	1,432	193	5,234	1,889	1,720	1,432	193	5,234
% of All Firms with DM	1.4%	0.3%	0.0%	0.0%	0.6%	0.4%	0.0%	0.0%	0.0%	0.1%	0.4%	0.0%	0.0%	0.0%	0.1%
% of all Firms without DM	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Source: Tables 5-6, 5-7 and 5-9. All firms excludes exempted but includes those assumed using variable barcodes.

Table 5-11. Estimated Revenues per Employee in the Medical Device Industries

NAICS	Industry	2007 Employment	2007 Value of Shipments/ Receipts ($000)	Revenue/Employee ($)
Initial Labelers				
325413	In vitro diagnostic substances manufacturing	30,548	$13,001,194	$425,599
334510	Electromedical and electrotherapeutic apparatus manufacturing	62,023	$22,514,375	$363,000
334517	Irradiation apparatus manufacturing	15,533	$10,772,941	$693,552
339112	Surgical and medical instrument manufacturing	108,455	$29,616,237	$273,074
339113	Surgical appliance and supplies manufacturing	107,322	$31,528,866	$293,778
339114	Dental equipment and supplies manufacturing	16,391	$4,368,274	$266,504
339115	Ophthalmic goods manufacturing	24,230	$5,664,577	**$233,784**
Repackagers/Relabelers				
423450	Hospital equipment and supplies	181,685	$134,593,534	$740,807
423460	Ophthalmic goods	22,501	$8,352,967	**$371,226**

Source: U.S. Census Bureau (2010a).

each size of establishment. Table 5-12 shows the results of this calculation. Value of shipments for initial labelers is estimated to range from about $600,000 to $175 million per establishment.

The table also shows costs per initial labeler establishment (not including costs that are incurred at the firm level), with and without DM requirements. Without DM requirements, no establishments are estimated to incur costs exceeding 1 percent of revenues. With DM, 32 establishments are expected to have costs exceeding 1 percent of revenues. (These are the same as the 32 firms expected to have costs exceeding 1 percent of revenues in the firm analysis, because in the affected size groups, firm and establishment are the same entity.)

A similar analysis is undertaken for R/Rs. As Table 5-11 shows, the smallest value of the calculated receipts per employee is about $370,000 per employee. Table 5-12 uses the same

Table 5-12. Impacts of Proposed Rule on Medical Device Labeling Establishments

Estab. Size	Initial Labelers Costs and Shipments				R/R Costs and Receipts		Costs as Percent of Shipments, Initial Labelers			Cost as a Percent of Receipts, R/Rs	Initial Labeler Impacts with DM		
	Annualized Per Estab., without DM	Annualized Cost Per Estab., Plus DM Multi-Use	Annualized Cost Per Estab., Plus DM Implant	Estimated Shipments per Estab.	Annual Cost per Estab.	Estimated Receipts per Estab.	No DM	With Multi-Use DM	With Implant DM		No. of Multi-Use Estabs.	No. of Implant Estabs.	No. Estabs. With Costs>1% of Shipments
1-4	$1,144	$6,961	$31,260	$584,460	$811	$928,066	0.2%	1.2%	5.3%	0.1%	19	8	27
5-9	$1,667	$7,484	$31,783	$1,636,488	$1,150	$2,598,585	0.1%	0.5%	1.9%	0.0%	13	5	5
10-49	$15,375	$21,192	$57,609	$7,013,520	$16,574	$11,136,794	0.2%	0.3%	0.8%	0.1%	38	14	0
50-99	$16,291	$22,742	$65,219	$17,533,800	$18,157	$27,841,986	0.1%	0.1%	0.4%	0.1%	12	4	0
100-249	$27,961	$78,065	$114,422	$40,912,200	$28,948	$64,964,634	0.1%	0.2%	0.3%	0.0%	13	3	0
250-499	$55,539	$220,592	$269,068	$87,669,000	$60,114	$139,209,930	0.1%	0.3%	0.3%	0.0%	6	1	0
500+	$87,619	$301,143	$361,737	$175,338,000	$100,437	$278,419,859	0.0%	0.2%	0.2%	0.0%	4	1	0
Total											103	35	32

Source: Tables 5-1, 5-9, and 5-11.

approach as described above to calculate a per-R/R establishment revenue by size of establishment. The calculated per-establishment revenues are then compared to costs. No establishments are expected to have costs exceeding 1 percent of revenues.

Based on these results, ERG determines that the establishment analysis does not indicate any additional potential for impact on medical device labelers.

SECTION SIX

ALTERNATIVES TO THE PROPOSED RULE

ERG investigated six alternatives to the proposed rule. These alternatives are:

- No action, with an assumed voluntary adoption of UDI over a 15-year period.
- A requirement for labeling only (no direct marking and no GUDID requirements)
- All UDI requirements, but for Class II and Class III devices only
- All UDI requirements, but for Class III devices only
- Static barcoding only (no variable information such as lot, batch, date, or serial numbers needs to be barcoded on label)
- The GUDID entry system and database would be a module within the FDA Unified Registration and Listing Service (FURLS). FDA estimates the costs for developing the entry system and database outside the FURLS system in the preamble to the proposed rule.

These six alternatives are discussed below in Sections 6.1 through 6.6 in terms of their costs and impacts on labelers.

6.1 NO ACTION—VOLUNTARY ADOPTION

ERG investigated a no-action alternative in which there is no regulatory mandate but under which we judge that manufacturers and R/Rs adopt UDI-type systems voluntarily. As a means to characterize this possibility, ERG compared the costs over a voluntary implementation period of 15 years as opposed to the regulation-imposed implementation period of up to 5 years (up to 7 years for DM) assumed in the base case. The voluntary implementation period reflects the premise that manufacturers and R/Rs will implement UDI eventually. Many are currently moving in that direction. For example, the international standards-setting organization, GS1, has been working to develop a UDI standard to coordinate medical device industry efforts. The choice of a 15-year voluntary implementation period reflects the presumption that while manufacturers are moving in the direction of UDI systems, the many small medical device companies, including those that do not sell products internationally, would be slow to adopt a UDI system. Under the proposed rule implementation requirements, labelers of Class I (and unclassified) devices would be allowed five years to meet the proposed rule, while labelers of Class II and Class III devices would need to come into compliance in three years and one year post-promulgation, respectively

(with those needing to directly mark devices allowed an additional two years beyond the time granted for their other UDI requirements). Based on information presented in Section Four, approximately 6 percent of establishments are assumed to come into compliance in the first year (these establishments list at least some devices that are considered Class III devices, although they might also label Class II or Class I/unclassified devices).[30] Another 51 percent label at least some Class II (or Class I/unclassified devices, but no Class III devices) and 43 percent label only Class I/unclassified devices. First-year label redesign and all recurring costs of labeling are placed in the first year (with recurring label costs occurring in subsequent years) due to the 90-day date format change requirement (see Section Four).

Table 6-1 presents the timeline of costs (1) under the schedule imposed by the proposed rule and (2) assuming an even, linear implementation pattern under a fifteen-year voluntary implementation schedule. For the latter, ERG assumed that 1/15 (6.67 percent) of the establishments adopts UDI (with DM, if applicable) each year. These estimates apply only to the establishments that have not already adopted UDI numbering on their devices. The table displays the first year costs (including one-half of the recurring year costs in the first year) and all subsequent year costs, and then sums the industry totals. Finally, ERG calculates the present value of the cost streams over a 20-year period using a 7 percent discount rate. Note that reinvestment costs for equipment and software are assumed after 10 years for each group of establishments coming into compliance in any given year. More details on the methodology can be seen in Section 4.4.

Under the voluntary implementation assumption, costs are incurred much later and the net present value of the total is smaller than under the regulation-mandated schedule. The net present value under the proposed regulation is $352.9 million greater, summing costs over a twenty-year time horizon. Annualized, the difference in NPV is $31.1 million per year. Under a voluntary scenario, there are no regulatory impacts, and any economic impacts from UDI would be less than those under the mandatory scenario. This is because firms would be able to implement UDI within a time frame that allows them the flexibility to keep their costs to a minimum (i.e., upgrade printing equipment when equipment replacement is necessary anyway, rather than when the proposed rule requires).

[30] Does not include the very small number of devices that are licensed under the PHSA (also required to come into compliance in the first year), but this number should not have a measurable effect on the overall percentage for first-year compliance developed in Section Four.

Table 6-1. Twenty-year Horizon of Annualized Costs Assuming Either Voluntary (over 15 Years) or Regulatory (Over 5 Years) Adoption of UDI

Year	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Industry Share	6.67%	6.67%	6.67%	6.67%	6.67%	6.67%	6.67%	6.67%	6.67%	6.67%	6.67%	6.67%	6.67%	6.67%	6.67%					
2012	$28,873,434	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674
2013		$28,873,434	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674
2014			$28,873,434	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674
2015				$28,873,434	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674
2016					$28,873,434	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674
2017						$28,873,434	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674
2018							$28,873,434	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674
2019								$28,873,434	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674
2020									$28,873,434	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674
2021										$28,873,434	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674
2022											$28,873,434	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674
2023											$17,992,527	$28,873,434	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674
2024												$17,992,527	$28,873,434	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674
2025													$17,992,527	$28,873,434	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674
2026														$17,992,527	$28,873,434	$4,908,674	$4,908,674	$4,908,674	$4,908,674	$4,908,674
2027															$19,028,156	$19,028,156	$19,028,156	$19,028,156	$19,028,156	$19,028,156
Total	$28,873,434	$33,782,108	$38,690,782	$43,599,456	$48,508,130	$53,416,804	$58,325,479	$63,234,153	$68,142,827	$73,051,501	$95,952,701	$100,861,376	$105,770,050	$110,678,724	$116,623,026	$92,658,266	$92,658,266	$92,658,266	$92,658,266	$92,658,266
PV	$28,873,434	$31,572,064	$33,794,028	$35,590,144	$37,006,620	$38,085,443	$38,864,729	$39,379,052	$39,659,746	$39,735,176	$48,777,488	$47,918,513	$46,963,167	$45,927,735	$45,228,420	$33,583,620	$31,386,561	$29,333,234	$27,414,238	$25,620,783
NPV over 20 yrs	**$744,714,194**																			

Year	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Industry Share	5.86%	0.00%	50.65%	0.00%	43.49%															
Class III	$20,672,070	$3,643,759	$16,105,191	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909	$4,488,909
Class II			$178,692,356	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174	$31,497,174
Class I					$153,457,531	$27,049,162	$42,539,747	$28,190,949	$28,190,949	$28,190,949	$28,190,949	$28,190,949	$28,190,949	$28,190,949	$28,190,949	$28,190,949	$28,190,949	$28,190,949	$28,190,949	$28,190,949
Labels	$57,054,077	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078	$9,453,078
Reinvestment											$15,812,909		$141,555,121		$117,385,923		$10,668,380			
Total	$77,726,148	$13,096,837	$204,250,625	$45,439,161	$198,896,693	$72,488,324	$87,978,909	$73,630,111	$73,630,111	$73,630,111	$89,443,020	$73,630,111	$215,185,232	$73,630,111	$191,016,033	$73,630,111	$84,298,491	$73,630,111	$73,630,111	$73,630,111
PV	$77,726,148	$12,240,034	$178,400,406	$37,091,891	$151,737,335	$51,683,173	$58,624,062	$45,853,132	$42,853,395	$40,049,902	$45,468,296	$34,981,135	$95,544,816	$30,553,878	$74,079,311	$26,686,941	$28,554,815	$23,309,407	$21,784,493	$20,359,339
NPV over 20 yrs	**$1,097,581,910**																			
Difference in NPVs:	**$352,867,715**																			
Annualized difference in NPV:	**$31,129,174**																			

Source: Total first-year and annual costs from Table 4-25. After 10 years, reinvestments in equipment and software are assumed. First-year costs for other items do not recur after 10 years. Half of recurring costs are assumed to be incurred in the initial year. NPV is calculated at 7 percent over 20 years.

6.2 LABELING ONLY

In the labeling-only alternative, only the costs associated with providing the UDI on labeling are assumed to be incurred. No DM is required, and submission of data to the GUDID is not required.

Therefore, the only cost categories that apply are administrative and planning costs, barcode registration costs, equipment costs, labeling costs and software-related costs. As Table 6-2 shows, this alternative would cost industry $123.4 million per year, under an assumption of immediate implementation, which is $6.7 million per year less than the cost of the proposed rule ($130.1 million per year). In terms of impacts, since costs exceed 1 percent of revenues only when DM is required, all firms would have costs less than 1 percent of revenues. As noted previously, under the proposed rule, 0.6 percent of firms would incur costs greater than 1 percent of revenues because of DM requirements.

Table 6-2 Total Investment and Annual Recurring Costs for UDI Implementation for Medical Device Manufacturers and R/Rs under Label-Only Alternative

Cost Element	First-Year	Annualized and Recurring
Administration and planning	$46,534,208	NA
Barcode registration costs	$2,156,044	NA
Equipment and other investments	$82,803,532	$39,573,903
Incremental label cost	NA	$9,453,078
Label redesign cost	$47,600,999	NA
Software (with training)	$187,084,368	$22,200,409
Total	$366,179,152	$71,227,390
Annualized Investment Total (a)		**$52,135,673**
Total Annualized Costs		**$123,363,063**
Total Annualized Costs Proposed Rule		**$130,052,387**
Difference in Annualized Costs		**$6,689,324**

(a) First-year costs are annualized at 7 percent over 10 years.
Source: Table 4-25.

6.3 ONLY CLASS II AND CLASS III DEVICES REQUIRE UDI

In this alternative, it is assumed that FDA requires UDI only for Class II and Class III devices, although DM requirements for all classes of affected devices continue to be assumed.[31] Establishments that label only Class II and Class III devices must be identified before cost and impact can be estimated. Section 6.3.1 presents the methodology for identifying these establishments. Section 6.3.2 presents the costs and impacts associated with this alternative.

6.3.1 Methodology for Identifying Class II and Class III Device Labelers

ERG used FDA's Registration & Listing database, which provides the product codes associated with each listed device for each establishment, and matched those product codes to Class identifiers in FDA's product codes database (FDA, 2010b). Those devices that were identified as Class II and Class III devices were captured in the analysis, and counts of firms and establishments by type (manufacturer, reprocessor, specification developer, and R/R) were recalculated, using the same methodology outlined in Appendix A and summarized in Section Three. ERG then assumed that the distribution by size and NAICS for both firms and facilities would continue to be the same distributions used to estimate numbers of affected establishments and firms for all affected entities (see Section Three for more information).

Table 6-3 presents the count of manufacturing establishments with any Class II or Class III devices. The total number of manufacturing establishments with Class II and Class III devices is 3,088 in comparison to the 4,901 total manufacturing establishments in FDA's Registration & Listing database. Table 6-4 presents the count of reprocessing and specification development establishments that label Class II and Class III devices. As this table shows, the count of reprocessing establishments drops from 21 to 13 and the count of specification developers drops from 1,346 to 700. Both tables array the counts of establishments by employment size, and Table 6-3 arrays the counts also by NAICS.

Table 6-5 then presents the number of firms whose establishments initially label Class II and Class III devices (i.e., manufacturers, reprocessors, and specification writers), distributed by

[31] This alternative is assumed to require UDI only on Class II and Class III device labels; unclassified devices are also assumed to be excluded. If unclassified devices were to be required to have a UDI on labeling under this alternative (a small percentage of all devices), the number of affected entities and costs would be a little greater.

Table 6-3. Number of U.S. Medical Device Manufacturing Establishments, Distributed Using 2007 Census Data on NAICS and Establishment Size Class under a Class II/Class III UDI Alternative

Establishment Size Class	325413	334510	334517	339112	339113	339114	339115	Total
1 to 4	23	103	27	188	386	169	132	1,027
5 to 9	19	37	12	98	189	97	48	500
10 to 19	17	39	16	95	174	54	44	438
20 to 49	28	57	13	101	158	37	46	440
Total with fewer than 50 employees	**87**	**235**	**68**	**482**	**907**	**356**	**269**	**2,405**
Percent of estab. with fewer than 50 emp.	**65%**	**69%**	**73%**	**71%**	**80%**	**91%**	**84%**	**78%**
50 to 99	15	31	12	65	98	19	24	264
Total with 50-99 employees	**15**	**31**	**12**	**65**	**98**	**19**	**24**	**264**
Percent of estab. with 50-99 employees	**11%**	**9%**	**13%**	**10%**	**9%**	**5%**	**8%**	**9%**
100 to 249	14	36	5	75	75	11	16	233
Total with 100-249 employees	**14**	**36**	**5**	**75**	**75**	**11**	**16**	**233**
Percent of estab. with 100-249 employees	**11%**	**11%**	**6%**	**11%**	**7%**	**3%**	**5%**	**8%**
250 to 499	11	23	4	32	38	5	5	117
500 to 999	3	10	2	14	10	1	3	43
1,000 or more	3	5	2	7	7	0	2	26
Total with 250+ employees	**17**	**37**	**7**	**54**	**55**	**6**	**10**	**186**
Percent of estab. with 250+ employees	**13%**	**11%**	**8%**	**8%**	**5%**	**1%**	**3%**	**6%**
Total	**133**	**339**	**93**	**676**	**1,136**	**392**	**320**	**3,088**

Source: U.S. Census Bureau, 2010a and b, FDA's Registration & Listing Database, FDA, 2010a, and FDA's Product Code Database, FDA 2010b.

Table 6-4. Distribution of Reprocessors and Specification Developers (Establishments) by Size under a Class II/Class III UDI Alternative

Code	Industry Code Description	Total Establishments	1-4	5-9 (a)	10-19	20-49	50-99	100-249	250-499	500-999	1000 or more
NA	Single-Use Device Reprocessors	13	0	3	0	2	2	2	4	0	0
	Engineering Services Estabs.	57,726	30,966	9,006	7,897	6,241	2,182	1,060	243	79	52
541330	Percent of Total		54%	16%	14%	11%	4%	2%	0%	0%	0%
NA	Specification Developers	700	376	109	96	76	26	13	3	1	1

(a) All counts of reprocessors by size remain the same as those in Table 3-8, except that ERG assumes that the reprocessors in the 5-9 employment size group are the likeliest to be currently reprocessing Class I devices. Therefore all but 3 of these reprocessors are removed from the analysis to match the total number of establishments reprocessing Class II and Class III devices.

Source: U.S. Census Bureau, 2010b; FDA, 2010a, b; ERG estimates (see notes above). Distribution percentages are the same as those in Table 3-8.

Table 6-5. Count of Initial Labeling Firms by Employment Size Class under a ClassII/Class III UDI Alternative

Code	Industry Code Description	Total Firms	1-4	5-19	20-99	100-199	200-499	500-999	1000+
NA	Single-Use Device Reprocessors	11	0	3	3	2	2	1	0
	Engineering Services Estabs.	46,761	27,530	12,562	5,109	664	407	160	329
541330	Percent of Total		59%	27%	11%	1%	1%	0%	1%
NA	Specification Developers	668	393	179	73	9	6	2	5
NA	Total Manufacturers	2,556	877	791	526	114	88	38	122
NA	All Initial Labelers	3,235	1,270	973	602	126	95	41	127

Source: FDA, 2010a,b; U.S. Census Bureau, 2010b. Eight reprocessing firms in the 5-19 employment group are assumed to label no Class II or III devices.

size. The number of initial labeling firms is reduced to 3,235 from 5,566 (before exceptions and baseline compliance are considered). All cost calculations then proceed the same way as was presented in Section Four, except with the reduced numbers of affected firms and establishments among the initial labelers. ERG continues to assume that the percentages of establishments currently barcoding with variable barcodes remain the same under this alternative. However, it is possible that establishments labeling Class II or Class III devices might be more likely to barcode with variable barcodes than those labeling Class I devices.

Table 6-6 presents numbers of R/R establishments arrayed by size, and Table 6-7 presents the counts of R/R firms arrayed by size. As Table 6-6 shows, the number of R/R establishments is reduced from 1,310 to 481, while the number of R/R firms is reduced from 1,212 to 438 (Table 6-7). These numbers of firms and establishments are also used in exactly the same way as the counts of establishments and firms were used to generate aggregate costs in Section Four. ERG continues to assume that no R/Rs currently print variable barcodes on their device labels.

Table 6-6. Industry Size Distributions for R/R Establishments Based on 2007 Census Data under a Class II/Class III UDI Alternative

	Numbers of Establishments							
Type of Industry (a)	**Total**	**1-4**	**5-9**	**10-49**	**50-99**	**100-249**	**250-499**	**>500**
Hospital Equipment & Supplies	8,578	4,856	1,365	1,779	310	177	60	31
Ophthalmic Goods	1,319	708	240	278	46	32	13	2
Total	9,897	5,564	1,605	2,057	356	209	73	33
Percent of Total	-	56.2%	16.2%	20.8%	3.6%	2.1%	0.7%	0.3%
Distribution	481	270	78	100	17	10	4	2

(a) The industries that are used to distribute the R/Rs identified in FDA's registration database are the Medical, Dental and Hospital Supplies Merchant Wholesalers Industry (NAICS 42345) and the Ophthalmic Goods Merchant Wholesalers Industry (NAICS 42346).

Source: U.S. Census Bureau, 2010b; FDA, 2010a,b

Table 6-7. Distribution of R/R Firms by Size under a Class II/Class III UDI Alternative

Type of Industry (a)	Numbers of Firms by Employment Size				
	Total	**1-4**	**5-19**	**20-499**	**>500**
Hospital Equipment & Supplies	7,031	4,282	1,811	795	143
Ophthalmic Goods	1,075	579	313	165	18
Total	8,106	4,861	2,124	960	161
Percent of Total	-	60.0%	26.2%	11.8%	2.0%
Distribution	438	263	115	52	9

(a) The industries that are used to distribute the R/R firms identified in FDA's registration database are the Medical, Dental and Hospital Supplies Merchant Wholesalers Industry (NAICS 42345) and the Ophthalmic Goods Merchant Wholesalers Industry (NAICS 42346).

Source: U.S. Census Bureau, 2010b; FDA, 2010a,b, SBA, 2006.

6.3.2 Costs and Impacts of an Alternative Covering Only Class II and Class III Devices

Using the establishment and firm counts discussed in Section 6.3.2, ERG computed the costs of meeting all of the requirements as discussed in Section Four. Table 6-8 summarizes the costs by cost category and compares these costs to the same costs presented in Section Four. Only U.S. industry costs are compared (costs to the issuing agencies remain the same).

As Table 6-8 shows, costs for all cost items are reduced under this alternative. The total annualized cost estimated for this alternative under an assumption of immediate implementation is $80.4 million per year, which is a $49.6 million reduction from the $130.1 million per year for industry estimated for the proposed rule. Impacts on firms remain the same as those estimated for the proposed rule, because this alternative does not affect the per-establishment costs, nor does it affect the need for DM.

6.4 ONLY CLASS III DEVICES REQUIRE UDI

In this alternative, it is assumed that FDA requires UDI only for Class III devices, with DM requirements applied only to Class III devices. Establishments that label Class III devices must be identified before costs and impacts can be estimated. Section 6.4.1presents the methodology for identifying these establishments. Section 6.4.2 presents the costs and impacts associated with this alternative.

Table 6-8. Aggregate Annualized Costs to All Labelers under the Class II/Class III UDI Alternative Relative to the Proposed Rule

Cost Element	Initial Labelers		R/Rs		Total		Proposed Rule	
	First-Year	Annualized and Recurring	First-Year	Annualized and Recurring	First-Year	Annualized and Recurring	First-Year	Annualized and Recurring
Labeling and Database Requirements								
Administration and planning	$26,563,707	NA	$1,206,036	NA	$27,769,742	NA	$46,534,208	NA
Barcode registration costs	$354,702	NA	$570,194	NA	$924,896	NA	$2,156,044	NA
Equipment and other investments	$44,060,539	$22,586,527	$4,135,788	$1,137,663	$48,196,327	$23,724,190	$82,803,532	$39,573,903
Incremental label cost and time	NA	$7,447,350	NA	$447,218	NA	$7,894,568	NA	$9,453,078
Label redesign cost	$26,648,398	NA	$1,706,731	NA	$28,355,129	NA	$47,762,669	NA
Software (with training)	$100,180,654	$12,155,836	$4,725,272	$399,352	$104,905,926	$12,555,188	$187,084,368	$22,200,409
Recordkeeping and Reporting (GUDID)	$1,625,588	$219,899	$163,780	$18,038	$1,789,367	$237,936	$3,148,757	$415,783
Total Labeling and Database Requirements	$199,433,586	$42,409,611	$12,507,801	$2,002,270	$211,941,387	$44,411,882	$369,489,579	$71,643,173
Direct Marking								
Implants	$12,038,857	$845,151	NA	NA	$12,038,857	$845,151	$14,091,249	$845,151
Multi-use devices	$14,919,691	$1,141,787	NA	NA	$14,919,691	$1,141,787	$16,892,574	$1,141,787
Total Direct Marking	$26,958,548	$1,986,938	NA	NA	$26,958,548	$1,986,938	$30,983,823	$1,986,938
Total--All Cost Items	**$226,392,134**	**$44,396,549**	**$12,507,801**	**$2,707,975**	**$238,899,935**	**$46,398,820**	**$400,473,402**	**$73,630,111**
Annualized Investment Total (a)		**$32,233,147**		**$1,780,829**		**$34,013,976**		**$56,422,276**
Total Annualized Costs		**$76,629,696**		**$4,488,804**		**$80,412,796**		**$130,052,387**

(a) Annualized at 7 percent over 10 years.

Source: Section Four and previous tables.

6.4.1 Methodology for Identifying Class III Device Labelers

ERG used FDA's Registration & Listing database, which provides the product codes associated with each listed device for each establishment, and matched those product codes to Class identifiers in FDA's product codes database (FDA, 2010b). Those devices that were identified as Class III devices were captured in the analysis, and counts of establishments by type (manufacturer, reprocessor, specification developer, and R/R) were recalculated, using the same methodology outlined in Appendix A and summarized in Section Three. The number of firms was not identified by Class III only, so ERG assumed that one firm operates one establishment. This assumption possibly overstates firm-level costs estimated for the software cost component because the assumption maximizes the number of firms that would be affected. ERG then assumed that the distribution by size and NAICS for both firms and facilities would continue to be the same distributions used to estimate numbers of affected establishments for all affected entities (see Section Three for more information). For this analysis, however, ERG assumed no Class III devices are sold with UPCs, so ERG made no adjustment for UPC exceptions.

Table 6-9 presents the count of manufacturing establishments with any Class III devices. The total number of manufacturing establishments with Class III devices is 359 in comparison to the 4,901 total manufacturing establishments in FDA's Registration & Listing database. Table 6-10 presents the count of reprocessing and specification development establishments that label Class III devices. As this table shows, the count of reprocessing establishments drops from 21 to 0 and the count of specification developers drops from 1,346 to 64, when compared with the original counts under the proposed rule. Both tables array the counts of establishments by employment size, and Table 6-9 also arrays the counts by NAICS.

Table 6-11 then presents the number of firms whose establishments initially label Class III devices (i.e., manufacturers, reprocessors, and specification writers), distributed by size. The number of initial labeling firms is reduced to 423 from 5,566 (before exceptions and baseline compliance are considered). All cost calculations then proceed generally the same way as was presented in Section Four, except with the reduced numbers of affected firms and establishments among the initial labelers. ERG continues to assume that the percentages of establishments currently barcoding with variable barcodes remain the same under this alternative. However, it is possible that establishments labeling Class III devices might be more likely to barcode with variable barcodes than those labeling Class I or Class II devices.

Table 6-9. Number of U.S. Medical Device Manufacturing Establishments, Distributed Using 2007 Census Data on NAICS and Establishment Size Class under a Class III UDI Alternative

Establishment Size Class	325413	334510	334517	339112	339113	339114	339115	Total
1 to 4	3	12	3	22	45	20	15	119
5 to 9	2	4	1	11	22	11	6	58
10 to 19	2	4	2	11	20	6	5	51
20 to 49	3	7	2	12	18	4	5	51
Total with fewer than 50 employees	**10**	**27**	**8**	**56**	**105**	**41**	**31**	**280**
Percent of estab. with fewer than 50 emp.	**65%**	**69%**	**73%**	**71%**	**80%**	**91%**	**84%**	**78%**
50 to 99	2	4	1	8	11	2	3	31
Total with 50-99 employees	**2**	**4**	**1**	**8**	**11**	**2**	**3**	**31**
Percent of estab. with 50-99 employees	**11%**	**9%**	**13%**	**10%**	**9%**	**5%**	**8%**	**9%**
100 to 249	2	4	1	9	9	1	2	27
Total with 100-249 employees	**2**	**4**	**1**	**9**	**9**	**1**	**2**	**27**
Percent of estab. with 100-249 employees	**11%**	**11%**	**6%**	**11%**	**7%**	**3%**	**5%**	**8%**
250 to 499	1	3	0	4	4	1	1	14
500 to 999	0	1	0	2	1	0	0	5
1,000 or more	0	1	0	1	1	0	0	3
Total with 250+ employees	**2**	**4**	**1**	**6**	**6**	**1**	**1**	**22**
Percent of estab. with 250+ employees	**13%**	**11%**	**8%**	**8%**	**5%**	**1%**	**3%**	**6%**
Total	**15**	**39**	**11**	**79**	**132**	**46**	**37**	**359**

Source: U.S. Census Bureau, 2010a and b and FDA's Registration & Listing Database, 2010a.

Table 6-10. Distribution of Reprocessors and Specification Developers (Establishments) by Size under a Class III UDI Alternative

Code	Industry Code Description	Total Establishments	1-4	5-9 (a)	10-19	20-49 (b)	50-99 (c)	100-249 (d)	250-499 (e)	500-999	1000 or more
NA	Single-Use Device Reprocessors	0	0	0	0	0	0	0	0	0	0
	Engineering Services Estabs.	57,726	30,966	9,006	7,897	6,241	2,182	1,060	243	79	52
541330	Percent of Total		54%	16%	14%	11%	4%	2%	0%	0%	0%
NA	Specification Developers (f)	64	34	10	9	7	2	1	0	0	0

Source: U.S. Census Bureau, 2010b; FDA, 2010a.

Table 6-11. Count of Initial Labeling Firms by Employment Size Class under a Class III UDI Alternative

Code	Industry Code Description	Total Firms	1-4	5-19	20-99	100-199	200-499	500-999	1000+
NA	Single-Use Device Reprocessors	0	0	0	0	0	0	0	0
	Engineering Services Estabs.	46,761	27,530	12,562	5,109	664	407	160	329
541330	Percent of Total		59%	27%	11%	1%	1%	0%	1%
NA	Specification Developers	64	38	17	7	1	1	0	0
NA	Total Manufacturers	359	123	111	74	16	12	5	17
NA	All Initial Labelers	423	161	128	81	17	13	6	18

Source: FDA, 2010a,b; U.S. Census Bureau, 2010b.

Table 6-12 presents numbers of R/R establishments arrayed by size, and Table 6-13 presents the counts of R/R firms arrayed by size. As Table 6-12 shows, the number of R/R establishments is reduced from 1,310 to 21, while the number of R/R firms is reduced from 1,212 to 21 (Table 6-13). These numbers of firms and establishments are also used in exactly the same way as the counts of establishments and firms were used to generate aggregate costs in Section Four. ERG continues to assume that no R/Rs currently print variable barcodes on their device labels.

For the DM analysis, ERG assumed that for multi-use devices, few would be classified as Class III. ERG determined that very few multi-use devices are Class III (many are surgical instruments that are Class I devices), so assumed that only 1 percent of multi-use device establishments would be affected. To keep the number of affected DM facilities from exceeding the number of total Class III establishments, ERG also assumed that only 40 percent of implant manufacturers and 20 percent of specification writers would be handling Class III implants. The combination of these assumptions results in an estimated 84 percent of all establishments handling Class III devices needing to also mark their devices.

Table 6-12. Industry Size Distributions for R/R Establishments Based on 2007 Census Data under a Class III UDI Alternative

	Numbers of Establishments							
Type of Industry (a)	**Total**	**1-4**	**5-9**	**10-49**	**50-99**	**100-249**	**250-499**	**>500**
Hosp. Equip. & Supplies	8,578	4,856	1,365	1,779	310	177	60	31
Ophthalmic Goods	1,319	708	240	278	46	32	13	2
Total	9,897	5,564	1,605	2,057	356	209	73	33
Percent of Total	-	56.2%	16.2%	20.8%	3.6%	2.1%	0.7%	0.3%
Distribution	21	12	3	4	1	0	0	0

(a) The industries that are used to distribute the R/Rs identified in FDA's registration database are the Medical, Dental and Hospital Supplies Merchant Wholesalers Industry (NAICS 42345) and the Ophthalmic Goods Merchant Wholesalers Industry (NAICS 42346). Total on distribution line does not add due to rounding.

Source: U.S. Census Bureau, 2010b; FDA, 2010a,b.

6.4.2 Costs of an Alternative Covering Only Class III Devices

Using the establishment and firm counts discussed in Section 6.4.1, ERG computed the costs of meeting all of the requirements as discussed in Section Four. Table 6-14 summarizes the costs by cost category and compares these costs to the same costs presented in Section Four. Only U.S. industry costs are compared (costs to the issuing agencies remain the same).

Table 6-13. Distribution of R/R Firms by Size under a Class III UDI Alternative

Type of Industry (a)	Numbers of Firms by Employment Size				
	Total	**1-4**	**5-19**	**20-499**	**>500**
Hospital Equipment & Supplies	7,031	4,282	1,811	795	143
Ophthalmic Goods	1,075	579	313	165	18
Total	8,106	4,861	2,124	960	161
Percent of Total	-	60.0%	26.2%	11.8%	2.0%
Distribution	21	13	6	2	0

(a) The industries that are used to distribute the R/R firms identified in FDA's registration database are the Medical, Dental and Hospital Supplies Merchant Wholesalers Industry (NAICS 42345) and the Ophthalmic Goods Merchant Wholesalers Industry (NAICS 42346).

Source: U.S. Census Bureau 2010b; FDA, 2010a,b, SBA, 2006.

As Table 6-14 shows, costs for all cost items are reduced under this alternative. The total annualized cost estimated for this alternative is $11.6 million per year, which is a $118.5 million reduction from the $130.1 million per year for industry estimated for the proposed rule and $68.8 million less than the estimate for Class II/III devices. The comparison to the previously defined Class II/III alternative is somewhat different from this present analysis because the DM costs for the Class II/III alternative were assumed unchanged from the costs of the proposed rule presented in Chapter Four. Had we assumed that DM only applied to Class II/III devices in the previous analysis, the difference in cost between the two alternatives (Class II/III and Class III only rule coverage) would likely be noticeably less, given that we believe many of the multi-use devices are Class I devices. Impacts on firms, in terms of numbers of firms, should be reduced below that estimated for the proposed rule under a Class III only alternative. This alternative does not affect the per-establishment costs, including those for DM, but the number of affected DM firms is substantially reduced, leading to a count of much fewer firms that would have costs exceeding 1 percent of revenues. However, because the number of total firms affected is substantially reduced as well, we cannot predict whether the percentage of firms and small firms with costs exceeding 1 percent of revenues under the Class III devices only alternative would be greater than, less than, or the same as that estimated under the proposed rule.

6.5 STATIC BARCODE UDI

Under this alternative, labelers would need to present their basic (static) manufacturer and product code information in an acceptable barcode format on their products' labels. Most of the assumptions outlined in Section Four apply under this alternative, except that variable information (lot,

Table 6-14. Aggregate Annualized Costs to All Labelers under the Class III UDI Alternative Relative to the Proposed Rule

Cost Element	Initial Labelers		R/Rs		Total		Proposed Rule	
	First-Year	Annualized and Recurring	First-Year	Annualized and Recurring	First-Year	Annualized and Recurring	First-Year	Annualized and Recurring
Labeling and Database Requirements								
Administration and planning	$2,998,556	NA	$52,654	NA	$3,051,210	NA	$46,534,208	NA
Barcode registration costs	$40,098	NA	$27,338	NA	$67,436	NA	$2,156,044	NA
Equipment and other investments	$4,957,181	$2,545,197	$180,565	$49,669	$5,137,746	$2,594,866	$82,803,532	$39,573,903
Incremental label cost and time	NA	$598,278	NA	$15,385	NA	$613,663	NA	$9,453,078
Label redesign cost	$3,006,505	NA	$74,514	NA	$3,081,019	NA	$47,600,999	NA
Software (with training)	$21,842,634	$2,538,629	$226,554	$19,147	$22,069,188	$2,557,776	$187,084,368	$22,200,409
Recordkeeping and Reporting (GUDID)	$182,989	$24,786	$7,150	$788	$190,139	$25,573	$3,148,757	$415,783
Total Labeling and Database Requirements	$33,027,963	$5,706,891	$568,776	$84,989	$33,596,739	$5,791,879	$369,327,910	$71,643,173
Direct Marking								
Implants	$4,505,461	$313,955	NA	NA	$4,505,461	$313,955	$12,038,857	$845,151
Multi-use devices	$149,197	$11,418	NA	NA	$149,197	$11,418	$14,919,691	$1,141,787
Total Direct Marking	$4,654,658	$325,373	NA	NA	$4,654,658	$325,373	$26,958,548	$1,986,938
Total--All Cost Items	**$37,682,621**	**$6,032,263**	**$568,776**	**$2,707,975**	**$38,251,397**	**$6,117,252**	**$396,286,458**	**$73,630,111**
Annualized Investment Total (a)		**$5,365,157**		**$80,981**		**$5,446,138**		**$56,422,276**
Total Annualized Costs		**$11,397,421**		**$2,788,955**		**$11,563,390**		**$130,052,387**

(a) Annualized at 7 percent over 10 years.

Source: Section Four and previous tables.

batch, serial number) would not have to appear in a barcode. ERG assumes that nothing else needs to change on the labeling (except as needed to meet the date format requirement) and that any existing variable information can be included in the labeling.

The effects of this alternative on each of the cost categories analyzed in Section Four are examined for initial labelers (manufacturers, reprocessors, specification developers) and R/Rs in the sections below.

6.5.1 Manufacturers, Reprocessors, and Specification Developers

The number of establishments and the level to which they are affected will be substantially reduced under this static barcode alternative. This section reviews the cost categories outlined in Section Four and addresses the costs under static barcoding assumptions and how they differ from the costs under the proposed rule.

6.5.1.1 UDI Planning Costs

Under this alternative, the only affected manufacturing establishments are those that do not currently barcode static manufacturer and product information. ERG estimates that most larger device labelers barcode static information (at a minimum). Those that do not barcode static information are assumed to be primarily small establishments. ERG assumes that the AdvaMed survey results (which indicate that two-thirds of manufacturers currently are barcoding) (AdvaMed, 2004) apply only to the larger establishments (50 employees or more). ERG assumes that 10 percent of initial labelers in the 50 to 99 employee size group, 30 percent in the 100 to 249 size group, 60 percent in the 250-499 size group and 85 percent in the 500+ employee size group are using static and/or variable barcodes. These assumptions result in two-thirds of establishments with more than 50 employees being estimated to use at least static barcoding. Additionally 5 percent of all establishments with fewer than 50 employees are assumed to use a static barcode. No reprocessors or specification developers are assumed to do static barcoding currently.

The planning and administrative costs associated with going from no barcodes to a static barcode are expected to be substantially less than those associated going from no barcodes to a variable barcode. The time to read and understand the rule would remain the same, but the other activities would require less time. ERG assumes that total time needed to plan for a static barcode application would be one-half of that for planning for a variable barcode. Table 6-15 shows the assumed per-establishment costs for the initial labelers that currently do no barcoding and now would plan for the static barcode alternative. Even

Table 6-15. First-Year Administrative and Planning Costs per Establishment, by Employee Size Class under a Static Barcoding Alternative

.Hours for Small Estab. (a)	Hourly Wage Rate with Benefits	Establishment First Year Cost by Size Class						
		1-4 (c)	5-9 (c)	10-49	50-99	100-249	250-499	500+
		(0.25 Times)	(0.50 Times)	(1 Times)	(1 Times)	(2 Times)	(4 Times)	(6 Times)
120	$75	$1,125	$2,250	$4,500	$4,500	$9,000	$18,000	$27,000

(a) Hours applicable to smaller size medical device establishment (10-99 employees).
(b) Based on the median hourly wage rate for management occupations in NAICS 3391 (BLS, 2009). Benefits are calculated at 29% of wages (BLS, 2010). Hourly wage rates do not vary substantially among the relevant NAICS; the wage rate for NAICS 3391 has been used for simplicity.
(c) The smallest establishments are judged to require one-half of the planning hours for compliance in the 5-9 employees group and one-quarter of the compliance time at the 1-4 employees group. Compliance will be largely manual for such firms and compliance actions will involve fewer technological and equipment decisions.
Source: BLS, 2010, Employer Costs for Employee Compensation; BLS, 2009; ERG estimates.

those who are not affected by this alternative (e.g., the two-thirds of all larger establishments) would require time to read and understand the rule. Under the static barcode alternative, unaffected facilities are expected to need one-half the time allotted for reading and understanding the rule than under the proposed rule, since they would only need to understand the rule up to the point that they realize they are already in compliance. Thus, 2.5 to 30 hours are assigned for this task, depending on the size of the facility.

The costs in Table 6-16 reflect the addition of these hours for the manufacturers expected to be unaffected by static barcode requirements. Establishments in the smallest employment group that are assumed to meet exceptions under this alternative remain the same as those with exceptions under the proposed rule. The costs for this group to read and understand their exception are assumed to be the same as those incurred under the proposed rule. These costs are added into Table 6-16. As the table shows, planning and administrative costs under the static barcode assumption are estimated to be $31.4 million in the first year. This is $11.8 million less than the $43.2 million estimated for initial labelers under the proposed rule.

6.5.1.2 Barcode Registration Costs

Barcode registration costs are assumed to be the same under the static barcode alternative as under the proposed rule, since whether the barcodes are static or variable does not affect the number of firms that must register. A total of $0.6 million is estimated as a first-year cost of barcode registration.

6.5.1.3 Equipment Costs

Under the static barcode alternative, manufacturers with no barcodes can continue to use their same labeling procedures, and simply add static barcodes to their existing labels. Since variable information is not needed, a one-time change to product labels would be needed. Printing plates can thus continue to be used. No additional equipment costs are expected, although label redesign costs would be incurred (see below). With no equipment costs, this alternative would result in a $71.5 million savings in initial costs and a $36.5 million savings in recurring costs for initial labelers compared to the costs under the proposed rule (see Table 4-15).

Table 6-16. First-Year Administrative and Planning Costs per Establishment, by Employee Size Class under a Static Barcoding Alternative

Establishment Type	Number of Establishments, by Size Class								Establishment First-Year Costs, by Size Class							Aggregate Costs
	1-4	5-9	10-49	50-99	100-249	250-499	500+	Total	1-4	5-9	10-49	50-99	100-249	250-499	500+	
325413	10	19	71	23	23	17	10	74	$15,567	$43,100	$608,511	$190,279	$288,780	$265,008	$104,054	$1,515,299
334510	44	37	151	49	57	36	23	397	$22,809	$4,399	$1,294,109	$402,344	$726,344	$550,168	$234,024	$3,234,197
334517	12	12	45	20	8	6	6	108	$5,947	$1,482	$386,658	$160,232	$105,221	$87,869	$57,503	$804,912
339112	81	98	311	104	119	51	34	797	$41,644	$11,719	$2,667,853	$842,246	$1,521,665	$785,351	$337,012	$6,207,490
339113	165	189	527	155	119	60	28	1,244	$85,326	$22,632	$4,518,059	$1,260,856	$1,532,383	$919,950	$277,858	$8,617,064
339114	72	97	145	30	18	7	2	370	$37,288	$11,549	$1,238,885	$241,843	$226,632	$110,605	$16,085	$1,882,887
339115	56	48	143	39	26	8	8	327	$29,165	$5,693	$1,223,903	$314,506	$334,041	$115,695	$75,712	$2,098,715
Spec. Dev.	722	210	330	51	25	6	3	1,346	$1,624,580	$944,970	$2,966,908	$457,900	$444,889	$203,978	$164,945	$6,808,170
Reproc.	-	11	2	2	2	4	-	21	$0	$49,500	$18,000	$18,000	$36,000	$144,000	$0	$265,500
Total, All NAICS	1,162	721	1,725	472	396	195	113	4,784	$1,862,326	$1,095,045	$14,922,885	$3,888,206	$5,215,956	$3,182,624	$1,267,193	$31,434,235

Source: ERG estimates based on Tables 4-12 and 6-8.

Note: numbers of establishments reflect the removal of numbers of labelers with exceptions to the proposed rule (i.e., ERG assumes that 70 percent of establishments in the 1-4 size class and 30 percent of the 5-9 size class meet exceptions because they manufacture custom devices). Additionally, 10 percent of the remaining manufacturers in these size groups are assumed to use UPCs only (meeting UDI requirements) and are removed from counts.

6.5.1.4 Direct Marking

Direct marking is assumed to be unaffected by a static barcode alternative. The cost of DM requirements are assumed to remain the same as those estimated in Section Four, $27.0 million in first-year costs and $2.0 million in recurring year costs.

6.5.1.5 Relabeling Costs

Labelers not already barcoding would need to create a barcode for each of their product labels, which would be either linear or 2D. Because new date formats are required, however, all initial labelers are expected to need to redesign their labels. ERG uses the same assumptions about the number of labelers affected as discussed in Section Four for labeling redesign. Therefore, the same cost of label redesign as under the proposed rule ($43.0 million) is incurred.

Materials costs for labelers not already printing static barcodes are assumed, but additional costs such as costs for supplemental labels and coordination with outside printers are avoided under the static barcode alternative.

Table 6-17 shows the costs of label materials, which total $2.8 million, a reduction of $5.7 million from label materials costs of $8.5 million estimated for initial labelers under the proposal.

Table 6-17. Derivation of Incremental Device Labeling Materials Cost, Per Establishment and Aggregate for a Static Barcode Alternative

Employ-ment Size	Incremental Annual Label Cost (Materials)		
	Per-Establishment Costs	No. of Affected Establishments	Total Cost
1-9	$41	1,836	$74,508
10-49	$221	1,655	$365,431
50-99	$869	430	$374,003
100-249	$3,151	285	$898,560
250-499	$5,121	84	$429,026
Over 500	$32,678	20	$639,433
Total		4,310	$2,780,961

(a) Includes only establishments not currently applying a static barcode to labels and excludes establishments associated with custom devices and those using UPCs for retail only.
Source: Costs per establishment from Table 4-12. For distributions by establishment size, see Table 6-9. All other estimates and calculations prepared by ERG.

6.5.1.6 Software Integration Costs

ERG assumes under the static barcode alternative that initial labelers without static barcodes on their labels would be able to print those barcodes in the same way as they currently print labels. Furthermore, static numbers can be or can replace the product numbers that are used throughout existing software systems, such as those used to track device information internally. Because variable information is not contained in the barcode, the firms can continue to use their current systems of tracking lot, batch or serial numbers and no new software is required. This results in a savings of $174.0 million in first-year costs and a $21.1 million savings in recurring costs (see Table 4-13 for costs of software integration).

6.5.1.7 GUDID Costs

GUDID costs remain the same under the static barcode alternative as under the proposed rule and total $2.7 million in the first year and $0.4 million in recurring years.

6.5.1.8 Total Costs to Manufacturers under the Static Barcode Alternative

Table 6-18 shows the total costs to initial labelers under the static barcode alternative. First year costs are $104.6 million and recurring annual costs are $5.1 million. Annualized, these costs are about $20.0 million per year, which is $99.9 million less per year than the costs for initial labelers estimated under the proposed rule ($120.0 million).

Table 6-18. Total Investment and Annual Recurring Costs for UDI Implementation for Medical Device Manufacturers under a Static Barcode Alternative

Cost Element	First-Year	Annualized and Recurring
Administration and planning	$31,434,235	NA
Barcode registration costs	$578,246	NA
Direct marking	$26,958,548	$1,986,938
Equipment and other investments	NA	NA
Incremental label materials cost	NA	$2,780,961
Label redesign cost	42,952,729	NA
Software (with training)	NA	NA
GUDID	$2,702,704	$366,658
Total	$104,626,463	$5,134,557
Annualized Investment Total (a)		$14,896,455
Total Annualized Costs		$20,031,012

(a) First-year costs are annualized at 7 percent over 10 years.
Source: See previous tables.

6.5.2 Relabelers/Repackagers

ERG assumes that R/Rs that currently label with static barcodes do so in the same percentages as those assumed for initial labelers and incur the same planning costs as initial labelers under the static barcode alternative as shown in Table 6-15. The one-time planning and administrative costs estimated using these assumptions are $2.9 million, as shown in Table 6-19.

Barcode registration costs are assumed to remain the same as under the proposed rule and total $1.6 million in the first year. Label redesign costs are also incurred. These redesign costs are the same as those estimated for R/Rs under the proposed rule because the date format change is assumed to affect all R/Rs. These costs total $4.6 million in the first year. GUDID costs of $0.4 million in the first year and $49,000 in recurring years is also assumed to remain the same as those under the proposed rule. As for initial labelers, no incremental equipment costs or software integration costs are assumed.

Table 6-19. Administrative and Planning Costs for R/Rs under the Static Barcode Alternative

Relabeler Size	Number of Relabelers	Percentage Without Static Barcodes	Number Needing Full Planning Effort	Planning Cost	Reading Cost (a)	Total Cost
1-4	736	95%	700	$787,102	$6,904	$794,006
5-9	212	95%	202	$454,097	$1,992	$456,089
10-49	272	95%	259	$1,163,960	$2,553	$1,166,513
50-99	47	90%	42	$190,841	$884	$191,725
100-249	28	70%	19	$174,283	$1,556	$175,839
250-499	10	40%	4	$69,570	$1,087	$70,657
>500	4	15%	1	$17,690	$696	$18,387
Total	1,310		1,226	$2,857,544	$15,671	$2,873,216

(a) 2.5 hours at a fully loaded management wage of $75/hour is assumed for those in compliance to read the rule.
Source: Table 4-16 and ERG estimates.

Because of changes to date formats, R/Rs, regardless of whether they currently barcode, are assumed to need to redesign their labels. Therefore, label redesign costs remain the same under this alternative as under the proposed rule, $4.6 million in the first year. The R/Rs that do not currently print barcodes on their labels could incur additional label materials costs. These recurring label materials costs are shown in Table 6-20 and total $0.2 million per year.

Table 6-20. Derivation of Incremental Device Labeling Materials Cost for R/Rs, Per Establishment and Aggregate for a Static Barcode Alternative

Employment Size	Number of Affected Establishments	Average Per Establishment Incremental Cost	Total Incremental Material Cost
1-9	901	$41	$36,578
10-49	259	$221	$57,163
50-99	42	$869	$36,854
100-249	19	$3,151	$61,018
250-499	4	$5,121	$19,793
500+	1	$32,678	$21,411
Total	1,226		$232,817

Source: See Tables 4-12 and 6-12.

Using these assumptions, the total costs to R/Rs are estimated to be $9.5 million in first-year costs, with recurring year costs of $0.3 million. Annualized, this is $1.6 million per year (see Table 6-21), which is a reduction of $8.5 million over the proposed rule costs to R/Rs of $10.1 million per year.

Table 6-21. Total Investment and Annual Recurring Costs for UDI Implementation under a Static Barcode Alternative for R/Rs

Cost Element	First-Year	Annual Recurring
Administration and planning	$2,873,216	NA
Barcode registration	$1,577,798	NA
Equipment and other investments	NA	NA
Incremental label materials cost	NA	$232,817
Label redesign cost	$4,648,270	NA
Software (with training)	NA	NA
GUDID	$446,053	$49,125
Total	$9,545,336	$281,942
Annualized Investment Total (a)		$1,359,041
Total Annualized Costs		$1,640,983

(a) First-year costs are annualized at 7 percent over 10 years.

Source: See previous tables.

When the static barcode alternative costs for R/Rs are added to the static barcode alternative costs for manufacturers, the total first year costs to all affected entities under the static barcode alternative are estimated to be $114.2 million, with recurring costs totalling $5.4 million per year. The total annualized cost for this alternative to all affected labelers is estimated to be $21.7 million per year. This is $108.4

million per year less that the costs estimated under the proposed rule, which total $130.1 million per year for industry under an immediate implementation assumption (see Table 6-22).

Table 6-22. Total Investment and Annual Recurring Costs for UDI Implementation for Medical Device Manufacturers and R/Rs under Static Barcode Alternative

Cost Element	First-Year	Annualized and Recurring
Administration and planning	$34,307,451	NA
Barcode registration costs	$2,156,044	NA
Equipment and other investments	NA	NA
Direct marking	$26,958,548	$1,986,938
Incremental label material cost	NA	$3,013,778
Label redesign cost	$47,600,999	NA
Software (with training)	NA	NA
GUDID	$3,148,757	$415,783
Total	$114,171,800	$5,416,499
Annualized Investment Total (a)		$16,255,496
Total Annualized Costs		$21,671,995

(a) First-year costs are annualized at 7 percent over 10 years.
Source: See previous tables.

6.6 CLASS II/III WITH VARIABLE BARCODING AND CLASS I WITH STATIC BARCODING (GMP-EXEMPT DEVICES EXCLUDED)

The next alternative that ERG investigates combines two alternatives. Under this alternative, the Class II and Class III devices are required to have variable barcodes on their labeling, whereas Class I devices are required only to have static barcodes. DM is still required for all devices, regardless of class of device. In addition to requiring Class I devices to meet static barcoding requirements, this alternative assumes a very small subset of Class I devices are exempt from all UDI requirements, but not the date formatting requirement. Such devices are those that are exempt from Good Manufacturing Practice (GMP) requirements. The GMP-exempt devices include items such as toothbrushes and bedpans. To estimate the costs of this alternative, we used the costs per establishment of requiring all devices to meet all UDI requirements, as presented in Section Four. We then used those costs along with the numbers of establishments associated with Class I only devices or GMP-exempt devices (depending on type of cost, e.g., equipment, software, GUDID) to compute costs savings by type of cost. When we determined all cost savings associated with this alternative compared to the analysis in Section Four, we subtracted these savings from the annualized $130.1 million aggregate cost reported in Section Four to estimate the cost of

the this alternative. See Section 6.5 for more information on why static barcoding results in cost savings in many of the cost categories.

The first step was to identify the count of establishments that would incur costs savings under this alternative. Table 6-23 shows the results of a query using FDA's Registration & Listing database (FDA, 2010), combined with a list of procodes that FDA identified as GMP-exempt (FDA, 2012). The counts of establishments reflect those establishments that handle only Class I devices or that handle only Class I GMP-exempt devices. As the table shows, initial labelers meeting the Class I only definition number 2,467, of which 550 handle GMP-exempt devices only. This leaves 1,917 establishments that would need to meet static barcoding requirements. Among repackagers/relabelers, 829 were identified as handling Class I only devices, of which 129 handle GMP-exempt devices only. This leaves 700 establishments that would need to meet static barcoding requirements.

ERG assumed that the size distribution of the establishments needing to meet static barcoding requirements or that would not be required to meet any UDI requirements because they handle only GMP-exempt devices are reflective of the size distributions used for all establishments as shown in Table 3-5 and Table 3-8. Table 6-24 distributes the count of initial labelers identified as Class I only that are subject to static barcoding requirements and the count of initial labelers identified as GMP-exempt establishments across the employment size groups used in the main analysis. This approximation of numbers of establishments by size could somewhat overstate cost savings estimates because Class I only establishments are somewhat likelier to be smaller establishments that specialize in one type of device. However, some establishments that handle Class I devices along with other classes of device could reduce costs on certain manufacturing lines. We are not able to perform a detailed device-by-device analysis, however. To the extent that some costs savings might be realized by other establishments, the total cost savings might just as easily be underestimated.

The next step, also shown in Table 6-24, is required to reduce the number of initial labeling establishments that would realize costs savings under this alternative because they are already likely to be excluded from meeting UDI requirements. The analysis in Section Four excluded a number of very small establishments because, for example, they meet a custom device exclusion or their labeling contains UPCs, which are considered to meet UDI requirements. Additionally, some establishments were assumed in Section Four to already barcode using variable barcodes and were removed from the analysis for that

Table 6-23. Numbers of Establishments Affected by Either Variable or Static Requirements, or Exempt from Most Requirements

Type of Labeler	Number of Establishments Subject to Variable Requirements		Number of Establishments Considered Class I Only (including unclassified devices)		Number of Establishments with GMP Exempt Devices Only		Number of Establishments Subject to Static Requirements	
	Number of Estabs.	Percent of All Estabs.	Number of Estabs.	Percent of All Estabs.	Number of Estabs.	Percent of All Estabs.	Number of Estabs.	Percent of All Estabs.
Manufacturer	3,088	40.7%	1,813	23.9%	399	5%	1,414	18.7%
Reprocessor	13	0.2%	8	0.1%	1	0%	7	0.1%
Specification Developer	636	8.4%	646	8.5%	150	2%	496	6.5%
Total Initial Labelers	3,737	49.3%	2,467	32.6%	550	7%	1,917	25.3%
Repackager/ Relabeler	481	6.3%	829	10.9%	129	2%	700	9.2%
All Labelers	4,218	55.7%	3,296	43.5%	679	9%	2,617	34.5%

Source: Table 4-28, Table 3-4, FDA (2010) and FDA (2012). Percentages are calculated relative to total labeling establishments (7,578).

reason. The same assumptions used to exclude establishments from the analysis in Section Four are used here, by size group, to reduce the number of establishments that would incrementally be affected by this new alternative relative to the main analysis. As shown, the numbers of establishments estimated to be subject to static barcoding requirements or that do not need to meet UDI requirements because they handle GMP-exempt devices are reduced by about 25 percent due to these exclusions. These counts are assigned the per-establishment costs either as estimated in Section Four or as calculated from aggregate cost estimates presented in Section Four.

Table 6-25 then presents the size distributions of R/Rs identified as handling only Class I devices that would be subject to static barcoding requirements or those that handle only GMP-exempt devices. All R/Rs were assumed to remain in the analysis in Section Four (none were assumed to currently use variable barcoding or to exclusively handle excluded devices or those with UPCs), so no further downward adjustments were made to the counts. The size distributions follow those shown in Table 3-10.

The remainder of this section presents the number of affected entities by size category, the first year cost savings, and the annualized cost savings over 10 years at 7 percent discount rate associated with the following cost categories for initial labelers and then presents cost savings for R/Rs:

Table 6-24. Distribution of Initial Labelers by Size, Adjustments for Excluded Establishments, and Final Counts of Initial Labelers Expected to Realize Cost Savings under the Class I Static Barcoding Alternative

Estab. Size	Total Manu-facturers	Total Spec. Develop-ers and Reproces-sors	Size Distrib-ution of Original Labelers	Size Distrib-ution of All GMP-Exempt	Size Distrib. All Estabs. Class I Only, Not GMP-Exempt	% Mfgs. Not Previously Exluded (a)	% Mfgs. without UPCs Only	% Mfgs. Without Variable Barcoding Now	Total Affected Mfgs.	% Affected Mfgs. plus Other Initial Labelers by Size	Affected GMP-Exempt	Affected Estabs. Subject to Static Require-ments	Total Affected Estabs. under Class I Static Alternative
1-4	1,630	722	38%	206	719	30%	90%	100%	440	49%	102	355	457
5-9	794	221	16%	89	310	70%	90%	100%	500	71%	63	221	284
10-49	1,393	332	28%	151	528	100%	100%	100%	1,393	100%	151	528	679
50-99	419	53	8%	41	144	100%	100%	95%	398	96%	40	138	178
100-249	369	27	6%	35	121	100%	100%	90%	332	91%	32	110	141
250-499	185	10	3%	17	60	100%	100%	85%	157	86%	15	51	66
500+	110	3	2%	10	35	100%	100%	80%	88	81%	8	28	36
Total	4,901	1,367		550	1,917				3,310		410	1,430	1,841

(a) Adjustment for GMP-Exempt and Other Class I only establishments subject to static requirements for custom devices and other exclusions.
Source: Table 3-5 for manufacturer counts and Table 4-2 for specification developers and reprocessor counts; uses assumptions discussed in Section Four concerning exclusions, UPC use and baseline variable barcoding use.

- Administration and planning
- Barcode registration
- Equipment
- Label material and printer coordination
- Software
- GUDID

Because all device labelers are assumed subject to the date format requirement and none were assumed to meet the requirement currently, no costs savings associated with label redesign are estimated. Also, because DM is still required for all affected devices, regardless of class, DM costs remain unchanged.

Table 6-25. GMP-Exempt R/R Establishments and R/R Establishments Subject to Static Barcoding Requirements Arrayed by Establishment Size

Relabeler Size	Total Number of Relabelers	% Distribution	GMP-Exempt	Number Subject to Static Requirements	Total Number Affected by Class I Static Alternative
1-4	736	56%	73	394	466
5-9	212	16%	21	114	134
10-49	272	21%	27	145	172
50-99	47	4%	5	25	30
100-249	28	2%	3	15	18
250-499	10	1%	1	5	6
>500	4	0%	0	2	3
Total	1,310		129	700	829

Source: See Table 4-16 for total establishment counts and Table 6-A for counts of GMP-exempt and establishments subject to static requirements.

6.6.1 Cost Savings for Initial Labelers

6.6.1.1 Administration and Planning

Table 6-26 presents the total first year and annualized cost savings associated with administration and planning. As noted in Section 6.5, which discusses an alternative in which all devices are subject to static barcoding, labelers needing to meet static barcoding requirements are assumed to require half the time to meet those requirements as they would if they had to meet variable barcoding requirements. The costs per establishment by size shown in Table 6-26 are half of those shown in Table 4-1. Total cost savings in the first year are about $8.4 million. The total annualized cost savings at 7 percent over 10

years is $1.2 million annually. These costs slightly overstate the costs under this alternative because ERG has not adjusted the costs to establishments that handle only GMP-exempt devices downward to reflect the fact that they will not have to plan or even read the rule to any great extent to determine they are not covered by the requirements.

6.6.1.2 Barcode Registration

Because GMP-exempt devices would not have to meet UDI requirements, they would not have to register with HIBCC or GS1 to obtain barcodes for their devices. Based on assumptions in Section 4.3.1.2 about the percentage of firms that would need to register in the main analysis, the number of firms that would be saved from having to register under this alternative is very small (we assume for simplicity throughout this alternative analysis that all the Class I only device labelers are single facility firms). The costs per firm from Table 4-4 are used. As Table 6-27 shows, total costs savings are about $30,000 in the first year, or about $4,000 annually.

Table 6-26. Initial Labelers: Estimated Cost Savings Associated with Administrative & Planning Expenditures Due to Class I Static Barcoding Alternative (Includes Savings from GMP-Exempt Device Exclusion)

Est. Size	Number Estabs. with Savings	First Year Incre-mental Cost/ Estab.	Total First Year Savings	Recur-ring Incre-mental Costs/ Estab.	Total Annual-ized Incre-mental Costs/ Estab.	Total Savings on Admin. & Planning
1-4	457	$1,125	$514,591	NA	$160	$73,266
5-9	284	$2,250	$638,562	NA	$320	$90,917
10-49	679	$4,500	$3,054,960	NA	$641	$434,958
50-99	178	$4,500	$799,213	NA	$641	$113,790
100-249	141	$9,000	$1,271,683	NA	$1,281	$181,059
250-499	66	$18,000	$1,184,158	NA	$2,563	$168,597
500+	36	$27,000	$968,363	NA	$3,844	$137,873
Total	1,841		$8,431,529			$1,200,460

Source: Table 4-1.

Table 6-27. Initial Labelers: Estimated Cost Savings Associated with Barcode Registration under the Class I Static Barcoding Alternative

Est. Size	Number GMP-Exempt	% Assumed to Be Registered	Number Assumed without Registration	Cost of Registra-tion	Total First Year Cost Savings	Annualized Cost Savings for Registration
1-4	102	85%	15	$500	$7,648	$1,089
5-9	63	85%	9	$500	$4,745	$676
10-49	151	90%	15	$500	$7,568	$1,077
50-99	40	95%	2	$500	$990	$141
100-249	32	95%	2	$4,000	$6,300	$897
250-499	15	95%	1	$4,000	$2,933	$418
500+	8	99%	0	NA	$0	$0
Total	410		44		$30,185	$4,298

Source: Table 4-4 and Section 4.1.3.2.

6.6.1.3 Equipment

Static barcodes do not require the digital printing equipment needed to meet variable barcoding requirements. Thus all Class I only establishments would save the costs of purchasing, installing and operating digital printing equipment. The costs per establishment are averaged using the facility counts and total capital costs and labor costs that are presented in Table 4-7 and used with the numbers of Class I only establishments expected to need to meet static barcoding requirements or that handle GMP-exempt devices only. Table 6-28 shows that the cost savings are $28.2 million in the first year and $14.4 million in recurring years. Annualized, this is $18.4 million a year in costs savings.

Table 6-28. Initial Labelers: Estimated Cost Savings Associated with Equipment Expenditures under the Class I Static Barcoding Alternative (Includes Savings from GMP-Exempt Device Exclusion)

Est. Size	Number Estabs. with Savings	First Year Incre-mental Cost/ Estab.	Total First Year Savings	Recurring Incremental Costs/ Estab.	Total Recurring Costs	Total Annualized Incremental Costs/ Estab.	Total Savings on Equipment
1-4	457	$414	$189,369	$41	$18,937	$100	$45,899
5-9	284	$414	$117,495	$41	$11,750	$100	$28,478
10-49	679	$23,341	$15,845,693	$9,281	$6,300,616	$12,604	$8,556,686
50-99	178	$23,341	$4,145,417	$9,281	$1,648,314	$12,604	$2,238,528
100-249	141	$24,236	$3,424,466	$16,317	$2,305,587	$19,768	$2,793,154
250-499	66	$41,641	$2,739,435	$36,583	$2,406,640	$42,511	$2,796,674
500+	36	$47,266	$1,695,199	$46,407	$1,664,415	$53,137	$1,905,773
Total	1,841		$28,157,075		$14,356,258		$18,365,192

Source: Averages taken from Table 4-7.

6.6.1.4 Label Material and Printer Coordination

Although all covered device labelers would be required to meet the date format change and would need to redesign their labels to accommodate this change, only those required to meet the static barcoding requirements under the Class I static barcoding alternative might need larger labels to accommodate the barcode. Thus labelers handling GMP-exempt devices would not incur the costs per establishment for labeling materials shown in Table 4-13. Additionally, those subject to static barcoding requirements would not incur costs for coordinating production numbering with their contract printers. Relatively few establishments are expected to use contract printers. The percentages shown in Table 6-29 reflect the percentages used to calculate the total number of establishments expected to need to coordinate with contract printers in Table 4-13. The hours shown in Table 4-13 for coordination by establishment size are multiplied by the assumed wage rate of $75, which was also used in Table 4-13, to produce the per-establishment cost savings shown in Table 6-29. Total costs savings using these assumptions are $1.5 million per year.

Table 6-29. Initial Labelers: Estimated Costs Savings for Label Materials and Printer Coordination under the Class I Static Barcoding Alternative

Est. Size	Number Estabs. with Savings	Number GMP-Exempt	Materials Savings per Estab.	Total Materials Savings (a)	% Assumed Needing to Coordinate with Printers Under Variable Barcoding	Coordin-ation Time Savings per Estab.	Total Coordina-tion Cost Savings	Total Recurring Label Cost Savings
1-4	457	102	$41	$4,138	8%	$3,750	$137,224	$141,362
5-9	284	63	$41	$2,567	8%	$3,750	$85,142	$87,709
10-49	679	151	$221	$33,415	5%	$7,500	$254,580	$287,995
50-99	178	40	$869	$34,417	4%	$15,000	$106,562	$140,979
100-249	141	32	$3,151	$99,263	3%	$60,000	$254,337	$353,600
250-499	66	15	$5,121	$75,111	3%	$90,000	$177,624	$252,735
500+	36	8	$32,678	$261,291	0%	$180,000	$0	$261,291
Total	1,841	410		$510,203			$1,015,468	$1,525,670

(a) Applies to GMP-exempt only.

6.6.1.5 Software

The costs in Table 4-13 were estimated for firms. As noted earlier, we are assuming the Class I only establishments are single facility firms. To compute the costs per establishment in this alternative

analysis, we used the first year aggregate costs by size shown in Table 4-13 and divided them by the original count of firms, also shown in Table 4-13 (this somewhat understates cost savings at the larger establishment sizes). Recurring year costs per establishment were also computed the same way, so they are somewhat lower than the average cost per firm shown in Table 4-13. The costs for firms in the 1-4 employees size group are assigned to establishments in the 1-4 employees size group.

ERG assigned costs in the following way:

- The costs for firms in the 5-19 employees size group are assigned to establishments in the 5-9 employees size group.
- The costs for firms in the 20-99 employees size group are assigned to the establishments in the 10-49 and the 50-99 employees size group.
- The costs for firms in the 100-199 employees size group are assigned to the establishments in the 100-249 employees size group.
- The costs for firms in the 200-499 employees size group are assigned to the 250-499 employees size group.
- The costs for firms in the 499-999 employees size group are assigned to establishments in the 500+ employees size group. No establishments were assigned the costs of the largest firms.

Table 6-30 shows the results of these assumptions. First year costs savings are estimated to be $52.4 million and recurring cost savings are expected to be about $7.2 million. Annualized, this is $14.6 million per year.

6.6.1.6 GUDID

Establishments handling only GMP-exempt devices would not have to submit information to the GUDID. Thus those establishments would save both the set up costs and recurring costs of submitting data. Table 6-31 shows the costs per establishment for both first year and recurring year activities, which were presented in Table 4-15. As Table 6-31 shows, the first year costs savings are about $229,000, and recurring year cost savings are about $31,000, for an annualized cost of about $63,000 per year.

6.6.1.7 Total Cost Savings for Initial Labelers

Table 6-32 shows the total annualized cost savings for initial labelers. These cost savings total $35.8 million per year.

Table 6-30. Initial Labelers: Estimated Cost Savings Associated with Software Expenditures under the Class I Static Barcoding Alternative (Includes Savings from GMP-Exempt Device Exclusion) (a)

Est. Size	Number Estabs. with Savings	First Year Incre-mental Cost/ Estab.	Total First Year Savings	Recur-ring Incre-mental Costs/ Estab.	Total Recurring Costs	Total Annual-ized Incre-mental Costs/ Estab.	Total Savings on Software
1-4	457	$900	$411,673	$61	$27,902	$189	$86,515
5-9	284	$10,500	$2,979,956	$1,700	$482,469	$3,195	$906,748
10-49	679	$25,966	$17,627,488	$3,991	$2,709,410	$7,688	$5,219,168
50-99	178	$25,966	$4,611,555	$3,991	$708,813	$7,688	$1,365,395
100-249	141	$62,229	$8,792,774	$8,290	$1,171,406	$17,150	$2,423,299
250-499	66	$114,731	$7,547,780	$14,689	$966,314	$31,024	$2,040,949
500+	36	$291,715	$10,462,423	$30,365	$1,089,043	$71,898	$2,578,657
Total	1,841		$52,433,649		$7,155,358		$14,620,730

Source: Table 4-13. Note that these costs were estimated for firms. It is assumed that most Class I Only establishments are single-facility firms, so these employment sizes also approximate the size of the firm.

Table 6-31. Initial Labelers: Estimated Costs Savings Associated with GUDID under the Class I Static Barcoding Alternative

Est. Size	Number GMP-Exempt	First Year Cost per Estab.	Total First Year Cost Savings	Recurring Year Cost per Estab.	Total Recurring Year Cost Savings	Annual-ized Cost per Estab.	Total Annualized Cost Savings
1-4	102	$450	$45,890	$75	$7,648	$139	$14,182
5-9	63	$450	$28,473	$75	$4,745	$139	$8,799
10-49	151	$750	$113,514	$75	$11,351	$182	$27,513
50-99	40	$438	$17,323	$75	$2,970	$137	$5,436
100-249	32	$438	$13,782	$75	$2,363	$137	$4,325
250-499	15	$438	$6,417	$75	$1,100	$137	$2,014
500+	8	$438	$3,498	$75	$600	$137	$1,098
Total	410		$228,896		$30,777		$63,367

Source: Table 4-14.

Table 6-32. Initial Labelers: Total Costs Savings under the Class I Static Barcoding Alternative (Includes Savings from GMP-Exempt Device Exclusion)

Est. Size	Total Admin. and Planning Savings	Total Regi-stration Savings	Total Equip-ment Savings	Total Recurring Label Cost Savings	Total Software Savings	Total GUDID Cost Savings	Total Class I Static Alternative Savings for Initial Labelers
1-4	$73,266	$1,089	$45,899	$141,362	$86,515	$14,182	$362,313
5-9	$90,917	$676	$28,478	$87,709	$906,748	$8,799	$1,123,327
10-49	$434,958	$1,077	$8,556,686	$287,995	$5,219,168	$27,513	$14,527,397
50-99	$113,790	$141	$2,238,528	$140,979	$1,365,395	$5,436	$3,864,269
100-249	$181,059	$897	$2,793,154	$353,600	$2,423,299	$4,325	$5,756,334
250-499	$168,597	$418	$2,796,674	$252,735	$2,040,949	$2,014	$5,261,386
500+	$137,873	$0	$1,905,773	$261,291	$2,578,657	$1,098	$4,884,692
Total	$1,200,460	$4,298	$18,365,192	$1,525,670	$14,620,730	$63,367	$35,779,717

Source: See previous tables.

6.6.2 Cost Savings for R/Rs

The costs savings for R/Rs are computed generally the same way as was done for initial labelers, using the costs per establishment or firm estimated for R/Rs (tables these costs were taken from are cited in each of the following tables.

Table 6-33 through Table 6-38 present the cost savings for administration and planning, barcode registration, equipment, label materials and coordination, software, and GUDID, respectively, among the Class I only R/Rs. Table 6-39 presents the total costs savings for this group of establishments, which are $5.9 million per year.

6.6.3 Cost Savings Realized by the Class I Static Alternative, Total Cost of the Alternative, and Impacts of the Alternative

Table 6-40 presents the total annualized costs savings combining the initial labeler savings and the R/R savings. These cost savings are $41.7 million per year.

Table 6-41 uses the first year and recurring year costs from the main analysis in Section Four with the first year and recurring year costs for each cost item as presented in the previous tables in this section to compute the total costs of the proposed rule under this alternative. The total annualized costs

estimated are $88.4 million per year, which reflects the total $41.7 million cost savings per year over the $130.1 million per year estimated in Section Four.

Table 6-33. Repackagers/Relabelers: Estimated Cost Savings Associated with Administrative & Planning Expenditures under the Class I Static Barcoding Alternative (Includes Savings from GMP-Exempt Device Exclusion)

Est. Size	Number Estabs. with Savings	First Year Incre-mental Cost/ Estab.	Total First Year Savings	Recur-ring Incre-mental Costs/ Estab.	Total Annual-ized Incre-mental Costs/ Estab.	Total Savings on Admin. & Planning
1-4	466	$563	$262,156	NA	$80	$37,325
5-9	134	$1,125	$151,244	NA	$160	$21,534
10-49	172	$2,250	$387,675	NA	$320	$55,196
50-99	30	$2,250	$67,094	NA	$320	$9,553
100-249	18	$4,500	$78,779	NA	$641	$11,216
250-499	6	$9,000	$55,032	NA	$1,281	$7,835
500+	3	$13,500	$37,316	NA	$1,922	$5,313
Total	829		$1,039,297			$147,972

Source: From Table 4-16.

Table 6-34. Repackagers/Relabers: Estimated Cost Savings Associated with Barcode Registration under the Class I Static Barcoding Alternative

Est. Size	Number GMP-Exempt	Cost of Registration	Total First Year Cost Savings	Annualized Cost Savings for Registration
1-4	73	$500	$36,261	$5,163
5-9	21	$500	$10,460	$1,489
10-49	27	$500	$13,406	$1,909
50-99	5	$500	$2,320	$330
100-249	3	$4,000	$10,897	$1,551
250-499	1	$4,000	$3,806	$542
500+	0	NA	$0	$0
Total	129		$77,150	$10,984

Source: Table 4-18.

Table 6-35. Repackagers/Relabelers: Estimated Cost Savings Associated with Equipment Expenditures under the Class I Static Barcoding Alternative (Includes Savings from GMP-Exempt Device Exclusion)

Est. Size	Number Estabs. with Savings	First Year Incre-mental Cost/ Estab.	Total First Year Savings	Recur-ring Incre-mental Costs/ Estab.	Total Recurring Costs	Total Annual-ized Incre-mental Costs/ Estab.	Total Savings on Equipment
1-4	466	$0	$0	$0	$0	$0	$0
5-9	134	$0	$0	$0	$0	$0	$0
10-49	172	$31,261	$5,386,259	$10,073	$1,735,560	$4,451	$2,502,442
50-99	30	$31,261	$932,187	$10,073	$300,369	$4,451	$433,092
100-249	18	$24,236	$424,281	$16,317	$285,655	$3,451	$346,064
250-499	6	$38,829	$237,427	$31,670	$193,653	$5,528	$227,457
500+	3	$50,078	$138,424	$51,320	$141,857	$7,130	$161,565
Total	829		$7,118,578		$2,657,094		$3,670,620

Source: Averages are taken from Table 4-19.

Table 6-36. Repackagers/Relabelers: Estimated Cost Savings Associated with Label Materials and Printer Coordination under the Class I Static Barcoding Alternative

Est. Size	Number Estabs. with Savings	Number GMP-Exempt	Materials Savings per Estab.	Total Materials Savings (a)	% Assumed Needing to Coordin-ate with Printers	Coordina-tion Cost Savings per Estab.	Total Coordina-tion Cost Savings	Total Recurring Label Cost Savings
1-4	466	73	$41	$2,943	8%	$3,750	$139,817	$142,759
5-9	134	21	$41	$849	8%	$3,750	$40,332	$41,181
10-49	172	27	$221	$5,919	5%	$7,500	$64,612	$70,532
50-99	30	5	$869	$4,033	4%	$15,000	$17,892	$21,925
100-249	18	3	$3,151	$8,584	3%	$60,000	$31,512	$40,096
250-499	6	1	$5,121	$4,873	3%	$90,000	$16,510	$21,382
500+	3	0	$32,678	$14,056	0%	$180,000	$0	$14,056
Total	829	129		$41,257			$310,674	$351,931

(a) Applies only to GMP-exempt establishments.
Source: Table 4-21.

Table 6-37. Repackagers/Relabelers: Estimated Cost Savings Associated with Software Expenditures under the Class I Static Barcoding Alternative (Includes Savings from GMP-Exempt Device Exclusion)

Est. Size	Number Estabs. with Savings	First Year Incre-mental Cost/ Estab.	Total First Year Savings	Recur-ring Incre-mental Costs/ Estab.	Total Recurring Costs	Total Annual-ized Incre-mental Costs/ Estab.	Total Savings on Software
1-4	466	$900	$419,450	$61	$28,429	$189	$88,150
5-9	134	$10,500	$1,411,612	$1,700	$228,547	$3,195	$429,528
10-49	172	$10,500	$1,809,150	$1,700	$292,910	$3,195	$550,492
50-99	30	$27,000	$805,128	$4,150	$123,751	$7,994	$238,383
100-249	18	$27,000	$472,673	$4,150	$72,652	$7,994	$139,950
250-499	6	$76,000	$464,716	$10,125	$61,911	$20,946	$128,076
500+	3	$190,000	$525,192	$24,325	$67,238	$51,377	$142,014
Total	829		$5,907,921		$875,438		$1,716,593

Source: Table 4-13. Note that these costs were estimated for firms. It is assumed that most Class I Only establishments are single-facility firms, so these employment sizes also approximate the size of the firm.

Table 6-38. Repackagers/Relabelers: Estimated Costs Savings Associated with GUDID under the Class I Static Barcoding Alternative

Est. Size	Number GMP-Exempt	First Year Cost per Estab.	Total First Year Cost Savings	Recurring Year Cost per Estab.	Total Recurring Year Cost Savings	Annual-ized Cost per Estab.	Total Annualized Cost Savings
1-4	73	$300	$21,757	$38	$2,720	$80	$5,817
5-9	21	$300	$6,276	$38	$784	$80	$1,678
10-49	27	$450	$12,065	$38	$1,005	$102	$2,723
50-99	5	$438	$2,030	$38	$174	$100	$463
100-249	3	$438	$1,192	$38	$102	$100	$272
250-499	1	$438	$416	$38	$36	$100	$95
500+	0	$438	$188	$38	$16	$100	$43
Total	129		$43,924		$4,838		$11,091

Source: Table 4-23.

Table 6-39. Repackagers/Relablers: Total Estimated Cost Savings under the Class I Static Barcoding Alternative (Includes Savings from GMP-Exempt Exclusion)

Est. Size	Total Admin. and Planning Savings	Total Regi-stration Savings	Total Equipment Savings	Total Recurring Label Cost Saving	Total Software Savings	GUDID Cost Savings	Total Class I Static Alternative Savings for Initial Labelers
1-4	$37,325	$5,163	$0	$142,759	$88,150	$5,817	$279,214
5-9	$21,534	$1,489	$0	$41,181	$429,528	$1,678	$495,410
10-49	$55,196	$1,909	$2,502,442	$70,532	$550,492	$2,723	$3,183,295
50-99	$9,553	$330	$433,092	$21,925	$238,383	$463	$703,746
100-249	$11,216	$1,551	$346,064	$40,096	$139,950	$272	$539,148
250-499	$7,835	$542	$227,457	$21,382	$128,076	$95	$385,388
500+	$5,313	$0	$161,565	$14,056	$142,014	$43	$322,991
Total	$147,972	$10,984	$3,670,620	$351,931	$1,716,593	$11,091	$5,909,192

Source: See previous tables.

Table 6-40. Total Cost Savings for All Labelers under the Class I Static Barcoding Alternative (Includes Savings from GMP-Exempt Exclusion)

Est. Size	Total Savings Planning & Adminis-tration	Total Regi-stration Savings	Total Savings Equipment	Total Savings Recurring Labeling Costs	Total Savings Software	Total Savings GUDID	Total Savings With Class I Static Altern-ative
1-4	$110,591	$6,252	$45,899	$284,122	$174,665	$19,999	$641,528
5-9	$112,451	$2,165	$28,478	$128,890	$1,336,276	$10,477	$1,618,737
10-49	$490,154	$2,986	$11,059,128	$358,527	$5,769,660	$30,236	$17,710,692
50-99	$123,343	$471	$2,671,620	$162,904	$1,603,778	$5,899	$4,568,014
100-249	$192,275	$2,448	$3,139,218	$393,695	$2,563,248	$4,597	$6,295,482
250-499	$176,433	$960	$3,024,131	$274,117	$2,169,025	$2,109	$5,646,774
500+	$143,186	$0	$2,067,338	$275,347	$2,720,671	$1,141	$5,207,683
Total	$1,348,433	$15,282	$22,035,812	$1,877,601	$16,337,323	$74,458	$41,688,909

Source: See previous tables.

Table 6-41. Total Costs Savings and Total Costs of the Class I Static BarcodingAlternative

Cost Element	First-Year Original Analysis	Class I Static (without GMP-exempt) Cost Savings	First Year Cost of Alternative with Class I Static Barcoding	Annual Recurring Original Analysis	Recurring Class I Static Cost Savings	Recurring Cost of Class I Static Alternative
Labeling and Database Requirements						
Administration and planning	$46,534,208	$9,470,826	$37,063,382	NA	NA	NA
Registration costs	$2,156,044	$107,335	$2,048,710	NA	NA	NA
Equipment and other investments	$82,803,532	$35,275,653	$47,527,879	$39,573,903	$17,013,352	$22,560,550
Incremental label cost	NA	NA	NA	$9,453,078	$1,877,601	$7,575,477
Label redesign cost	$47,600,999	$0	$47,600,999	NA	NA	NA
Software (with training)	$187,084,368	$58,341,570	$128,742,798	$22,200,409	$8,030,796	$14,169,612
Recordkeeping & Reporting (GUDID)	$3,148,757	$272,820	$2,875,937	$415,783	$35,615	$380,169
Total Labeling and Database Requirements	$369,327,910	$103,468,204	$265,859,705	$71,643,173	$26,957,365	$44,685,808
Direct Marking						
Implants	$12,038,857	$0	$12,038,857	$845,151	$0	$845,151
Multi-Use Devices	$14,919,691	$0	$14,919,691	$1,141,787	$0	$1,141,787
Total Direct Marking	$26,958,548	$0	$26,958,548	$1,986,938	$0	$1,986,938
Total	**$396,286,458**	**$103,468,204**	**$292,818,254**	**$73,630,111**	**$26,957,365**	**$46,672,746**
Annualized Investment Total (a)						**$41,690,732**
Total Annualized Costs for Industry						**$88,363,478**

(a) First-year costs are annualized at 7 percent over 10 years.
Source: See previous tables.
Note: GMP-Exempt exclusion is not fully reflected in administration & planning costs and is not reflected at all in incremental label costs, and GUDID costs. Class I Static savings for a small portion of incremental label costs (costs of coordinating labels with contract printers) is also not reflected in the incremental label costs.

Because DM will still be required, the impacts on firms shown in Section Five could still occur. However, some multi-use device manufacturers, if they manufacture Class I devices only, could face substantially reduced costs. To the extent that this situation occurs, this alternative could possibly reduce the number of firms estimated to have costs exceeding 1 percent of revenues. We do not, however, have any information on whether firms that manufacturer only Class I devices that require DM are among the groups of firms considered likely to face costs exceeding 1 percent of revenues.

6.6.4 Timing of Investments under the Class I Only Static Barcoding Alternative

For another comparison, we arrayed the costs over time, replacing the costs for Class I only devices as shown in Table 4-29 with the costs for Class I only devices to meet static labeling requirements and excluding GMP-exempt establishments.[32] We used all the same timing assumptions for Class I devices that were used in Table 4-29. We have not presented the entire array here but show the results of the arrayed costs compared to the original present value and annualized costs shown in Table 4-29 in Section 4.4. As Table 6-42 shows, when costs are arrayed over time, this alternative saves less than one might think from seeing the cost savings above. This is because most of the cost savings do not appear until six years out when Class I devices must meet UDI requirements and because all device labels (including those on GMP-exempt devices) require the date format change, triggering the cost of label changes. Over a 10-year period of analysis, the alternative costs $66.5 million, saving $26.2 million over the costs presented in Section Four. Over a 20-year period, the alternative costs $66.1 million and saves $30.7 million over the costs presented in Section Four.

6.7 COSTS TO FDA FOR ESTABLISHING THE GUDID UNDER FURLS

FDA is not currently planning to implement the GUDID within the Electronic Registration and Listing System (FURLS), but ERG investigated the costs to do so. Because a module could be relatively easily attached to the present FURLS system, such an approach would be less expensive than setting up the GUDID as a separate system.

Currently, all medical device labeling establishments are required to register annually with FDA and list the medical devices on which they perform a number of activities, including manufacturing, reprocessing, specification development, and repackaging/relabeling (see Appendix A). Unless they

[32] Costs for label redesign remain the same as shown in Table 4-29, but the recurring costs for labeling line uses the costs shown in Table 6-41. DM costs also remain the same. All reinvestment costs for Class I only are eliminated. These costs are for software and equipment, which are not needed for static barcoding.

receive a waiver, establishments must provide registration and listing information electronically, using FURLS. Establishments may submit registration and listing information on screen or by completing and uploading an electronic form.

Table 6-42. Class I Static Barcoding with GMP-Exempt Devices Excluded and with Implementation Time Considered

	Original Analysis (Table 4-29)	Class I Static, GMP-Exempt Not Covered	Cost Savings
NPV over 20 yrs. at 7%	$1,097,581,910	$749,304,294	$348,277,615
Annualized (7%, 20 yrs.)	$96,826,138	$66,101,892	$30,724,246
NPV over 20 yrs. at 3%	$1,488,576,565	$989,303,972	$499,272,593
Annualized (3%, 20 yrs)	$97,141,483	$64,559,968	$32,581,515
NPV over 10 yrs. at 7%	$696,259,478	$499,415,109	$196,844,368
Annualized (7%, 10 yrs.)	**$92,646,435**	**$66,453,716**	**$26,192,719**
NPV over 10 yrs. at 3%	$811,901,404	$571,474,054	$240,427,350
Annualized (3%, 10 yrs.)	$92,407,391	$65,042,906	$27,364,486

Source: See previous tables and Table 4-29.

Under this alternative, FDA would require labeling establishments to upload additional information on their medical devices into a database (the GUDID), functioning within the FURLS. The data for this database would be collected by adding new functionality to FURLS. This new functionality would allow the establishments and FDA to do the following:

- Establishments would be able to submit the UDI and associated product information for each medical device they label and sell. As with registration and listing information, UDI listing information could be submitted on screen or uploaded from an electronic form.
- FDA would be able to view a set of standard reports and run queries (and view resulting ad hoc reports) on submitted UDI information.
- The public would be able to view a set of standard reports containing publicly available UDI listing information.

ERG assumes that, as with the rest of FURLS, the UDI input and reporting functionality would be English-only.

Providing this new functionality would require designing and developing the following additions to FURLS:

- New screens, linked to existing fields for a listed medical device, for submitting/updating/deleting the UDI for a product and for submitting/updating associated product information.
- An electronic form that can be uploaded to FURLS.
- A set of standard reports for viewing medical device and UDI listing information.
- An interface for the public to use to select and view reports.
- A secure interface for authorized personnel to use to run special queries and reports.

6.7.1 Initial Development and Deployment

To develop the new UDI listing and reporting functionality, FDA would need to develop:

- A set of detailed requirements.
- A specifications document.
- New data tables for the FURLS database.
- Mockups and actual screens for submitting information.
- Electronic form for uploading information.
- Mockups and actual screens for selecting reports (public).
- Mockups and actual screens for selecting reports and running queries (secure).
- Mockups and actual functionality for reports.
- On-screen help information and detailed documentation.

FDA would then need to:

- Conduct testing and make any revisions required.
- Submit the application for review and clearance, making any revisions required.
- Deploy the application.
- Conduct outreach to the medical device community to communicate UDI listing requirements and methods.

As Table 6-43 shows, ERG estimates that this task to create the GUDID module within the FURLS system would take about 4,700 hours to set up. Using an approximate weighted average hourly

wage between software engineers and support staff of $100 per hour, ERG estimates that the initial cost of set up would be $470,000.

6.7.2 Operation and Maintenance

Once the application is deployed, FDA would need to:

- Host and maintain the UDI listing and reporting functionality along with the rest of FURLS.
- Provide Helpdesk services for the UDI listing and reporting functionality within FURLS.

Although the operating ease of this system is uncertain at this point, ERG judged that the database might continue to need development and maintenance work over time, especially in earlier years because of possible growing pains associated with a new system. ERG estimated that 4,700 hours per year would need to be added to the FURLS tasks to accommodate these operations. See Table 6-43 for the cost calculations. The recurring costs associated with these tasks total $470,000 per year. (The constancy of the first-year and recurring annual expenses is coincidental.)

6.7.3 Annualized Costs to FDA of the GUDID System

When the first-year costs and recurring costs are annualized, ERG estimates that the cost to set up and maintain the GUDID would cost FDA about $0.1 million per year, assuming a discount rate of 7 percent over 10 years.

Table 6-43. Cost to FDA of Creating and Maintaining the GUDID within the FURLS System

Module Development Tasks	Hours	Cost
Initial Development and Deployment		
Requirements and specifications	600	$60,000
Screen and report mockups	300	$30,000
Web, database, and form development	2,000	$200,000
Testing and revisions	600	$60,000
FDA review, revision, and clearance	300	$30,000
Initial outreach/training	500	$50,000
Initial deployment	400	$40,000
Unit Costs - One-Time	**4,700**	**$470,000**
Operation and Maintenance		
Hosting and maintenance	1500	$150,000
Helpdesk	3,200	$320,000
Unit Costs – Annual	**4,700**	**$470,000**

Source: ERG estimates.

SECTION SEVEN

INITIAL REGULATORY FLEXIBILITY ANALYSIS

The Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) requires all notice and comment rulemaking to be accompanied by a Regulatory Flexibility Analysis (RFA) unless the agency can certify that the rule would have no significant impact on a substantial number of small entities. FDA has decided to perform an Initial Regulatory Flexibility Analysis (IRFA), regardless of whether the proposed rule is ultimately certified.

When an RFA is prepared for a proposed rulemaking, the analysis is an IRFA, and this IRFA must address the following (as cited in P.L. 104-121):

- a description of the reasons why action by the agency is being considered;
- a succinct statement of the objectives of, and legal basis for, the proposed rule;
- a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- a description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;
- an identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule;
- a description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities.

This section addresses each of these major areas in the following sections.

7.1 NEED FOR THE PROPOSED RULE

The need for the proposed rule is laid out in the Preamble to the Proposed Rule.

7.2 OBJECTIVES AND LEGAL BASIS OF THE PROPOSED RULE

The primary objectives of the proposed rule are discussed in the Preamble to the Proposed Rule.

7.3 ESTIMATE OF SMALL ENTITIES AFFECTED BY THE PROPOSED RULE

Section Four provides estimates of the number of small entities affected by the proposed rule. As Table 3-6 in Section Three showed, ERG identified a total of 6,569 domestic firms that are considered labelers. For all relevant initial labeling NAICS, small entities are those with fewer than 500 employees, while for R/Rs, small entities are those with fewer than 100 employees (SBA, 2008).

Many of these small entities, however, are expected not to be affected by the proposed rule because FDA has offered exceptions to labelers of certain devices such as custom devices, and labelers who label only with UPCs for retail sale (see Section 4.2.2). These latter devices are considered to be in compliance with UDI labeling requirements already. Therefore, many of the smallest labelers are considered very likely to be unaffected by the proposed rule. An estimated 1,334 small businesses out of 6,345 small businesses estimated to be currently registered with FDA as labelers (21 percent) are considered likely to be unaffected. Table 7-1 presents the counts of firms, both initial labelers and R/Rs, by size, after the exceptions and exclusive UPC use are considered. As the table shows 5,234 out of the 6,569 firms identified as labelers (80 percent) are expected to be subject to the proposed rule. Of these, 5,010 (96 percent of affected) are identified as small entities. An additional 41 small firms are estimated to use variable barcodes, therefore, 4,969 small firms are estimated to be affected by the UDI labeling requirements of the proposed rule.

7.4 RECORDKEEPING, REPORTING AND OTHER COMPLIANCE REQUIREMENTS OF THE PROPOSED RULE

7.4.1 Recordkeeping and Reporting Requirements

The primary recordkeeping and reporting requirements of the proposed rule are organized by cost category as follows:

- Administrative and Planning Costs—these costs include costs for creating and revising SOPs. Approximately 25 percent of the cost of this cost category was considered to apply to this task. All affected small entities would need to consider whether the requirements affect their SOPs and revise existing SOPs or create new ones. This is considered a managerial task primarily, although clerical work might be required. Medical device labelers of all sizes routinely create and revise SOPs.

- Barcode Registration Costs—only a fraction of small entities are expected to need to register. ERG estimates that 474 small entities will need to register. The time needed to fill out the web-based form is considered a minimal portion of the overall planning

Table 7-1. Number of Small Entities Affected by the Proposed Rule

Type of Firm	Employment Size by Firm							Total Firms	Total Small
	Smallest (1-4)	Small (5-19)	Medium (20-99)	Large (100-199)	Larger (200-499)	V. Large (500-999)	Largest (1000+)		
No. of Initial Labeling Firms	1,162	1,403	988	189	111	44	125	4,022	3,853
No. of R/R Firms	727	318	112	18	13	24	NA	1,212	1,157
Total Labeling Firms	1,889	1,720	1,101	207	124	69	125	5,234	5,010
Total Labeling Firms Affected (variable barcoding firms removed)	1,889	1,720	1,092	190	109	60	89	5,149	4,969

Source: From Tables 5-3 and 5-9 (all counts exclude firms assumed to use UPCs or label custom devices).

effort. The registration form asks for identifying information, the type of applicant (e.g., manufacturer), the revenue class to which the applicant belongs, a check off box for each revenue class for identifying the appropriate fee, and credit card information. ERG assumes a manager would be completing this form.33

- Equipment Costs—a portion of this cost category is the labor to operate verifiers. ERG assumes that a part of the task of operating the verifiers is to indicate in records the outcome of the verification task and what was done to correct any problems found. Most small entities were assumed to need to meet this requirement incrementally. The labor category assumed for this task was a quality control inspector. Maintaining records of this type is routine in the medical device labeling industries.

- Direct Marking—only a relatively small fraction of small entities are expected to need to do DM. ERG estimates, however, that 106 small entities might need to file exceptions for DM, which is expected to require 10 hours per exception and could involve submission of an exception notification to FDA. The submission would document the reason for the exception. It is assumed that this is not a routine staff function and, therefore, is a management-level task. Additionally, among those small entities not filing exceptions, 135 firms are expected to need to verify the safety of marking systems for implants and multi-use equipment. (See Section 4.3.1.4 for more information on these numbers and assumptions.) Because many similar products are already marked by other firms, this task would entail literature searches for information on the products that are already marked and preparing a summary of the information found. Management time is assumed for this type of task.

- Software—integration of variable barcoding into IT systems requires acquisition of software modules, testing, verification, and validation of those software systems. Even the smallest facilities would require some testing, so all small entities are expected to need to document testing, verification, and in some cases, validation outcomes, both on a one-time basis, and to a more limited extent, on a recurring basis. This task is likely to be performed by inspection or QA workers. However, except for the very smallest entities, this software installation should automate all UDI-related recordkeeping tasks, which mostly involve ensuring that the UDI appear on all device records that FDA currently requires to be maintained. Personnel running the reports are assumed to be the same personnel who ordinarily run similar IT reports that currently do not contain the UDI. These might be IT staff, accounting staff, or clerical workers, depending on the size and sophistication of the operation. The incremental task of ensuring a UDI appears on device records, where this is assumed to be done manually (among the 1-4 employees size group), is considered negligible for the very few products likely to be labeled by entities in this size group. This is judged to be a clerical task.

- GUDID—this is the major recordkeeping and reporting task in this proposed rule, because so much of the recordkeeping and reporting tasks associated with device records are assumed to become automated using the software discussed above. Adding a UDI to existing or future device records is considered a minimal task with automation. The GUDID task requires that firms input additional information on each device they manufacture. Currently all device manufacturers must list devices by type and provide some information on the device. The proposed rule would require them to provide UDI information for each device type, which could cover, for example, several dozens of individual products. For each product, the entities

[33] HIBCC's form is used as the basis for detailing these requirements.

would need to provide the UDI assigned and a number of other relatively easily obtained information items (see Section 4.3.1.7 for a list of the data required). For the smallest firms, this task is made simple by the relatively small number of products for which they would need to provide data and by the (presumed) ease of use of FDA's web-based data entry system. Those entities with many more products would use an upload process, with an assumed upload function provided by FDA online. The software systems assumed to be used at the larger entities (within the small firm group) should automate much of the uploading. Because all of these entities already use similar web-based systems or upload similarly formatted data to FDA's FURLS system for the registration and listing process, all should have personnel familiar with using web-based or SPL-uploading systems. Much of this work can be handled by whoever handles these tasks now (IT personnel, managers, or even trained technicians or clerical staff). A total of 3 to 4.5 hours per small entity is assumed in the first year, followed by one hour per year to add or edit information.

7.4.2 Other Compliance Tasks

Other compliance tasks include planning implementation of the UDI requirements, running new labeling equipment, running new direct marking lasers, applying supplemental labels, and designing new labels. All small entities either currently perform such tasks (planning for implementation of new FDA rules and designing labels), are assumed to have personnel that would be trained to perform such tasks with new equipment (running new printing/labeling equipment or DM lasers), or the tasks require little to no new skills (adding a supplemental label).

7.5 OTHER FEDERAL RULES

There are no known Federal rules that duplicate, overlap, or conflict with the proposed rule.

7.6 COSTS TO AND IMPACTS ON SMALL ENTITIES AS A RESULT OF THE PROPOSED RULE

The proposed rule would cost small entities approximately $68.2 million per year, or about 52 percent of the total annualized costs of the rule to industry (see Table 7-2). Most small entities would face costs ranging from $1,000 per year per entity at the smallest firms to about $34,000 at the largest small firms (250-499 employees. With DM costs considered, the highest costs per firm are estimated at $111,000 per year per firm at the largest small firms ($78,000 plus $34,000). A very few small entities might face such costs (17 small entities in the 250-499 employees size group that would be required to mark implants) (see Table 5-3 in Section Five for additional breakouts of costs by size). Costs as a percentage of revenues do not exceed 1 percent at all firms except for the very few that would be required to mark devices. Among those firms, 32 small firms out of a total of 115 estimated small firms that are expected to directly mark devices would have costs exceeding 1 percent of revenues (28 percent of small firms expected to mark devices) (see Table 5-10 in Section Five). These percentages range from about 1.6

percent to 8.6 percent of revenues (primarily affecting the smallest entities with 1 to 4 employees) (see Table 5-7 in Section Five). The 32 small firms represent 0.6 percent of the small entities affected by the rule. (See Section Five for more information on impacts.)

Table 7-2. Aggregate Annualized Costs of Proposed Rule to Small Entities

Cost Element	Employment Size by Firm			Total
	Smallest (1-4)	**Small (5-19)**	**Medium (20-499)**	
Number of initial labeling firms (adjusts double counting)(a)	1,135	1,384	1,178	3,697
Planning, labeling, equipment & GUDID/firm	$1,144	$7,150	$20,672	
Software costs per firm, annualized	$189	$3,195	$13,111	
Total costs per initial labeling firm annualized	$1,333	$10,345	$33,782	
Aggregate annualized cost (no DM)(initial labelers)	**$1,513,546**	**$14,316,461**	**$39,807,877**	**$55,637,884**
Number of affected firms with implant estabs.	8	5	17	30
Additional annualized costs for DM implants	$30,115	$30,115	$77,545	
Number of affected firms with multi use estabs.	19	13	53	85
Additional annualized costs for multi-use	$5,817	$5,817	$47,365	
Total aggregate annualized costs for initial labelers	**$1,891,808**	**$14,750,562**	**$45,947,039**	**$62,589,409**
Number of R/R firms(b)	727	318	112	1,157
Cost per firm for R/Rs	$1,072	$5,958	$25,835	
Total aggregate annualized costs for R/Rs	**$778,971**	**$1,892,177**	**$2,904,870**	**$5,576,018**
Total aggregate annualized costs, all labelers	**$2,670,778**	**$16,642,739**	**$48,851,909**	**$68,165,426**

(a) Excludes count of DM firms. Also excludes count of firms using variable barcodes (41 firms in the 20-499 employee group), and firms assumed to use UPCs or label custom devices.

(b) Number of R/R firms reflects only those in the 20-99 group in the column labeled 20-499 employees. Cost per firm might be slightly overstated for this group. The costs used are the per-firm costs calculated in Section Five for the 20-199 group.

Source: See Table 5-5 and Table 5-9.

7.7 SIGNIFICANT ALTERNATIVES TO THE PROPOSED RULE

The significant alternatives to the rule with respect to small businesses, other than the no action alternative, which is associated with no regulatory impacts, are: (1) an alternative requiring UDI labeling only (no direct marking or GUDID requirements), (2) an alternative requiring UDI only on Class II and Class III devices, (3) an alternative requiring static barcodes on labels only (all other requirements remain in place), and (4) an alternative allowing Class I devices to have a static barcode on their labels, with Class I and Class II devices meeting variable barcode requirements). These four major alternatives are discussed below.[34]

7.7.1 Labeling Only Alternative

The major effect of this alternative is the elimination of the DM requirement and GUDID requirements. This alternative has an effect on cost. Costs to small entities would be reduced by about $4.4 million per year—a 7 percent reduction. Additionally, no small entities would experience costs that are greater than 1 percent of revenues. See Section Six for more details on this alternative.

7.7.2 Class II/Class III UDI Requirement

This alternative would require only Class II and Class III devices to meet UDI requirements.[35] This alternative removes the most numerous devices on the market, Class I devices, from the analysis and any establishments and firms that make such devices (although Class I devices that must be marked under the proposal are assumed to be marked in this alternative). Therefore, this alternative would reduce overall costs to small entities, because fewer small entities would be affected by the rule. It would not, however, have an effect on costs to the typical affected small entity. A total of 2,588 small entities (compared to the 4,969, small entities affected under the proposed rule that do not already barcode using variable barcodes) would be considered affected under this alternative. This is a 48 percent reduction in the number of small entities estimated to be affected, relative to the proposal. Costs to small entities are $42.4 million per year, which is a $25.8 million per year reduction from the $68.2 million per year cost of

[34] Although we performed an abbreviated analysis in Section Six of an alternative that would cover Class III devices only, this alternative is not discussed here. Because of differences in assumptions we needed to make to analyze this alternative, we cannot estimate cost and impacts to the level of detail required for comparison to the other alternatives discussed in Section Seven.

[35] This alternative is assumed to require UDI only on Class II and Class III device labels; unclassified devices, a small portion of all devices, are also assumed to be excluded. If unclassified devices were to be required to have a UDI on labeling under this alternative, the number of affected small entities and costs would be a little greater.

the proposed rule to small entities (see Table 7-2 and Table 7-3). This reduction in cost is solely due to the reduction in the number of affected small entities. Measurable impacts would remain the same under this alternative because DM is still assumed to be required, regardless of the class of the device. See Section Six for more details on this alternative.

7.7.3 Static Barcode Alternative

The static barcode alternative would require that only a barcode identifying the labeler and the product would need to appear on the label. Because some small entities already have such static barcodes on their labels, this alternative reduces the number of affected small entities. ERG estimates, assuming that the percentages used for calculating unaffected firms are the same as those for calculating unaffected establishments, that a total of 4,719 small entities (compared to the 4,969 small entities under the proposed rule who are not currently labeling with variable barcodes) are affected by a static barcode requirement (see Table 7-4), or 281 fewer small firms. It also reduces the costs to these small entities because many of the cost categories, such as new printing equipment and software, are no longer needed. Thus this alternative simplifies the compliance tasks, and costs per establishment (and, therefore, per firm) would be substantially reduced. Just the exclusion of software costs alone would reduce costs to the smallest initial labeling firms (1-4 employees) by about 14 percent, rising to nearly a 40 percent reduction for firms with 20-499 employees (see Table 7-2). Measurable impacts (those greater than 1 percent of revenues) would remain the same under this alternative, however, because DM is still assumed to be required. See Section 6.4 for more details on this alternative.

7.7.4 Class II/III Variable, Class I Static Barcoding Alternative

The alternative allowing Class I devices to use a static barcode would require that only a barcode identifying the labeler and the product would need to appear on the label. It also excludes devices that are exempt from GMP requirements. Table 7-5 presents the count of small initial labelers and R/Rs that must meet either variable or static barcoding requirements. Approximately 174 small businesses subject to Class I static barcoding requirements under this alternative are estimated to be using static barcodes, based on the percentages of static barcoding establishments calculated using the numbers shown in Table 7-4. ERG estimates that a total of 4,268 small entities (compared to the 4,969 small entities under the proposed rule who are not currently labeling with variable barcodes) are affected by a static barcode requirement (see Table 7-5), or 701 fewer small firms. It also reduces the costs to these small entities because many of the cost categories, such as new printing equipment and software, are no longer needed

(see Section 6.6). Thus, this alternative simplifies the compliance tasks, and costs per establishment (and, therefore, per firm) would be substantially reduced.

Table 7-3. Aggregate Annualized Costs to Small Entities under the ClassII/Class III UDI Alternative

Cost Element	Employment Size by Firm			Total
	Smallest (1-4)	**Small (5-19)**	**Medium (20-499)**	
Number of initial labeling firms (adjusts double counting)(a)	603	791	660	2,055
Planning, labeling, equipment & GUDID/firm	$1,061	$8,240	$22,714	
Software costs per firm, annualized	$189	$3,195	$12,896	
Total costs per initial labeling firm annualized	$1,250	$11,435	$35,611	
Aggregate annualized cost (no DM)(initial labelers)	**$754,336**	**$9,044,779**	**$23,514,532**	**$33,313,647**
Number of affected firms with implant estabs.	8	5	17	30
Additional annualized costs for DM implants	$30,115	$30,115	$78,668	
Number of affected firms with multi use estabs.	19	13	53	85
Additional annualized costs for multi-use	$5,817	$5,817	$48,600	
Total aggregate annualized costs for initial labelers	**$1,130,384**	**$9,499,314**	**$29,864,523**	**$40,494.221**
Number of R/R firms	263	115	41	418
Cost per firm for R/Rs	$939	$5,653	$24,593	
Total aggregate annualized costs for R/Rs	**$246,519**	**$648,774**	**$999,323**	**$1,894,616**
Total aggregate annualized costs, all labelers	**$1,376,902**	**$10,148,088**	**$30,863,846**	**$42,388,837**

(a) Excludes count of DM firms. Also excludes count of firms using variable barcodes (23 firms in the 20-499 employee group).

Source: See Table 5-5.

Table 7-4. Count of Affected Small Firms Adjusted for Static Barcoding Assumption

Type of Firm	Employment Size by Firm							Total Firms	Total Small
	Smallest (1-4)	Small (5-19)	Medium (20-99)	Large (100-199)	Larger (200-499)	V. Large (500-999)	Largest (1000+)		
Total Labeling Firms (includes those labeling with variable barcodes)	1,889	1,720	988	189	124	69	125	5,234	5,010
Number Assumed Affected When Variable Barcoding Firms Removed	1,889	1,720	1,092	190	109	60	89	5,149	4,969
Number Assumed Not Currently Barcoding with Static Barcode	1,816	1,655	1,043	139	67	NA	NA	NA	4,719
Difference between Counts of Small Firms under Static Alternative and Proposed Rule	73	66	49	51	42	NA	NA	NA	281

(a) ERG assumes that percentage of firms using variable or static barcoding is the same as that for the equivalent size establishments among small firms. Where firm sizes overlap establishment sizes, weighted averages of numbers using static barcoding have been calculated.

Source: Table 7-1 and assumptions in Section Four and Section Six about percentages of establishments assumed using variable and static barcodes.

Table 7-5. Number of Small Entities Affected under the Class I Static Barcoding Alternative

Type of Firm	Employment Size by Firm						
	Smallest (1-4)	**Small (5-19)**	**Medium (20-99)**	**Large (100-199)**	**Larger (200-499)**	**V. Large (500-999)**	**Largest (1000+)**
No. of Initial Labeling Firms	1,060	1,339	797	158	96	36	125
Estimated No. Using Static for Class I	4	2	153	8	6	NA	NA
No. of R/R Firms	654	297	81	18	8	24	NA
Total Labeling Firms (includes those using static)	1,714	1,636	878	176	104	60	125
Total Labeling Firms Affected (variable and static barcoding firms removed)	1,710	1,634	717	150	83	52	89

Measurable impacts (those greater than 1 percent of revenues) would remain the same under this alternative, however, because DM is still assumed to be required. See Section 6.6 for more details on this alternative. To the extent that firms handling Class I only multi-use devices face lower costs, however, some reduction in impacts might be seen.

Tables 7-6 and 7-7 provide some indication of the level of cost savings that might be associated with this alternative relative to the main analysis. The per-entity costs in these tables are created using the following assumptions. First, we assume the firms that handle only Class I devices subject to UDI requirements are single facility firms, so costs per establishment developed in Section 5 are used to compare to the per establishment cost savings estimated in Section 6 for this alternative. Second, only some of the costs are used to avoid overstating savings. The cost savings per establishment that are used are only those that would apply to all establishments that are subject to the Class I static barcoding requirement. Certain cost savings apply only to establishments handling GMP-exempt devices or to a small fraction of the affected entities. These cost savings are not considered in these tables.

As these tables show, costs savings reduce the per entity costs to small entities handling Class I devices only from 27 percent to 91 percent depending on size and whether the entity is an initial labeler or an R/R. The total cost savings to small entities is estimated to be $35.6 million (see Tables 6-31 and 6-38 in Section 6.6). Thus total costs to small entities are estimated to be reduced from $68.2 million (see Table 7-2) to $32.6 million, or an overall reduction in costs to small entities of over 50 percent.

Table 7-6. Cost Savings and Total Costs per Small Initial Labeling Firm Handling Class I Only Devices under the Class I Static Alternative (a)

Estab. Size	Number Estabs. with Savings	Per Estab. Annualized Cost Savings for Planning	Per Estab. Annualized Costs for Equipment	Base Case Cost per Estab. (w/o Software)	Software Cost	Total Base Case	Costs after Savings	% Reduction
1-4	355	$160	$100	$1,144	$189	$1,333	$884	34%
5-9	221	$320	$100	$1,667	$3,195	$4,862	$1,247	74%
10-49	528	$641	$12,604	$15,375	$7,688	$23,063	$2,130	91%
50-99	138	$641	$12,604	$16,291	$7,688	$23,979	$3,046	87%
100-249	110	$1,281	$19,768	$27,961	$17,150	$45,112	$6,912	85%
250-499	51	$2,563	$42,511	$55,539	$31,024	$86,563	$10,465	88%
Total	1,402							

(a) These firms are assumed to be single-facility firms, so the establishment costs are compared. Note that the costs savings per establishment only include those costs where all Class I only establishments subject to the static barcoding requirements are expected to save. GUDID, label materials, and barcode registration cost savings apply only to GMP-exempt only establishments, and only a very few establishments are expected to save printer coordination costs.

Source: Tables 6-25, 6-27, 6-29, and Table 5-2.

Table 7-7. Cost Savings and Total Costs per Small R/R Firm Handling Class I Only Devices under the Class I Static Alternative (a)

Estab. Size	Number Estabs. with Savings	Per Estab. Annualized Planning Cost Savings	Equipment Savings per Estab.	Base Case Cost per Estab. (w/o Software)	Software Cost	Total Base Case	Costs after Savings	% Reduction
1-4	394	$80	$0	$811	$189	$1,001	$731	27%
5-9	114	$160	$0	$1,150	$3,195	$4,345	$989	77%
10-49	145	$320	$4,451	$16,574	$3,195	$19,769	$11,802	40%
50-99	25	$320	$4,451	$18,157	$7,994	$26,151	$13,386	49%
Total	678	$881						

(a) These firms are assumed to be single-facility firms, so the establishment costs are compared. Note that the costs savings per establishment only include those costs where all Class I only establishments subject to the static barcoding requirements are expected to save. GUDID, label materials, and barcode registration cost savings apply only to GMP-exempt only establishments, and only a very few establishments are expected to save printer coordination costs.

Source: Tables 6-32, 6-34, 6-36, and Table 5-2.

SECTION EIGHT

UNCERTAINTY ANALYSIS

The cost estimate presented in Section Four is associated with uncertainty, with some cost categories more uncertain than others. This section qualitatively discusses the uncertainty of the cost estimates for each of the major cost categories and presents an upper bound and lower bound estimate for each cost category, as well as total cost.

The maximum number of firms and establishments expected to be affected by the proposed rule is reasonably certain. All entities that would be affected by the proposed rule should be registered with FDA. If there are any that should be registered with FDA but are not, they are out of compliance with FDA's registration and listing requirements. Therefore, they would be unlikely to incur costs because if they did not know that registration and listing requirements apply to them, then they probably would not realize UDI applies to them. More uncertain are the share of establishments involved in labeling devices for retail outlets only. These uncertainties are handled within bounding estimates ERG has made for each cost category. These bounding estimates depend on factors that ERG has developed based on our sense of the uncertainty in each cost category (see Table 8-1).

It is not as certain, however, how many establishments would meet an exception to the proposed rule on the basis of labeling of devices such as custom devices that would be covered by the general exceptions. ERG estimated that 1,141 establishments in the 1-4 employee size group and 238 establishments in the 5-9 employee size group would meet an exception for this reason. However, at $1,333 and $4,862 per establishment (see Section Five),[36] respectively, if none of these establishments met such an exception, this would add only $2.7 million per year to the costs of the rule (a 2 percent increase).

Table 8-1 presents ERG's bounding assumptions for each of the cost categories. The first category, Planning and Administrative Costs, is ERG's best estimate of the time needed for companies to undertake basic compliance preparations, although some entities might spend more or less time. The true overall average across most entities is unlikely to vary too widely (i.e., an order of magnitude) from the estimate. However, the requirement to meet the date format change in 90 days could have an effect on

[36] Table 5-3 reports the cost for the 1-4 employee size group; the costs for the 5-9 employees size group is calculated as the annualized cost for software for this group in Table 5-3 ($3,195) plus the annualized cost for all other requirements except DM for this size group in Table 5-2 ($1,667). The number of establishments excludes any estimates of establishments assumed to be using UPCs exclusively beyond those estimated under the proposed rule.

planning and administrative costs for certain establishments. Establishments needing to make this change might need to change the way they assign lot numbers (if their lot numbers are based on the date that appears on the label). Furthermore, the speed with which this requirement must be implemented could result in inefficient planning or less cost-effective implementation as establishments scramble to meet the requirement. ERG is not certain of the number of establishments this requirement might affect, but because of this short implementation period, has estimated a relatively wide bounding assumption, setting costs between 50 percent lower and 50 percent higher than that estimated in Section Four.

Table 8-1. Bounding Assumptions for the Major Cost Categories

Cost Element	Lower	Higher
Labeling and Database Requirements		
Administration and planning	50%	50%
Registration costs	10%	10%
Equipment and other investments	50%	50%
Incremental label cost	25%	25%
Label redesign cost	60%	60%
Software (with training)	50%	50%
Recordkeeping & Reporting (GUDID)	25%	25%
Direct Marking		
Implants	80%	80%
Multi-Use Devices	50%	50%

Source: See text.

Barcode registration costs are considered reasonably reliable. A plus or minus 10 percent factor is used to bound the estimate for this cost category.

The cost estimates for equipment are somewhat less certain. The costs for smaller establishments are reasonably certain, but those for the largest establishments could vary widely and could become very expensive if certain types of device packages are being labeled. If establishments must create new levels of packaging and labeling for certain devices, additional equipment for packaging and labeling might need to be purchased than was estimated in Section Four. For example, Class II devices that are not labeled separately within another device package (a shelf pack), combination products with a separable device that is not individually labeled, and certain devices intended for more than one use that are currently placed unlabeled within kits could be affected. FDA, however, does not believe there are any products that would be affected in this manner. Furthermore, ERG does not have information about the

prevalence of such devices or the number of establishments to which this situation might apply. Alternatively, establishments would be able to judge which of several options (e.g., switching from outside printing to in-house printing) are the least expensive for them in complying with UDI requirements. ERG did not attempt to judge which options would be chosen on the basis of cost, which could overstate the equipment costs. To account for these uncertainties, ERG has estimated uncertainty factors of plus or minus 50 percent for equipment costs.

It is possible that few establishments would need additional materials for labels. The lower bound of the material costs could be substantially smaller than our estimate because:

- The proposed rule allows for shelf packs to be labeled in lieu of individual items,
- 2D barcodes (which are very small) can be used to represent UDI information, and
- Label redesign should solve many label size issues without the need to expand label area.

However, ERG is also uncertain that the approximation of label materials costs (2 percent of all packaging materials costs) and the potential cost increase associated with larger packaging/labeling areas (estimated at 10 percent). We are also uncertain about the cost implications of the need to change label designs within 90 days of implementation. This requirement could lead to less cost-effective means of complying as establishments rush to meet the deadline, including, possibly, the need to go through two separate rounds of label redesign to accommodate, first, the date format change, and second, the UDI change. However, we are not certain of the number of such affected entities and may have overstated the costs under the timing assumption that all affected establishments would redesign labels in the first year. Device labelers that are currently *required* to have dates on their labels have a previously established date format and are not affected by the proposed rule requirement. The number of labelers who choose to use a date on their labels is not known, but could be relatively small. All of these uncertainties and assumptions could make costs too low or too high. An uncertainty factor of plus or minus 25 percent has been chosen for this cost category.

Label redesign costs are more speculative, given the range of technical, regulatory, and marketing considerations at play. It is not known how many establishments might be able to integrate UDI requirements into usual label redesign cycles, which could reduce the incremental cost of label redesign, although the long lead times offered by the proposed implementation schedule implies that many establishments might be able to do this (but the number who must meet an earlier deadline for date format changes is not known). Alternatively, costs could be much higher at establishments with unusual

packaging and labeling issues, including any that might be affected by the need to label and package at a new level. A plus or minus 60 percent factor is used to create the upper and lower bound estimate for this cost item.

Software costs are also considered highly speculative. ERG believes that costs could be overstated because it is not certain how much of the integration costs would be performed as a result of complying with the proposed rule and how much would be performed as a result of corporate preferences for integration. The integration would, however, yield benefits in terms of recordkeeping and reporting cost savings, so the lower bound factor reflects the judgment that some integration might be performed to reduce incremental costs of recordkeeping and reporting. ERG estimates that uncertainty factors of plus or minus 50 percent are reasonable for this cost item. GUDID costs are considered reasonable estimates, so have been given factors of plus or minus 25%.

Direct marking costs range in their certainty. Implants are considered the most uncertain, due to the paucity of data about the extent to which implants are currently directly marked and whether extensive health and safety testing might be required among those not currently marked. Although contacts have indicated that most implants that can be marked (subject to size and material constraints) are directly marked and that health and safety issues should not arise, ERG judges that information is too limited to reduce the uncertainty and that higher costs for marking implants could arise. On the other hand, if all of the implants currently able to be marked are being marked, and those not currently marked would meet the exceptions for direct marking, costs for marking implants could be overstated. Additionally, if "technologically feasible" implies that a plain-text UDI must be marked, even if it must be magnified to be read, this could substantially increase costs. If any exceptions needed to be made on the basis of health and safety, which could be a much lengthier process than the exception process considered in Section Four, costs for exceptions could be higher. Also, if FDA were to deny a portion of the exceptions currently estimated to be requested, substantially more establishments would need to install equipment, increasing the equipment and operating costs for DM. Because of all these uncertainties, ERG estimates an uncertainty factor of plus or minus 80 percent.

For multi-use devices, ERG believes the uncertainty is significant, again due mainly to the paucity of data on current marking practices and, to a lesser extent than that for implants, the issue of technological feasibility. Therefore, ERG has selected a factor of plus or minus 50 percent to calculate bounding estimates.

These factors produce the bounding estimates shown in Table 8-2. As the table shows, with uncertainty considered (and with no implementation schedule used), ERG has estimated that the low end of the cost of the proposed rule to U.S. industry would be $66.3 million per year, where the high end of the cost of the proposed rule would be $193.8 million per year, compared to the central-estimate costs to U.S. industry of $130.1 million per year.

ERG also performed a cost bounding estimate for the Class I Static Barcoding Alternative discussed in Section 6.6. After reviewing the uncertainty ranges in Table 8-1, ERG determined that these ranges sufficiently captured the uncertainty not only in the costs presented in Section 4, but also the cost savings presented in Section 6.6 and has not changed those assumptions. Then, using the costs shown in Table 6-41, ERG recalculated results for the bounding table using the lower costs for the Class I Static Barcoding Alternative and presented the results in Table 8-3. As the table shows, with uncertainty considered (and with no implementation schedule used), ERG has estimated that the low end of the cost of the Class I Static Barcoding Alternative to U.S. industry would be $44.9 million per year, where the high end of the cost of the alternative would be $131.8 million per year, compared to the central-estimate costs to U.S. industry of $88.4 million per year.

Table 8-2. Bounding Estimates Reflecting Uncertainty in the Estimates Presented in Section Four

Cost Element	First-Year	Low	High	Annual Recurring	Low	High
Labeling and Database Requirements						
Administration and planning	$46,534,208	$23,267,104	$69,801,312	NA	NA	NA
Registration costs	$2,156,044	$1,940,440	$2,371,649	NA	NA	NA
Equipment and other investments	$82,803,532	$41,401,766	$124,205,299	$39,573,903	$19,786,951	$59,360,854
Incremental label cost	NA	NA	NA	$9,453,078	$7,089,809	$11,816,348
Label redesign cost	$47,600,999	$19,040,400	$76,161,599	NA	NA	NA
Software (with training)	$187,084,368	$93,542,184	$280,626,553	$22,200,409	$11,100,204	$33,300,613
Recordkeeping & Reporting (GUDID)	$3,148,757	$2,361,568	$3,935,947	$415,783	$311,838	$519,729
Total Labeling and Database Requirements	$369,327,910	$181,553,462	$557,102,357	$71,643,173	$38,288,802	$104,997,544
Direct Marking						
Implants	$12,038,857	$2,407,771	$21,669,942	$845,151	$169,030	$1,521,272
Multi-Use Devices	$14,919,691	$7,459,846	$22,379,537	$1,141,787	$570,893	$1,712,680
Total Direct Marking	$26,958,548	$9,867,617	$44,049,480	$1,986,938	$739,924	$3,233,952
Total	**$396,286,458**	**$191,421,079**	**$601,151,837**	**$73,630,111**	**$39,028,726**	**$108,231,496**
Annualized Investment Total (a)	**$56,422,276**	**$27,254,055**	**$85,590,497**			
Total Annualized Costs for Industry Proposed Rule	**$130,052,387**					
Total Annualized Costs for Industry Low Estimate	**$66,282,781**					
Total Annualized Costs for Industry High Estimate	**$193,821,993**					

(a) First-year costs are annualized at 7 percent over 10 years.

Source: See previous tables.

Table 8-3. Bounding Estimates Reflecting Uncertainty in the Estimates Presented for the Class I Static Barcoding Alternative

Cost Element	First-Year	Low	High	Annual Recurring	Low	High
Labeling and Database Requirements						
Administration and planning	$37,063,382	$18,531,691	$55,595,073	NA	NA	NA
Registration costs	$2,048,710	$1,843,839	$2,253,581	NA	NA	NA
Equipment and other investments	$47,527,879	$23,763,939	$71,291,818	$22,560,550	$11,280,275	$33,840,826
Incremental label cost	NA	NA	NA	$7,575,477	$5,681,608	$9,469,346
Label redesign cost	$47,600,999	$19,040,400	$76,161,599	NA	NA	NA
Software (with training)	$128,742,798	$64,371,399	$193,114,197	$14,169,612	$7,084,806	$21,254,418
Recordkeeping & Reporting (GUDID)	$2,875,937	$2,156,953	$3,594,922	$380,169	$285,127	$475,211
Total Labeling and Database Requirements	$265,859,705	$129,708,221	$402,011,190	$44,685,808	$24,331,816	$65,039,801
Direct Marking						
Implants	$12,038,857	$2,407,771	$21,669,942	$845,151	$169,030	$1,521,272
Multi-Use Devices	$14,919,691	$7,459,846	$22,379,537	$1,141,787	$570,893	$1,712,680
Total Direct Marking	$26,958,548	$9,867,617	$44,049,480	$1,986,938	$739,924	$3,233,952
Total	**$292,818,254**	**$139,575,838**	**$446,060,669**	**$46,672,746**	**$25,071,739**	**$68,273,753**
Annualized Investment Total (a)	**$41,690,732**	**$19,872,459**	**$63,509,004**			
Total Annualized Costs for Industry Proposed Rule	**$88,363,478**					
Total Annualized Costs for Industry Low Estimate	**$44,944,198**					
Total Annualized Costs for Industry High Estimate	**$131,782,757**					

(a) First-year costs are annualized at 7 percent over 10 years.

Source: See Table 6-40.

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APPENDIX A

DEVELOPMENT OF COUNTS OF LABELERS POTENTIALLY SUBJECT TO THE PROPOSED RULE

Definition of Labeler in the Draft Proposal

The draft proposal (Version 4, dated December 17, 2009) requires a label placed on a device to bear a unique device identifier, subject to a few exceptions. Therefore, an entity that labels a device would, in most cases, be affected by the proposal.

The definition of a labeler is as follows:

> Labeler means—(A) any person who causes a label to be applied to a device with the intent that the device will be introduced into interstate commerce without any subsequent replacement or modification of the label; (B) any person who causes the label of a device to be modified with the intent that the device will be introduced into interstate commerce without any subsequent replacement or modification of the label.

This definition is subject to the following limitation:

> The term labeler does not include a person who labels a device, or who modifies the label of a device, pursuant to the instructions of the person who places the device into interstate commerce. Instead, the person who places the device into interstate commerce is deemed the labeler.

FDA's Registration and Listing Database

To determine who is a labeler, we turned to FDA's registration and listing database. The registration and listing database contains the names, addresses and device types of all entities responsible for reporting to FDA about medical devices they handle in some way. All entities that would be considered a labeler should be registered and list each of their devices in this database. However, not all registrants are labelers.

Table A-1 presents the list of all domestic entities that are involved in some manner with medical devices. Foreign firms generally fall into similar categories.[37] The table indicates who must register and list. It also provides an indication of who should be counted as a labeler and the rationale for this determination (FDA's database does not indicate who must label, but the type of establishment and

[37] The only difference is the category of foreign exporter of devices located in a foreign country. Unless such an establishment also manufactures or repackages/relabels, it is not a labeler. This establishment type appears in the database as "export device to United States but perform no other operation on device."

Table A-1. Identification of Labelers

Type of Establishment	Register	List	Count as Labeler?	Rationale
Manufacturer	Yes	Yes	Yes	The manufacturer of a listed device is always a labeler
Manufacturer of Custom Device	Yes	Yes	Yes*	Appears as a manufacturer in the database; would most likely not be affected by UDI requirements (meet an exception in proposal)
Manufacturer of components that are packaged and labeled for distribution	Yes	Yes	Yes	Appears as a manufacturer in the database
Manufacturer of components distributed only to finished device manufacturer	No	No	No	Do not appear in the registration and listing database
U.S. Manufacturer of export only device	Yes	Yes	No	Appears separately from manufacturers in database; would not be affected by UDI proposal
Repackager or Relabeler	Yes	Yes	Yes	Modifies the label; appears as repackager/relabeler in the database
Contract manufacturer who distributes device for specification developer	Yes	Yes	No	Applies label pursuant to instructions (specification developer registers and lists device); appears as custom manufacturer in database
Contract manufacturer who does not commercially distribute	No	No	No	Does not appear in the database
Contract manufacturer of component	No	No	No	Does not appear in database
Contract labeler or packager	No	No	No	Does not appear in database
Contract sterilizer who distributes the device	Yes	Yes	No	Unless they are a relabeler, they do not change the label, therefore any sterilizer not also listed as relabeler is not a labeler; appear in database as contract sterilizer
Contract Sterilizer who does not distributes the device	No	No	No	Does not appear in database
Kit assembler	Yes	Yes	Yes	Subset of repackager/relabeler establishment type
Domestic distributor	No	No	No	Does not appear in database

Type of Establishment	Register	List	Count as Labeler?	Rationale
Specification developer	Yes	Yes	Yes	Contracts with contract manufacturer and instructs on the application of the label; appears as specification developer in the database. May also be instructed by 3rd party or private labeler (domestic distributor—does not register and list), but the specification developer is responsible for the labeling specifications and records
Specification consultant	No	No	No	Does not appear in database
Initial distributor/importer	Yes	No	No	Unless also a relabeler/repackager, does not change the label, therefore is not a labeler; appears in the database as initial distributor/importer
Investigational device	No	No	No	Does not appear in database
Reprocessor of single-use device	Yes	Yes	Yes	Reprocessed device is considered different from original device so new labeling is required; appears in database as reprocessor
Remanufacturer	Yes	Yes	No	Unless also a relabeler/repackager, does not change the label; appears in the database as remanufacturer

*Label devices but would not be subject to UDI requirements; cannot be distinguished from other manufacturers in the database.
Source: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm

certain other considerations indicate which should be considered labelers). All of these establishment types are present in the Registration and Listing database, although several types are subsumed under other headings, as indicated in the table, and do not appear as individual establishment types.

The establishment types as they appear in the registration and listing database are listed in Table A-2. This table presents the registration and listing establishment types as coded in the database and identifies the labelers.

Table A-2. Establishment Type Field Codes in FDA's Registration and Listing Database

Establishment Type ID	Establishment Type Description	Counted as Labeler
1	Manufacture medical device for another party (contract manufacturer)	No
2	Sterilize medical device for another party (contract sterilizer)	No
3	Export medical device to the United States but perform no other operation	No
4	Initial distributor/importer	No
5	Manufacture medical device	Yes
6	Remanufacture medical device	No
7	Repack or Relabel medical device	Yes
8	Reprocess single-use device	Yes
9	Develop specifications but do not manufacture at this facility	Yes
10	Manufacture medical device in the United States for export only	No

Therefore, four establishment type codes were identified as labelers: (5) manufacturers, (7) repackagers/relabelers, (8) reprocessors, and (9) specification developers.

Method for Using the Registration and Listing Databases to Count Labelers

The online registration and listing database is organized as several relational databases, most of which can be linked using registration key, device listing ID, contact ID, or other field found in one or more of the database tables. The following databases were used to identify the count of firms and establishments considered likely to be affected by the draft proposed rule:

Registration—The registration database contains all current and pending registrants (as of March 4, 2010, FDA's latest update available online when this analysis was performed). It establishes the registration key, a field that uniquely identifies all registrants, active and pending, and is the link between the Registration database and several of the other databases (pending registrants do not have a registration number yet, so registration number cannot be used as a link among the various databases).

- **Listing Establishment Type**—This database contains the IDs for current devices listed by all registrants required to list and indicates the establishment type (Table A-2). The listing ID is not used at this time but it will become useful for linking to product codes that identify the type of device in the database named Listing PCD, also included among the online databases.
- **Owner Operator**—This database provides the firm name and ID (both owner operator ID and a contact ID) associated with the owner firm of the registrants in the Registration database.
- **Contact Addresses**—This database provides the address information for the firms in the Owner Operator database, which can be accessed using the contact ID found in the Owner Operator database.
-

The Registration database was filtered prior to any work to link databases. We eliminated all records associated with agents rather than establishments (since each establishment also has an agent and, therefore, there are two records associated with each registrant). To do this, we used the address type field. An "F" in this field identified records associated with a facility; a "U" identified information associated with the facility's agent. All records with a "U" in that field were deleted. The Registration database needed to be linked to the Listing Establishment Type database to identify registrants by type (Table A-2). Thus, we linked the Registration database to the Listing Establishment Type using the registration key. A number of registration keys drop out in this linked database; these registration keys are

those registrants with no listings. Registrants with no listings are (barring database errors) initial distributors/importers (the only group required to register but not list; see Table A-1).

We then created a database of the linked Registration and Listing Establishment Type, which included the registrant (as represented by the registration key), much of their registration data, including address, the information device listing ID, and the establishment type code. Establishment type, however, depends on the device listing, so a registrant can be listed as more than one establishment type. For example, a registrant might manufacture one listed device, relabel another, and custom manufacture a third. Therefore, we determined that in order to ensure that no affected entities were missed and that none were double counted, we ranked the establishment types and queried the database in the following way. We ranked manufacturers first, reprocessors second, specification writers third, repackagers/relabelers fourth, remanufacturers fifth, sterilizers sixth, custom manufacturers seventh, and all others last.

With this ranking scheme in mind, we first queried the master database of registrants and listings for all registrants with a listing associated with the manufacturer ID (establishment type = 5). We pulled out of the master database all of these registrants, including all of the data found in the master database to create a separate database of all manufacturers. All of these registrants, therefore, manufacture at least one listed device.

The remaining master database no longer contained manufacturers. We then identified all registrants with a device listing associated with reprocessing among those registrants remaining in the master database, pulled these records and created a database of reprocessors. The master database, now with manufacturers and reprocessors removed, was then queried to identify the specification writers, and so on. At the end of this process we had created eight databases: manufacturers, reprocessors, specification developers, repackagers/relabelers, remanufacturers, sterilizers, custom manufacturers, and all others. Note that the databases for remanufacturers, sterilizers, custom manufacturers and all others do not contain any registrants that have been identified as performing any functions related to labeling for any listed device.

At this point we queried each of these databases to output unique registration key counts (each registration key could be associated with numerous devices, so to identify numbers of registrants, rather than numbers of device listings, unique registration keys needed to be identified). These counts are shown in Table A-1 in the column labeled “Total Registrants.” Additionally, using the address information included in the original Registration database (carried through to each establishment type database), we were able to identify which establishments were domestic and which were foreign, using a field labeled

"Country Code" (US = domestic and all other codes = foreign). Unique registration key counts were then identified for all domestic and foreign establishments in each of the establishment type databases (except for the "all other" database, which was not analyzed further). These counts are shown in Table A-1 by establishment type.

We then wanted to identify which of the foreign establishments were owned by foreign firms and which were owned by domestic firms. Continuing to use the establishment type databases, we linked each of the establishment type databases to the owner-operator file using the registration key. The owner-operator file contains the contact ID, which was used to link to a contact address file that lists the owner-operator address [38].The owner-operator can be identified as foreign or U.S. based using the country code in the contact address file. We then present information on all owner firms by whether those owners are foreign or domestic and what types of labelers they own (see Table A-2). Note that double counting occurs because some firms own more than one labeler type. We then counted unique registration keys to count domestic or foreign establishments owned by domestic firms or domestic or foreign establishments owned by foreign firms. This information is presented in Table A-1 by labeling establishment type.

One additional change was made manually to all tables. Two domestic reprocessing establishments (with one domestic owner) were found to be missing device listing information in the Device Listing Database as well as the Establishment Type Database, thus dropped out of this analysis. ERG was familiar with these establishments based on our previous work in 2008 to identify reprocessors when we last analyzed possible UDI impacts. FDA's web-based search of the registration and listing databases provides the correct listing information for these establishments, so they have been added into the counts of reprocessors obtained from the downloaded databases.

[38] Every registered establishment has an owner operator. The owner operator can be the official correspondent or might assign another person to act as the official correspondent. When the owner operator opts to be the official correspondent, this means the owner operator address and the official correspondent address are the same and that the contact ID in the R&L database is the same (and there is no sub-account). If the owner operator assigns another person as official correspondent, this is set up as a sub-account. When the official correspondent is set up in a sub-account, this creates another contact ID. This contact ID has its own address. Therefore, the R&L file Contact Addresses contains both the owner operator contact IDs and the official correspondent contact IDs (but only if a sub-account has been set up) and there could be two different addresses associated with an establishment (owner operator and official correspondent). Because the owner operator is considered the legal corporate entity, the address associated with the owner operator defines whether that owner operator is a foreign or domestic entity; the address of the official correspondent would generally not be useful for identifying whether the registered establishment has a foreign affiliation.

Counts of Labelers by Type of Establishment and Location (Domestic vs. Foreign)

As Table A-1 shows, there are 7,578 domestic registrants that can be counted as labelers (as defined in the draft proposal), based on the forgoing analyses. An additional 7,091 foreign registrants are also labelers. Therefore, the labelers are approximately half domestic and half foreign. Most of the domestic labelers are manufacturers (65 percent). Specification developers make up another 18 percent, with relabelers/repackagers making up nearly all of the remaining labelers (17 percent). Foreign establishments are more predominantly manufacturers (92 percent), with specification developers and relaberlers/repackagers being rarer than among domestic establishments.

Counts of Owner Firms with Labeling Establishments by Location

Table A-2 shows counts of all owner firms of these establishments by labeling types and by whether they are domestic or foreign owners. There are a total of 6,569 domestic owner firms that own labeling establishments (both foreign and domestic) out of a total of 12,484 owner firms of labeling establishments (the total number of owner firms in the Registration and Listing Database is not calculated). Thus, about 53 percent of all owner firms of registered labelers are domestic.

Table A-1. Count of Labelers Using FDA's Online Registration and Listing Database

Type of Registrant	Total Establishments		Total Registrants
	Domestic	Foreign	
Manufacturers	4,901	6,492	11,393
Reprocessors	21	3	24
Specification Developers	1,346	276	1,622
Relabelers/Repackagers	1,310	320	1,630
Total Labelers	**7,578**	**7,091**	**14,669**
Remanufacturers	49	52	101
Sterilizers	16	49	65
Contract Manufacturers	278	576	854
All Others (distributors, importers, U.S. export only, export only to U.S.	NA	NA	5,453
All Registrants			**21,142**

Note: These counts include registrants whose applications are pending. Two facilities were manually added to the count of reprocessors. Although FDA's web-based search indicates a firm with two facilities acting as a 3rd party reprocessor, the online database shows the establishments registered but no listings link to these registrations.

Source: FDA Registration & Listing Database, online version, March 4, 2010.

Table A-2. Number of Firms with Labeling Establishments Listed in FDA's Registration and Listing Database

Firms	Manufacturers	Reprocessors	Specification Developers	Repackagers/ Relabelers	All Labelers
Domestic	4,241	21	1,306	1,212	6,569
Foreign	5,440	4	242	330	5,915
Total Firms	**9,681**	**23**	**1,548**	**1,542**	**12,484**

Note: Sum of firms by specific establishment types will not add to all labelers because some firms own more than one type of establishment. A total of 211 domestic firms have been double counted (that is, the difference between the sum of all domestic labelers and the sum of all firms listed as manufacturers, reprocessors, specification developers and repackagers/relabelers is 211). Six firms listed two contact IDs, leading to double-counting when domestic and foreign firms are counted separately. The counts for these six firms were removed from the foreign count but not from the domestic count. Additionally, five foreign establishments are identified as being owned by both a foreign parent and a U.S subsidiary; they are counted as foreign owned. Finally, one firm with two establishments was added to the count of reprocessors; see Table A-1.

Source: FDA Registration & Listing Database, online version, March 4, 2010.

Domestic and Foreign Establishments by Location of Owner Firm

Domestic owner firms do not own only domestic establishments and foreign owner firms also do not own only foreign establishments. Table A-1 provides a count of establishments, foreign and domestic, by the ownership location (foreign or domestic) of their owner firms. This information is useful for identifying the potential numbers of firms and their establishments that would not be considered small under Small Business Administration definitions. Foreign firms, even if owning U.S. establishments and meeting SBA size criteria, would not be considered small businesses under SBA definitions. However, U.S. firms, if they meet size criteria, even if a portion of their business is associated with a foreign establishment, would be considered small businesses under SBA definitions. Note that only 226 domestic establishments have a foreign owner firm, but 794 foreign establishments have a U.S. owner firm. Generally, though, domestic establishments have domestic owner firms and foreign establishments have foreign owner firms.

Table A-1. Numbers of Domestic and Foreign Establishments by Location of Owner Firm

Type of Labeler	Domestic Establishments			Foreign Establishments	
	With U.S. Owner Firm	With Foreign Owner Firm	Total	With U.S. Owner Firm	With Foreign Owner Firm
Manufacturers	4,748	153	4,901	715	5,777
Reprocessors	20	1	21	-	3
Specification Developers	1,324	22	1,346	49	227
Relabelers/Repackagers	1,260	50	1,310	30	290
Total Labelers	**7,352**	**226**	**7,578**	**794**	**6,297**

Source: FDA Registration & Listing Database, online version, March 4, 2010. An additional firm was added to domestic reprocessor establishments with U.S. owner firm. See Table A-1.

APPENDIX B

SUMMARY OF DEVICE MANUFACTURER INTERVIEWS

ERG interviewed a selection of medical device manufacturers about the impacts of a UDI requirement on their operations and their perceptions about the implications for the industry as a whole. These manufacturers produce a wide range of medical devices, from implants to gloves. Most of them are barcoding their products in some capacity.

These calls covered a wider range of assumptions than those on which the present analysis is based, often addressing issues involving full serialization, direct marking, and labeling below the current level of labeling. Based on the manufacturers' comments, the smaller manufacturers might incur a relatively large cost burden to convert to UDI because they have made fewer of the investments. The larger manufacturers, however, because of the potentially greater complexity and automation of their manufacturing lines, might also face high costs for integrating a UDI system into their current lines (e.g., Medical Device Manufacturer F in the discussion below, 2006). ERG also contacted manufacturers of printing equipment to confirm some of the current trends regarding the printing technologies used by medical device manufacturers.

Some of the manufacturers said they would prefer to print the barcode directly on the label, rather than by adding a sticker, in order to avoid the testing required to ensure that the sticker adheres (especially after sterilization). The manufacturers noted that changes are regularly made to medical device labels. Changes occur regularly, ranging from 2 to 4 times a year. The manufacturer interviews are summarized below.

Medical Device Manufacturer A

Medical device manufacturer A (2006) is barcoding products already and recently changed barcode formats (from the Health Industry Bar Code, a US-based bar code standard, to the European Article Number code) to facilitate greater international recognition of their label. Their barcode currently identifies employed to identify the product and the product lot.

The cost to modify the structure of the barcode from the HIBCC to the EAN format was minimal. The manufacturer already had digital printers that could easily convert from one barcode format to another. The company paid $20,000 to $30,000 in registration costs to obtain the new barcode numbers for their 27,000 products. Another $50,000 was spent on administrative tasks associated with the changeover and on using the printer software to change the barcode structure.

Overall, their cost to modify the barcode was approximately $70,000 to $80,000. The manufacturer noted that costs would be much higher for manufacturers who had not yet purchased barcode printers or who did not have the "right" barcode printer.

Medical Device Manufacturer B

Medical device manufacturer B implemented barcoding in compliance with the basic requirement that all medical and surgical supplies be marked with a universal product number (UPN) but has not implemented the more demanding DOD UID requirement.[39] The company does not present lot or serial numbers on its labeling. The company spent 2 years preparing for the UPN labeling task. Linear barcodes are used on most of the products' primary and secondary packaging, while a few products are labeled with 2D barcodes.

The investment required to comply with the UPN requirement was limited because the company already had the necessary printers. Two verification scanners were installed on each production line. Significant IT costs were incurred to tie the barcode data to the company's Enterprise Resource Planning (ERP) system, which tracks manufacturing information. Personnel also needed to familiarize themselves with the HIBCC standard and write SOPs for barcoding and the requisite training. Training was conducted at every manufacturing plant. The manufacturer lost some label inventory, but the cost of label redesign and label reapprovals far outweighed that of label inventory loss.

[39] DOD requires that all medical and surgical supplies purchased by the Department must be marked with a UPN to facilitate identification of such products and to expedite ordering and receiving these products. The UPN is encoded in a bar code on the packaging or device.

Medical Device Manufacturer C

Medical device manufacturer C has been compliant with the UPN initiative for the past 5 or 6 years using linear bar codes and has considered lot or serial number additions. They are fully compliant with the UPN requirement on secondary packaging and 95 percent compliant on primary packaging. The remaining 5 percent of products do not have enough space on the packaging to accommodate a bar code, but this issue could be resolved with the purchase of new equipment.

In order to include the bar code on its product labels, the company had to purchase a new printing plate for each of its 300 catalog numbers at a cost of roughly $500 each. Digital printers will be needed if the firm is to print lot numbers on their labels. The company has not thus far attempted to print any UDI-type information on their labels and has not wanted to modify their form, fill, and seal machines on each of several packaging/labeling lines.

Planning for the UPN effort required 40 percent of a supervisor's time and 30 percent of the time for 4 subordinates for a year or roughly 3,200 hours. Assuming a modest overall hourly cost of $75 per hour (fully loaded), this translates to a cost of $240,000.

For secondary packaging, the manufacturer changed to digital printing and spent $75,000 on 13 thermal transfer printers. Some primary packaging is still preprinted (roughly 20 percent), but all secondary packaging is printed in-house. For the secondary packaging, they also purchased customized software for quality control of labeling at a cost of $130,000. They employ 12 barcode verifiers for production of 300 products. Further, validation of equipment and training required 20 percent of a supervisor's time for 8 months. The manufacturer noted that validation instructions are not readily available, so they found the calibration of the equipment to be very challenging.

Packaging scrap loss was about $20,000 to $30,000. However, they are no longer holding such inventories, so these losses would be less if they were to take on a similar project at the present time.

When asked to try to determine what it would cost them to go to a UDI system involving placing a serialized UDI on existing packaging, the manufacturer indicated that putting on a serial number is a huge project. ERG judged that printing a lot number on packages would also be a very large project and generate as many new equipment requirements. They are not currently set up with a labeling system that

can put a unique serial or lot number on product labels. They have many primary packaging systems, which form, fill, and seal packages. The lid is printed online and sealed. This type of system is widely used in medical device manufacturing.

They currently use printing plates in a flexographic printing system. To print any variable information on their labels, they would have to buy new printing and label application devices. The manufacturer believes that a thermal transfer applicator device would be needed at $100,000 per machine (a thermal transfer printer would also be needed). This machine would print, place and apply the label all as one function.

They also estimated that they would need one verifier per line. In order to perform QA verification on the output of the process, they'd need a barcode reader on each product. This facility has 4 automated and 10 manual lines and therefore they would need 14 verifiers. Equipment validations would take months to do. The contact estimated that an engineer would need to spend two months on "paperwork."

While serialization is beyond the FDA scope, this company estimated that a serialization project would involve a team, tying up resources for a year or two, or even longer. Software integration would be needed. Their current system does everything for them, including planning production, assigning lot numbers, and determining what to bill. In a serialized UDI system, the software would need to perform additional functions. Software integration would cost $200,000-$250,000 plant wide. Additionally, software validation is very involved. A total of 4 to 5 people's time for a year would be needed for software validation.[40] This company judged that validation work would cost about $10,000 per line. If validation is done well, product scrap rates probably will not be affected. Recurring costs include additional QA staff, maintenance on equipment, and systems administration.[41]

Medical Device Manufacturer D

Medical device manufacturer D has implemented the DOD UID on its equipment that costs $5,000 or more (mainly electromagnetic machines). They comply by adding a label that is similar to the one already there and encoding it with the unique identifier. The costs to develop their system included

[40] According to the manufacturer, equipment validation would entail 2 person-months of time. ERG assumes this would not add appreciably to the overall labor needs of 4-5 person-years for software validation.

[41] The latter two categories do not necessarily appear incremental to existing costs, however.

the investment cost of two thermal transfer Zebra printers at $5,000 each, printing ribbons, printer software, and training. The manufacturer considered the DOD effort to have a relatively low start-up cost but noted that uniquely identifying all medical devices (specifically, serialization) could generate much higher costs. The products affected by the DOD requirement are often low-volume, made-to-order items. Other medical devices are made in much larger quantities and thus the volume of labels that need to be printed will be greater.

The manufacturer noted that the cost to implement unique identification can vary by product, noting especially the technological challenge for marking implants. Directly marking an implant can affect its clinical use as the mark could affect the smoothness of the device or present toxicological issues. Other products, however, such as in-vivo products, that have some component that is outside the body, such as catheters, are prime candidates for serialized unique identification. Manufacturer D also indicated that at least 5 years would be needed to implement serialized unique identification.

Medical Device Manufacturer E

In this interview the company described its analysis of a full serialization requirement for its devices. At present this manufacturer reported using only conventional lot numbering techniques. The manufacturer reported lot sizes from a few units to over 100,000 items, with many lots numbering in the thousands.

The manufacturer reported that implementation of a serialized UDI would require complex manufacturing changes in each of more than a dozen plants in four countries. The manufacturer estimated that production costs overall would increase by 5 percent. Included in this estimate are:

- Capital investments in specialized barcode printers, verifiers, and supporting computers and software;
- Incremental costs for new labels at a cost of $0.01 to $0.03 each. They estimated that 900 million labels would be needed;
- An increase in direct labor costs of 5 percent.

This company appeared to interpret the serialization concept as requiring direct marking on each device rather than serialization at the existing level of labeling. This estimate, therefore, probably overstates costs if serialization at the current level of labeling is to be employed.

Medical Device Manufacturer F

Manufacturer F, a large manufacturer, noted that the greatest challenge to implementing UDI will be the enormous diversity of devices. Assuming that the diversity issue can be addressed, uniquely identifying devices by assigning a serialized number to each item would still be a major challenge for the industry. While the technology is available to get the serial number onto devices, reading the numbers might pose a challenge for some further down the chain of distribution. UDI will also require electronic printing and only a small percentage of firms are currently using these techniques.

This contact argued that serialization would be a very large effort for large companies. While they may have the capital to invest in the changes required, it is a huge undertaking nonetheless. Small companies would likely require 3 to 8 years for implementation, while large manufacturers might need 4 to 10 years.

The economic burden imposed by implementing serialization would vary with the number of products and volume produced. Significant infrastructure would be required. First, it can be assumed that UDI would require compliance with standards. These standards would need to be developed and larger companies would assume a part of this requirement. Further, UDI would necessitate having a system in place that allows tracking and tracing product through the chain of distribution. The infrastructure cost to do this might be larger for small manufacturers because large manufacturers already have some of this in place a result of working together with large health care product distributors. For the larger manufacturers, the cost is in implementing it for the wide array of products. Also, one potential side effect of serialization or of lot numbering will be more scrapped product. Product will need to be removed if the label is incorrectly produced.

Assuming 5 products per production line, the cost to implement unique identification might be $3 million per line or more for a serialized barcode.[42] These estimates include equipment changes, such as the purchase of a printer, verifier, and software, and the associated validation. In addition, the manufacturer noted that training of various personnel will be required, including 1 hour for packaging line operators, 3 hours for those in distribution, and 10 to 15 hours for end users.

[42] This cost is considered reflective of the highly automated and complex manufacturing scenario posited by this manufacturer and is considered applicable to the larger manufacturers. If direct marking was required, that would increase those costs significantly (as much as another $3 million per line).

Medical Device Manufacturer G

A large manufacturer reported that a federally mandated UDI requirement would have no impact on its operations, assuming that the federal requirement is consistent with the GS1 international standards on product identification. The company has implemented a UDI system, employing the Global Trade Identification Number (GTIN) protocol, fully throughout its organization. This manufacturer decided several years ago to undertake a UDI-like implementation program in order to meet likely forthcoming international requirements and as part of their overall business plan. The company uses the GTIN as the internal identifier for each of its products.

The company has purchased a number of other medical device manufacturers, including some relatively small companies (i.e., fewer than fifty employees) and all of these companies have been brought within the umbrella of the company's device identification system. The company representative noted a lot of internal satisfaction with the decision to move toward UDI comprehensively. All parts of the organization are subject to a consistent set of requirements.

The company could not estimate the cost of implementing UDI. The representative had sought to obtain such information from some of the larger operating units but none of the divisions had been able to reliably describe their costs. The move toward UDI was combined over time with enhancements of their enterprise software program and could not be isolated. Corporate headquarters helped some of the smallest business units in the company to implement UDI. The consistency of the UDI requirement across divisions also facilitated the compliance actions for each division.

The company representative noted that the company purchased a number of common printers, verifiers, and software packages across the operating divisions. The representative noted that the more electronically integrated a company's divisions are, the easier it will be develop a consistent UDI system. Companies that use a lot of paper communications and are more loosely integrated will incur higher UDI implementation costs.

Small Manufacturer A

This very small manufacturer acts mostly as a distributor (they import items and do catalog sales), but they do manufacture two items that would be classified as medical devices. One is a voice

amplification system for people with voice problems, which FDA classifies as a Class II device. The other is a cloth “handkerchief with ties” for covering stoma (holes in airways) to keep dust out. Therefore, only two products would be affected by a barcoding requirement. They primarily do catalog sales, but occasionally are called on by a pharmacy to provide for a customer, but they do not operate as a retail operation (i.e., they don’t use UPCs on their labels). They consider themselves a “mom & pop” operation, with four children helping out, for a total of 6 working.

Their production lines are completely manual, including labeling. They manufacture a group of voice amplification systems and put them in a box. When they have assembled 25 or so items, they then affix labels and put them in inventory, when they determine that they are low on inventory, the put together another 25 systems. They make about 200 systems per year. For stoma cloths, they bring in the material, stitch up the cloths, put 5 in a bag, then when they have accumulated about 25, they label them, and put them in inventory. They make about 50 bags of 5 stoma cloths a year. If they had to put a barcode on their labeling, they’d use a supplemental sticker.

They currently have a barcode on one product (but not one they themselves manufacture, so this is a relabeling exercise). The customer is a California public utility commission. The commission orders a few artificial larynxes per year. The commission requested that the Very Small Manufacturer A affix a barcode, but didn’t specify what barcode to use. The barcode is just a product identifier (they are not registered with GS1 or HIBCC). Our contact was not sure what type of barcode it was. The barcoding software they purchased offered a variety, and they picked one out that looked like it might be useful. It was a 16-digit code where the numbers appear under the bars [linear barcode; static]. Their customer was not certain what they wanted, but did approve the one selected. They use an inkjet printer to print the barcode on the labels.

If they were required to barcode their other items, they would continue with the same labels and would just add a supplemental label to their current labels.

Our contact mentioned that he has had some experience with redesigning labels. When asked to consider what it might cost to add a supplemental label, he stated that he estimated the entire cost of everything, including planning, redesign, labor to put on extra sticker, purchasing equipment, software, etc. to cost about 50 cents per label, which he did not think would be different whether a variable or static barcode was required. This is not a problem for their voice amplifier, since they make about a $60-$70 profit on each one, but their profit on their stoma cloths is much smaller—about $1.85 per bag of 5. A 50

cent per label increase in cost would be large on a per-item basis. Overall, though he thought costs would be small [about $100 per year for the 200/per year amplifier and $300 per year for the 50/month stoma cloths bags.]

Small Manufacturer B

Very Small Manufacturer B is an Original Equipment Manufacturer (OEM), with 10-14 persons who serves many other companies that market and distribute the product under their own name. They produce various electrocardiographs (Class II devices) and medical recorders. They operate one production line, but it is operated as Just in Time, and they can change the line any time to another product. The line is manual and labels are applied manually at the end of the process and labels change depending on which customer has ordered the equipment (the customer's name, mostly manufacturers or distributors, is the one that goes on the label, not theirs). They do not currently do any barcoding and outsource all of their label printing.

If they had to add a barcode to their labeling, they would probably continue to use their contract printer, but might bring it in house if given enough lead time and had a chance to redesign with this in mind. They need to label inside battery boxes in some cases; printing equipment needed for those types of labels is very expensive; a redesign might help avoid a label there and have it go outside the box. Their outside printer can handle barcoding without any problem, but variable barcoding would be more expensive. Some of their products are serialized; their printer handles this, but with barcoding, another layer of complexity is added. Also, another issue on some of their devices is that the labels need to withstand washing.

When asked to consider what effect a barcoding requirement might have on their costs, the representative indicated that he thought it was mostly just a per-label cost increase if variable information is needed in the barcode. If only static information was required, he did not believe any costs would be incurred. If variable information was required on labels that are not already serialized, he thought the costs could be 4-5 times as much per label (now on the order of a few cents). On small orders (some of their customers only order 2 to 500 units) variable labels could cost as much as $2-4 per label; for large lot customers, the cost might be $0.50- $0.60 per label. Overall, though, in terms of total costs, he did not expect costs to be significant.

He felt that a barcode requirement (static or variable) would cause no real problems, except that he felt they might be getting into size issues on some of their devices that are very small, with limited labeling room on the device, especially if FDA wanted both a human readable and machine readable number on the label.