DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses"

Docket No. FDA-_____

Regulatory Impact Analysis
Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

Economics Staff
Office of Planning
Office of Policy, Planning, and Legislation
Office of the Commissioner

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the clarifications in this final rule will not significantly increase costs on manufacturers of products made or derived from tobacco, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

The final rule will reduce ambiguity in the market for products made or derived from tobacco and clarify FDA's interpretation and application of its existing intended use regulations. The rule clarifies the types of intended uses, as determined by manufacturer claims and other evidence, that would result in these products being regulated as drugs, devices or combination products rather than tobacco products. Products made or derived from tobacco that are intended to 1) diagnose, cure, mitigate, treat or prevent disease, including use in smoking cessation, or 2) affect the structure or any function of the body in any way that is different from effects related to nicotine that were commonly and legally claimed in the marketing of cigarettes and smokeless tobacco prior to March 21, 2000, such as an intended use for improving respiratory function, will be subject to regulation as drugs, devices or combination products. We estimate that there would be one-time costs for tobacco manufacturers to evaluate current product communications such as labeling and associated promotional materials in light of the clarifications in this final rule, and to revise them if needed. We expect that only a small number of products will undergo a one-time change to communications such as labeling and associated materials as a result of this rule.

The final rule will provide greater clarity to producers regarding the regulatory requirements for products made or derived from tobacco and to consumers to distinguish products intended for medical uses from those marketed for other uses. The reduction in ambiguity will enhance consumers' understanding of the products they purchase and may increase consumer welfare as a result.

Table 1.-- Economic Data: Costs and Benefits Statement

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized					7%		

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
	Monetized $millions/year					3%		
	Annualized Quantified					7%		
						3%		
	Qualitative	Reduce regulatory ambiguity						
Costs	Annualized Monetized $millions/year	$0.246	$0.126	$0.365	2014	7%	10 years	
		$0.202	$0.104	$0.301	2014	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year					7%		
						3%		
		From:			To:			
	Other Annualized Monetized $millions/year					7%		
						3%		
		From:			To:			
Effects	State, Local or Tribal Government: Small Business: Wages: Growth:							

II. Comments on the Preliminary Regulatory Impact Analysis and Our Responses

We received public comments on the benefits, costs, and the effects on small entities reported in the preliminary regulatory impact analysis.

A. Comments on Costs

(Comment 1) Approximately 20 submissions provided comments on costs. A tobacco product manufacturer disagreed with FDA's assertion that the rule would not impose new significant costs on industry. The comment argued that FDA's approach would alter the analysis for determining whether a product qualifies for regulation as a tobacco product or a medical product, and potential impacts would include the costs of review and correction of labels and other marketing materials.

(Response 1) We agree with the comment that costs of the rule will include the costs to review and make any corrections to communications such as labeling and associated promotional materials that may be appropriate. We have added estimates of these one-time costs in the analysis. Because the final rule only clarifies FDA's interpretation of the drug and device definitions in the FD&C Act with respect to products made or derived from tobacco, we anticipate the degree to which communications such as labeling and associated promotional materials will undergo changes is small.

(Comment 2) A comment predicted that the vast majority of e-cigarette products would be eliminated because of paperwork burdens. The comment also described the loss to consumers, including the cost for e-cigarette users who return to smoking cigarettes. Another comment added that the approval process for a product classified as a medical drug may cost tens or hundreds of millions of dollars.

(Response 2) We disagree with the comments. We are unsure to which paperwork burden the commenter refers since there are no explicit paperwork requirements in the proposed or final rule. With regard to the loss to consumers from the possibility that e-cigarette users return to smoking cigarettes, the final rule clarifies the types of intended uses, as determined by manufacturer claims and other evidence, that would result in products being regulated as drugs, devices, or combination products rather

than as tobacco products. We do not expect users of e-cigarettes to return to smoking cigarettes as a result of the clarifications in this final rule.

(Comment 3) Comments stated that we underestimated the cost of the rule because it would reduce access to an electronic nicotine delivery system (ENDS) and other products and would reduce consumer surplus.

(Response 3) We disagree with these comments. This rule is not expected to change the number of ENDS or other products on the market or alter the cost or prices of ENDS products or other products. As a result, we do not expect that this rule will change consumer access to ENDS products or reduce consumer surplus.

B. Comments on Benefits

(Comment 4) One comment stated that FDA failed to include the largest benefit of the proposed rule--the welfare gains to consumers of being provided with improved information regarding the safety and effectiveness of tobacco products. The comment cited studies indicating that any regulations that reduce misleading claims will improve the well-being of consumers.

(Response 4) We agree that a benefit of the rule will be welfare gains to consumers from clarifying the regulatory status of products made or derived from tobacco (including when products made or derived from products will be regulated as medical products, as suggested by reference to the "safe and effective" standard in the comment). While the final rule does not address the veracity of claims by manufacturers, the clarifying regulations may reduce confusion by consumers with regards to the intended uses of products. As we note in Section III.D of our final regulatory impact analysis below, "In addition, we assume that the regulation will clarify for consumers when products made or derived from tobacco are intended for medical uses rather than for other uses. None of the comments provided

any data that would allow us to quantify these benefits and we leave them unquantified in the final rule." Without data to quantify these benefits, we cannot state with certainty that they are the largest of the rule.

(Comment 5) One comment stated that we overestimated the benefits to industry because we incorrectly assumed that firms are ambiguity averse whereas it is generally assumed that profit-maximizing firms are risk neutral. Consequently, the comment claims that in principle the industry should not benefit from the proposed rule.

(Response 5) While we agree with the comment that profit-maximizing firms are risk neutral, we disagree with the comment that industry cannot benefit from the final rule. As stated, the final rule will provide greater clarity to producers regarding the regulatory requirements for products made or derived from tobacco and may create efficiency gains to firms during the application and approval process. We have explicitly described these benefits in this final regulatory impact analysis.

(Comment 6) An individual and an advocacy group expressed the belief that we have not provided any substantive data about benefits the regulation will provide. The advocacy group added that we have not identified any material harm that would be reduced by imposition of the rule and has not provided evidence that any material confusion exists.

(Response 6) We disagree with these comments. The intention of the final rule is to reduce ambiguity that exists around when we regulate a product made or derived from tobacco as a drug, device, or combination product rather than as a tobacco product. There is some ambiguity about what types of intended uses, as determined by manufacturer claims and other evidence, might result in a product made or derived from tobacco being regulated as a medical product rather than as a tobacco product. The final rule will provide greater clarity to producers regarding the regulatory requirements for

products made or derived from tobacco. In addition, consumers of products made or derived from tobacco may incorrectly perceive some products to be intended for medical uses rather than for other uses, and vice versa. These comments didn't provide any information to change the benefits estimate and we leave it as a qualified description.

C. Comments on Small Entity Impacts (Regulatory Flexibility Act)

(Comment 7) Approximately 25 submissions provided comments on small entity impacts. Several individual commenters expressed concern that the rule would adversely impact small e-cigarette retailers and may drive them out of business. One commenter stated that the premarket application fees would be too burdensome for most small businesses to handle.

(Response 7) We disagree with these comments. As stated previously, the rule merely clarifies the types of intended uses, as determined by manufacturer claims and other evidence, that would result in a product made or derived from tobacco being regulated as a medical product rather than as a tobacco product. In our final regulatory impact analysis in Section III below, we estimate that firms engaged in the manufacture of tobacco products, drugs, devices, and combination products would incur one-time costs to access and learn the rule. Moreover, we estimate that manufacturers of tobacco products will incur one-time costs to review labeling and make any appropriate changes. We estimate that these one-time costs are small.

D. Other Comments on Impacts of the Rule

(Comment 8) Approximately eight submissions provided other comments on impacts of the rule. An advocacy group warned that asserting jurisdiction over e-cigarettes in the fashion proposed would have devastating consequences for consumers who rely on these products to reduce or replace their smoking habit. The comment asserted that the current marketplace is far better for consumers than the

marketplace that would exist in the wake of the proposed regulations. The comment predicted that the regulation would drive most manufacturers into shadow or black markets, and consumers may begin do-it-yourself manufacturing. A health care provider suggested that e-cigarettes and related vapor devices are most likely responsible for recent reductions in both teen and adult smoking.

(Response 8) We disagree with the assertions about the impacts of the rule. We intend for the final rule to clarify current ambiguity that exists around when we regulate a product made or derived from tobacco as a drug, device, or combination product rather than as a tobacco product. The final rule will provide greater clarity to producers regarding the regulatory requirements for products made or derived from tobacco. In addition, consumers of products made or derived from tobacco may incorrectly perceive some products to be intended for medical uses rather than for other uses, and vice versa. We expect these clarifications to enhance consumers' understanding of intended use of products made or derived from tobacco.

E. Summary of Changes

We add a background section to the Preliminary Regulatory Impact Analysis as well as sections that address the need for the rule, the number of entities affected by the rule, the one-time costs of learning the rule by all manufacturers of products made or derived from tobacco, and the one-time costs of reviewing and making changes to communications such as labeling and associated promotional materials, by manufacturers of tobacco products.

III. Final Regulatory Impact Analysis

A. Background

The Tobacco Control Act (TCA) was enacted on June 22, 2009, amending the FD&C Act and providing us with the authority to regulate tobacco products. In general, a "tobacco product" is defined as any product made or derived from tobacco that is intended for human consumption. The FD&C Act excludes from the definition of a tobacco product any article that is defined as a drug, a device, or a combination product, and provides that we regulate these products as medical products. Although not a cost of this final rule, one factor firms consider when they decide whether to position their product as a tobacco product or a medical product is the potential research and development costs. These costs vary depending on the type of product. For example, in the Deeming Final Regulatory Impact Analysis (Ref. 1, Table 12a, pages 90-91), we estimated that an initial premarket tobacco application (PMTA) process could cost firms from about $0.3 million to $2.6 million for ENDS; that application process could cover multiple products. Nicotine containing drugs are expected to be approved through NDAs or abbreviated new drug applications (ANDAs) and many are sold over-the-counter (OTC), so we assume here that a reasonable proxy for development costs of a new nicotine-containing drug would be testing for a novel route of delivery for an OTC drug product. Based on safety testing costs cited in the preliminary regulatory impact analysis for the Consumer Antiseptics Rub Products Proposed Rule (Ref. 2, page 23), we estimate that safety tests for a novel route of delivery could cost up to $13.3 million, with additional clinical testing costs depending on the indications and development course chosen. However, the final rule does not change the PMTA or NDA application processes and thus will not change these research and development costs.

There is some ambiguity about what types of intended uses, as determined by manufacturer claims and other evidence, might result in a product made or derived from tobacco being regulated as a medical product rather than as a tobacco product. This final rule addresses this ambiguity and establishes the criteria that we will rely on to determine whether a product made or derived from tobacco

is intended to be used as a medical product or as a tobacco product and provides clarity regarding our interpretation of the drug and device definitions in the FD&C Act with respect to products made or derived from tobacco.

B. Need for the Rule

Ambiguity around when we regulate a product made or derived from tobacco as a drug, device, or combination product rather than as a tobacco product creates a market failure and leads to inefficiencies in the markets for these products. Manufacturers may spend resources to comply with regulatory requirements and processes that may not apply to their products, and consumers may incorrectly perceive some products to be intended for medical uses when they are not and vice versa. The final rule will provide greater clarity to producers regarding the regulatory requirements for products made or derived from tobacco. Moreover, consumers will more clearly understand that products made or derived from tobacco that claim to, say, "treat nicotine dependence" will have undergone premarket clinical investigations and have complied with all of our regulatory requirements for products intended for medical use. Without clarifying the appropriate regulatory frameworks for products made or derived from tobacco, the markets for these products would continue to function at suboptimal levels of efficiency.

C. Baseline Conditions

Number of Entities Affected by the Rule

We assume that most entities affected by the rule will be tobacco product manufacturers. This is consistent with the intent of the rule, which will clarify the jurisdictional boundaries for when a product made or derived from tobacco will be regulated as a tobacco product and when it will be regulated as a

medical product. Consequently, we estimate the number of manufacturers of drugs, devices, and combination products that will be affected by the final rule will be small.

We use 2013 information on domestic tobacco product manufacturers from the Alcohol and Tobacco Tax and Trade Bureau (TTB) as well as our own internal data to estimate the number of entities that will be affected by this rule. The TTB estimates that there are 135 domestic manufacturers and 200 importers of cigarettes, RYO, chewing tobacco, snuff, large cigars, small cigars, and pipe (including waterpipe) tobacco. The 2013 TTB data did not include information on the number of manufacturers and importers of ENDS products. Based on logo counts from trade association Web sites and information from FDA listening sessions, we estimate there are between 168 to 204 manufacturers of ENDS products that will be affected by this rule.

We also estimate a small number of manufacturers of medical products made or derived from tobacco will be affected by this rule. According to FDA's Orange Book, there are 10 sponsors of 57 active prescription and OTC nicotine-containing products that will be affected by this rule. We sum over all manufacturers to obtain a total estimate of between 513 and 549 manufacturers of products made or derived from tobacco that will be affected by this rule.

Table 2.--Number of Entities Affected by the Rule

Affected entities	Count
Domestic tobacco product manufacturers	135
Importers of tobacco products	200
ENDS product manufacturers	168 – 204
Manufacturers of active prescription and OTC nicotine-containing products	10
Total	513 – 549

D. Benefits of the Final Rule

The final rule clarifies the regulatory status of products made or derived from tobacco and our interpretation and application of the existing intended use regulations. This will reduce the ambiguity and may create some efficiency gains associated with submitting an application for approval or marketing authorization of a new tobacco-derived product, or with initiating research for a new tobacco-derived product. In addition, we assume that the regulation will clarify for consumers when products made or derived from tobacco are intended for medical uses rather than for other uses. None of the comments provided any data that would allow us to quantify these benefits, and we leave them unquantified in the final rule. The costs to prepare and submit an application to the appropriate center will not change with this rule.

E. Costs of the Final Rule

We assume that all tobacco-derived product manufacturers would incur one-time costs to learn the rule. There may also be a one-time cost incurred by a small number of manufacturers of tobacco products to review and revise product communications such as labeling and associated promotional materials. We assume that manufacturers of products intended for medical uses would not incur any costs to review or revise communications such as labeling and associated promotional materials.

One-Time Costs to Learn the Rule

We model the one-time learning costs as the time required by manufacturers' regulatory affairs experts to access and read the proposed rule. We estimate that a regulatory affairs expert would incur a burden of between 15 minutes and 30 minutes to access the rule and would read the provisions at a rate of 200 to 250 words per minute. The preamble and codified regulatory text are approximately 23,100 words, and we estimate that it would take between 1.5 to 2 hours for a legal affairs expert to read the rule.

We estimate the mean hourly wage of a regulatory affairs expert using wages reported in the Bureau of Labor Statistics, Occupation Employment Statistics, May 2014 National Industry-Specific Occupational Employment Estimates for a Lawyer ($64.17), which are doubled to account for overhead. Applying the fully loaded mean hourly wage to the hourly burdens described previously, we obtain a cost of between $228.87 and $320.85 for a regulatory affairs expert to access and read the final rule (i.e., between 0.25 hours and 0.5 hours to access the rule + between 2 hours and 1.5 hours to read the rule x $128.34 per hour). The total access and learning costs for all affected entities equals between $117,412 and $176,147 (i.e., between 513 and 549 manufacturers of products made or derived from tobacco incurring per entity learning costs of between $228.87 and $320.85). We assume that each manufacturer would incur the access and reading costs the first year following publication of the rule. Consequently, over 10 years at a discount rate of 7 percent, we estimate the annualized one-time learning costs range from $16,717 to $25,079. When we assume a discount rate of 3 percent, the annualized one-time costs range from $13,764 to $20,650.

One-Time Costs to Review Communications Such As Labeling and Associated Promotional Materials

We assume that all manufacturers of tobacco products would incur one-time costs to review all communications such as labeling and associated promotional materials. Communications such as labeling and promotional materials may include but are not limited to information on the inner packaging, outer packaging, package inserts, and in pamphlets provided by the manufacturer that accompany packages containing products made or derived from tobacco at the point of sale, and also information provided by the manufacturer on the internet. We estimate the costs to review communications such as labeling and associated promotional materials using the 2014 FDA Labeling Cost Model Report (LCM) (Ref. 3). We obtain the total number of tobacco product labels from the

LCM. The LCM uses Nielsen Scantrack Data to estimate that there are 7,574 Universal Product Codes (UPC) for tobacco products.

We assume that the communications such as labeling and associated promotional materials for each UPC would need to be reviewed for any potential ambiguity that a claim might communicate. We assume that it takes a regulatory affairs expert an average of 0.5 hours to review communications such as labeling and promotional materials associated with each product label. We assume that the average of 0.5 hours to review communications such as labeling and associated promotional materials per UPC takes into account that UPCs for the same product may differ only by package configuration or other non-label or promotional considerations, and also that promotional material may apply to more than one UPC.

Using the fully loaded wage for a regulatory affairs expert, we estimate one-time label review costs of $486,024 (i.e., 7,574 UPCs x 0.5 hours x $128.34 per hour). Over 10 years at a discount rate of 7 percent, we estimate the annualized label review costs are $69,198. When we assume a discount rate of 3 percent, the annualized label review costs are $56,977.

<u>One-Time Costs for Changes to Communications Such As Labeling and Associated Promotional Materials</u>

Comments did not provide estimates of the number of tobacco products that would undergo changes to communications such as labeling and associated promotional materials as a result of this final rule. Because the final rule only clarifies our interpretation of the drug and device definitions with respect to products made or derived from tobacco, we assume the degree to which communications such as labeling and associated promotional materials will undergo changes is small. We assume that no

more than 5 percent of communications such as labeling and associated promotional materials will undergo changes as a result of the final rule.

We use the LCM to estimate the costs for minor changes to communications such as labeling and associated promotional materials for 5 percent of tobacco products. We assume the costs for a 3-month compliance period (i.e., the shortest compliance period available in the LCM) are the same as the costs for a 30-day compliance period, as provided in the rule. The default package label-types included in the model for tobacco products do not include package inserts; however, for this analysis we add the costs of package inserts for tobacco product packages to capture any costs to change promotional materials that may not be included in the LCM. We estimate the total one-time costs for changes in communications such as labeling and associated promotional materials to range between $283,003 and $1,901,841. Over 10 years at a discount rate of 7 percent, we estimate the annualized costs of any changes to communications such as labeling and promotional materials range between $40,293 and $270,779. When we assume a discount rate of 3 percent, the annualized costs for changing communications such as labeling and promotional materials range between $33,177 and $222,954.

Table 3 shows the estimated total one-time costs of the final rule range from about $0.9 million to $2.6 million. Table 4 shows that the annualized one-time costs over 10 years range from about $0.1 million to $0.4 million with a 7 percent discount rate; Table 5 shows that the annualized one-time costs over 10 years range from about $0.1 million to $0.3 million with a 3 percent discount rate.

Table 3.--One-Time Costs

Type of Cost	Low	High
Learning costs	$117,412	$176,147
Review communications such as labeling and promotional materials	$486,024	$486,024
Changes to communications such as labeling and promotional materials	$283,003	$1,901,841
Total	$886,438	$2,564,011

Table 4.--Annualized Costs at 7 Percent

Type of Cost	Low	High
Learning costs	$16,717	$25,079
Review communications such as labeling and promotional materials	$69,199	$69,199
Changes to communications such as labeling and promotional materials	$40,293	$270,779
Total	$126,209	$365,058

Table 5.--Annualized Costs at 3 Percent

Type of Cost	Low	High
Learning costs	$13,764	$20,650
Review communications such as labeling and promotional materials	$56,977	$56,977
Changes to communications such as labeling and promotional materials	$33,177	$222,954
Total	$103,918	$300,580

IV. Final Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to prepare a regulatory flexibility analysis if a final rule would have a significant effect on a substantial number of small businesses, nonprofit organizations, local jurisdictions, or other entities. This final rule will reduce ambiguity in the regulatory environment for products made or derived from tobacco. We do not expect this clarification to significantly increase costs associated with marketing products made or derived from tobacco, and thus certify that the final rule will not significantly affect a substantial number of small businesses, nonprofit organizations, local jurisdictions, or other entities. The discussion in this section and the previous sections of the economic analysis constitute the regulatory flexibility analysis.

A. Description and Number of Affected Small Entities

The Regulatory Flexibility Act requires a description of the small entities that would be affected by the rule, and an estimate of the number of small entities to which the rule would apply. This final

rule will affect domestic tobacco product manufacturers and importers of foreign tobacco products. We assume that there are no small manufacturers of medical products that would be affected by this final rule. Consequently, we exclude them from the analysis.

We use U.S. Census data to estimate the percentage of manufacturers and importers that are small and apply that estimate to the number of manufacturers and importers reported earlier in the economic analysis. Manufacturers of tobacco products covered by this final rule may be designated as "tobacco product manufacturers" under the North American Industry Classification System (NAICS) code 312230. Importers may be designated as wholesalers or retailers. Most tobacco product-importing wholesalers would be classified as "tobacco and tobacco product merchant wholesalers" under NAICS code 424940. We assume that the size distribution of importers covered by this final rule would be the same as that reported in the U.S. Census for NAICS 424940.

Table 6 shows the Small Business Administration (SBA) size thresholds for small businesses for NAICS codes 311230 and 424940, as well as the comparable size categories available from the U.S. Census (Refs. 4 and 5). Because the U.S. Census size categories nearest to the SBA size thresholds are so much smaller than the SBA size thresholds, the proportion of businesses found to be small will be underestimated.

Table 6.--SBA Size Standards and Census Size Categories for Tobacco Product Manufacturers and Importers

NAICS Code	Description of NAICS Category	SBA Size Standard (employees)	U.S. Census Size Category (employees)
312230	Tobacco Manufacturing	1,500	500

424940	Tobacco and Tobacco Product Merchant Wholesalers	250	100

According to the size distributions reported in the 2012 U.S. Census, 89 percent of tobacco product manufacturers are small and 92 percent of tobacco product importers are small. We apply the higher estimate of tobacco product manufacturers that are small (i.e., 92 percent) to acknowledge the bias in using U.S. Census data to estimate the number of firms that meet the small definition using the SBA size thresholds. We assume that the percentage of small manufacturing establishments affected by this rule is the same as the percentage of small tobacco product manufacturing firms reported in the U.S. Census. Consequently, we estimate that between 463 and 496 (i.e., 503 and 539 * 0.92) small tobacco product (including ENDS products) manufacturing establishments will be affected by this final rule.

In addition to those described above, there are other important considerations that may bias these estimates: (1) Many ENDS manufacturers are likely too new to be reflected in 2012 data, (2) the U.S. Census manufacturing category excludes manufacturers without payroll, which would by definition be small, and (3) large firms are more likely to have multiple establishments, and applying the fraction of small firms from the U.S. Census to the total number of firms estimated using the average number of establishments per firm may underestimate the fraction of firms that are small.

B. Description of the Impacts of the Rule on Small Entities

From the final regulatory impact analysis, we estimate that the one-time costs for tobacco product manufacturing firms to access and learn the rule, review communications such as labeling and associated promotional materials, and make any changes is between $ 1,118.23 and $ 1,362.86 per firm (i.e., $613,907 / 549 and $699,145 / 513). Data from the 2013 U.S. Census, County Business Patterns

series (Ref. 5) indicate that there were 248,155 manufacturing firms with fewer than 500 employees under NAICS codes 31-33 with a total payroll of approximately $231,682,438,000, or $933,620 per firm. We assume that this represents the average payroll of a tobacco manufacturer or importer covered by this final rule.

The upper value of the range in one-time cost estimates of the final rule (i.e., $1,362.86 per firm) would represent approximately 0.1 percent of the annual payroll for a small firm with fewer than 500 employees. Because the clarifications in this final rule will not significantly increase costs on manufacturers of products made or derived from tobacco, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

V. References

1. U.S. Food and Drug Administration. Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements (Final Rule), Docket FDA-2014-N-0189, http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM500254.pdf

2. U.S. Food and Drug Administration. Safety and Effectiveness of Consumer Antiseptics Rub Products; Topical Antimicrobial Drug Products for Over-the-Counter Human use; Proposed Amendment of the Tentative Final Monograph; Preliminary Regulatory Impact Analysis, Docket FDA-2016-N-0124, http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM510753.pdf

3. RTI, Final Report, 2014 FDA Labeling Cost model, Contract No. HHSF-223-2011-10005B, Task Order 202

4. US Small Business Administration Table of Small Business Size Standards, https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf

5. US Census, 2013 County Business Patterns, http://thedataweb.rm.census.gov/TheDataWeb_HotReport2/econsnapshot/2012/snapshot.hrml?NAICS=424940