DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Sunscreen Drug Products for Over-The-Counter Human Use; Proposal to Amend and Lift Stay on Monograph

Docket No. FDA-1978-N-0018

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, 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). Executive Order 13771 requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." We believe that this proposed rule is an economically 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 many sunscreen manufacturers are small entities and the one-time costs of the proposed rule represent a significant fraction of annual revenue to small sunscreen manufacturers, we find that the proposed rule will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "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 $150 million, using the most current (2017) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would result in an expenditure in any year that meets or exceeds this amount.

We have developed a comprehensive preliminary regulatory impact analysis that assesses the impacts of the proposed rule. We present this analysis below.

B. Summary of Costs and Benefits

If finalized, the proposed rule would update and make effective regulations to ensure the safety and effectiveness of sunscreen products marketed under the over-the-counter drug monograph. The rule would update sunscreen product labeling standards, address the safety of sunscreen active ingredients, revise and clarify our expectations for testing and recordkeeping by entities that conduct sunscreen testing, and address other sunscreen safety or efficacy concerns, like combination sunscreen-insect repellents and alternative dosage forms.

Consumers would benefit from less exposure to sunscreen products containing active ingredients about which safety questions remain, less exposure to sunscreen products labeled with potentially misleading sun protection information, increased consumption of products with better UVA protection, less exposure to flammable spray sunscreens, and less exposure to spray and powder sunscreen products posing inhalation risks. Consumers would also experience transaction cost savings. The costs of the rule to sunscreen manufacturers include administrative costs, costs to fill data gaps for active ingredients and powder dosage forms, product formulation

testing costs, and costs to reformulate and relabel sunscreen products. Finally, testing entities would incur recordkeeping costs if they do not already maintain adequate records of testing equipment, methods, and observations in final formulation testing.

Table 1 summarizes the costs and benefits of the proposed rule, if finalized. The annualized benefits of the proposed rule, if finalized, would range from $0.00 million to $3.72 million at a 7 percent discount rate and from $0.00 million to $3.62 million at a 3 percent discount rate. Our primary estimate of annualized benefits would equal $0.91 million at a 7% discount rate and $0.88 million at a 3% discount rate. The annualized costs of the proposed rule, if finalized, would range from $15.57 million to $75.84 million at a 7 percent discount rate and from $12.40 million to $60.42 million at a 3 percent discount rate. Our primary estimate of annualized costs would be $47.55 million at a 7% discount rate and $37.79 million at a 3% discount rate.[1]

Table 1. Summary of Benefits, Costs, and Distributional Effects of the Proposed Rule

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized ($m/year)	$0.91	$0.00	$3.72	2017	7%	20 years	
		$0.88	$0.00	$3.62	2017	3%	20 years	
	Annualized Quantified (mil oz /year)[2]	201.79	98.16	286.26				Increased use of products with improved UVA protection
	Annualized Quantified (mil oz /year)[3]	51.42	19.43	83.41				Less exposure to sunscreens containing active ingredients about which safety questions remain
	Annualized Quantified	161.04	159.88	162.20				Less exposure to

[1] The primary estimate of the costs is not the average of the lower bound costs and the upper bound costs.
[2] Values represent the 2016 consumption of sunscreens that would provide improved UVA protection under the proposed rule.
[3] Value represent the 2016 consumption of sunscreens that contain active ingredient about which safety questions remain.

	(mil oz /year)[4]							sunscreens with potentially misleading sun protection information
	Annualized Quantified (mil oz /year)[5]	386.44	384.86	388.02				Less exposure to spray and powder sunscreens posing inhalation risks.
	Qualitative	Quicker responses to adverse events, improved inspections, and better protection of human subjects. Potential transaction cost savings related to changes in the effort required to choose a sunscreen.						
Costs	Annualized Monetized ($m/year)	$47.55	$15.57	$75.84	2017	7%	20 years	
		$37.79	$12.40	$60.42	2017	3%	20 years	
	Annualized Quantified							
	Qualitative	Recordkeeping costs to testing entities that do not already maintain adequate records.						
Transfers	Federal Annualized Monetized ($m/year)							
		From:			To:			
	Other Annualized Monetized ($m/year)							
		From:			To:			
Effects	State, Local, or Tribal Government: None Small Business: Some small businesses could exit the sunscreen market by discontinuing their products or going out of business. Wages: None Growth: None							

Table 2 shows the Executive Order 13771 summary over an infinite time horizon. In this analysis we assume that the costs of the rule would continue indefinitely. We estimate that this rule generates $29.85 million in net annualized costs, discounted at 7 percent, over a perpetual

[4] Values represent the 2016 consumption of sunscreens with potentially misleading sun protection information.

[5] Values represent the 2016 consumption of potentially inhalable spray sunscreens and powder sunscreens.

time horizon. Based on these costs, this proposed rule would be considered a regulatory action under EO 13771.

Table 2. EO 13771 Summary Table (in $ Millions 2016 Dollars, Over an Infinite Time Horizon)[6]

	Primary Estimate (7%)	Lower Bound (7%)	Upper Bound (7%)	Primary Estimate (3%)	Lower Bound (3%)	Upper Bound (3%)
Present Value of Costs	$456.33	$149.22	$730.46	$618.16	$201.53	$1,002.22
Present Value of Cost Savings	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Present Value of Net Costs	$456.33	$149.22	$730.46	$618.16	$201.53	$1,002.22
Annualized Costs	$29.85	$9.76	$47.79	$40.44	$13.18	$65.57
Annualized Cost Savings	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Annualized Net Costs	$29.85	$9.76	$47.79	$40.44	$13.18	$65.57

II. Preliminary Regulatory Impact Analysis

A. Background

1. Key Terms, Inputs, and Assumptions

In Table 3, we describe the key terms used in this document in plain language. We describe some of the terms in Table 3 to provide additional explanation to correspond to assumptions and data definitions we make for purposes of the economic analysis. For the complete data definitions used to construct our sunscreen market data, see our technical appendix (Ref. 1).

Table 3. Key Terms in the Regulatory Impact Analysis

Term	Description
OTC	OTC stands for "over-the-counter." Sunscreens are OTC drugs.
OTC Monograph	Monographs for OTC drugs are regulations for various categories of OTC drugs. These regulations include the conditions under which a product marketed without an approved NDA is generally recognized as safe and effective, and not misbranded. Firms may market drug products that meet the standards in an applicable OTC monograph, the conditions contained in 21 C.F.R. Part 330, and any other applicable regulatory and statutory requirements for OTC drugs, without prior approval.
OTC Sunscreen Monograph	The OTC sunscreen monograph is the subject of this proposed rule. If finalized as proposed, the OTC sunscreen monograph would include information about, among other things, the labeling, testing, dosage forms, and active ingredients permitted for products marketed without

[6] We assume that the benefits and costs of the proposed rule would diminish after 20 years. Negative values denoted in parentheses.

	new drug applications (NDAs) or abbreviated new drug applications (ANDAs) under the sunscreen monograph. In this analysis, the OTC sunscreen monograph refers to the sunscreen monograph at 21 C.F.R. Part 352.
Stayed Sunscreen Monograph	The stayed sunscreen monograph refers to stayed 21 C.F.R. Part 352. Firms currently market sunscreen products containing active ingredients listed in the stayed sunscreen monograph without approved NDAs under an enforcement policy described in FDA guidance.
GRASE	GRASE stands for "generally recognized as safe and effective." In general, a drug is GRASE if experts agree that the substance is safe and effective for its intended uses based on adequate, well-controlled clinical investigations generally from the published scientific literature. If we determine that a sunscreen containing a particular active ingredient would be GRASE under its conditions of use in a final rule, then manufacturers may use that active ingredient in sunscreen monograph products. If we determine that a sunscreen containing a particular active ingredient would not be GRASE in a final rule, then manufacturers must remove that ingredient from the sunscreen market or obtain prior FDA approval for its marketing.
UVA Radiation	Sunlight includes a form of electromagnetic radiation called ultraviolet A (UVA) radiation. Exposure to UVA radiation plays a role in adverse health effects like sunburn, early skin aging, and some skin cancers. There are two forms of UVA radiation: UVA I and UVA II.
UVB Radiation	Sunlight also includes ultraviolet B (UVB) radiation. Exposure to UVB radiation plays a role in adverse health effects like sunburn, early skin aging, and some skin cancers.
Principal Display Panel (PDP)	The principal display panel is the part of an OTC product's labeling that is mostly likely to be displayed, presented, shown, or examined when the product is displayed for retail sale. Sunscreen manufacturers include applicable SPF, broad spectrum, and water resistance statements on the PDP.
SPF	SPF stands for "sun protection factor." The SPF of a sunscreen product is a measure of how well a sunscreen protects against sunburn, which is primarily caused by UVB radiation. Sunscreen products must include an SPF statement on their label.
Determined SPF	The "determined" SPF value is the value that results from the SPF testing required under FDA regulation. The determined SPF value of a sunscreen product may differ from the SPF statement on that sunscreen product's labeling.
Broad Spectrum	Broad spectrum is a statement that manufacturers may make on sunscreen labeling if the sunscreen meets the broad spectrum requirements.
Current Broad Spectrum Requirement	To satisfy the current broad spectrum requirement, sunscreen products must satisfy a pass/fail critical wavelength test.
New Broad Spectrum Requirements	To meet the new broad spectrum requirements, sunscreen products must meet the current broad spectrum requirement as well as a UVA I/UV ratio of 0.7 or higher. Manufacturers would calculate this ratio

	using data from the existing test used to meet the current broad spectrum requirement.
Final Formulation Testing	Final formulation testing is any testing conducted on a sunscreen product under 201.327. Final formulation testing includes SPF, broad spectrum, water resistance, flammability, particle size, and drying time testing.
Testing Entity	A testing entity is any firm conducting final formulation testing on sunscreen products.
Sunscreen-Only Products	Sunscreen-only products are a category of sunscreen products. A sunscreen-only product is a product whose primary purpose is to be a sunscreen.
Colorless Cosmetic Sunscreen Products	Colorless cosmetic sunscreen products are another category of sunscreen products. Colorless cosmetic sunscreen products include moisturizers, anti-aging products, hand and body lotions, and other face and body creams with sunscreen, but whose primary function is not to be a sunscreen. Any facial or body cream without a tint is a colorless cosmetic product.
Color Cosmetic Sunscreen Products	Color cosmetic sunscreen products are a category of sunscreen products. Color cosmetic sunscreen products usually come in multiple scents or tints and generally alter the appearance of the skin. Color cosmetic sunscreen products consist primarily of lip balms, lipsticks, and facial cosmetics. Any facial or body cream with a tint is a color cosmetic product.
Sunscreen Brand	The brand of a sunscreen product is the most prominent major brand name on the sunscreen label. Some examples of sunscreen brands include Coppertone, Neutrogena, and Hawaiian Tropic
Responsible Person	Like a sunscreen brand, the responsible person is the manufacturer, packer, or distributor whose name appears on the labeling of a sunscreen product covered by this section. Responsible persons have data retention responsibilities under the proposed rule.
Sunscreen Manufacturer	In this analysis, a sunscreen manufacturer is the firm that would directly bear most of the costs associated with this proposed rule, if finalized. We call a firm a sunscreen manufacturer if it owns an establishment that manufactures a sunscreen product in our registration and listing database.
Sunscreen Firm	In this analysis, a sunscreen firm is a labeler or manufacturer that lists a sunscreen product in our registration and listing database. All sunscreen manufacturers are also sunscreen firms.
Sunscreen Product Line	A sunscreen product line is a set of products with similar characteristics and labeling. In our data, we identify product lines as unique combinations of brand and product category (i.e. sunscreen-only product, colorless cosmetic sunscreen product, or color cosmetic sunscreen product).
Sunscreen Product	In this analysis, sunscreen products are products marketed under the OTC monograph system and subject to 21 CFR 201.327. Unless specifically noted, references to sunscreen products do not refer to those marketed under a NDA or ANDA. We define a sunscreen product as unique on all product dimensions except for tint, scent, or size. These product dimensions include all active ingredients and label information, like SPF.

Sunscreen Formulation	A sunscreen formulation is a unique sunscreen product with a specific tint or scent.
Private Label	Private label products are also known as “store brand” products. Many grocery stores, pharmacies, department stores, and large discount retailers sell sunscreens under their own private label. A single manufacturer may produce sunscreens for many different private label brands.

Throughout this analysis, we assume that the final OTC sunscreen monograph would publish in 2019, the deadline for publication established by statute. Firms would incur any one-time costs in the first year after publication, and benefits to consumers would begin in the second year after publication.

In this analysis, we use average wage data from the Bureau of Labor Statistics to estimate labor costs to industry (Ref. 2). The cost of labor is the fully-loaded wage, which includes overhead and benefits, and we assume that the cost of overhead and benefits equals 100% of the wage. Table 4 contains the fully loaded wages to industry used in this analysis.

Table 4. The Cost of Labor

Occupation	2017 Mean Hourly Wage	Fully Loaded Hourly Wage
Management Occupations	$71.06	$142.12
Production, Planning, and Expediting Clerks	$25.75	$51.50
Medical Scientists	$45.64	$91.28

In our analysis of the benefits of the proposed rule, we use population projections from the U.S. Census Bureau (Ref.5). We estimate the sunscreen consumption of the average consumer by dividing consumption in 2016 by the population in 2016 (324 million). To estimate sunscreen consumption in a future year, we multiply the consumption of the average consumer by the projected population in that year. Table 5 contains the population estimates used in this analysis for the years 2019 to 2038.

Table 5. U.S. Population Projections for 2019 to 2038 (millions)

Year	Projected Population	Year	Projected Population
2019	329	2029	355
2020	332	2030	357
2021	335	2031	359
2022	337	2032	362
2023	340	2033	364
2024	342	2034	366
2025	345	2035	368
2026	347	2036	370
2027	350	2037	372
2028	352	2038	374

Finally, in response to the proposed rule, sunscreen manufacturers would have the option to submit an NDA or ANDA rather than relabel a sunscreen product, reformulate a sunscreen product, or take a sunscreen product off the market. We expect that the cost of obtaining market approval through another pathway is higher than the cost of reformulating. Therefore, in our analysis, we assume that obtaining an NDA or ANDA is not an economically feasible option for sunscreen manufacturers.

2. Updating and Making Effective the Sunscreen Monograph

New scientific information suggests that chronic exposure to sunscreen active ingredients could have potential systemic health risks for consumers. Since the sunscreen monograph rulemaking began in 1972, patterns of sunscreen use have changed substantially. Many more people use sunscreen products routinely and in large amounts, covering a large proportion of the body surface. Additionally, we now know that some sunscreen active ingredients can penetrate the skin. As explained in further detail in the preamble, these developments raise questions about the potential systemic effects from long-term, frequent sunscreen use, including both hormonal and carcinogenic effects. Therefore, in 2014, the Nonprescription Drugs Advisory Committee concluded that we need additional data to address concerns about the potential systemic effects of sunscreen use.

Also in 2014, Congress passed the Sunscreen Innovation Act (SIA) (Public Law 113-195 (Nov. 26, 2014)). The law set a statutory deadline in 2019 for finalizing the OTC sunscreen monograph, and established new procedures for determining whether additional active ingredients are GRASE for use in sunscreen products. In response to the SIA and the recommendations of the Nonprescription Drugs Advisory Committee, we undertook a review of the available safety data on the 16 sunscreen active ingredients included in the stayed sunscreen monograph to determine whether we should include these active ingredients in the final OTC sunscreen monograph. We also reviewed available data on other sunscreen issues, like dosage forms, SPF values and broad spectrum requirements. If finalized, this proposed rule would address the safety concerns described in the preamble.

B. Market Failure Requiring Federal Regulatory Action

This proposed rule, if finalized, would address the market failure arising from inadequate information on potential systemic health risks from frequent and long-term use of OTC sunscreen products. If using a sunscreen product active ingredient causes an immediate adverse reaction, like skin irritation, consumers would likely stop using sunscreen products containing that active ingredient and the market would adjust. An example of this market response is what occurred with the active ingredient PABA, which became widely associated with adverse skin reactions. Firms no longer market sunscreen products containing PABA; the market response to PABA was so strong that some firms have included “PABA-free” labeling on their sunscreen products. However, we expect that the market would have difficulty adjusting to adverse reactions associated with long-term use of sunscreen products because consumers may not associate the adverse reaction with use of the sunscreen product.

This proposed rule, if finalized, would also address the market failure arising from consumers’ incomplete information about the efficacy of sunscreen products across the entire range of the UVA spectrum. When consumers use a sunscreen product and get a sunburn, they

are likely to adjust their behavior by retreating indoors, using more sunscreen, or using a different sunscreen product. In this case, the market would adjust to provide sunscreen products with adequate protection against sunburn. However, consumers often expect their sunscreen products to protect them against longer-term effects like skin cancer and early skin aging, and not only against sunburn (Ref.6). Currently marketed sunscreen products may not protect against these harms. The market is less likely to adjust to failures of products to protect against these harms.

Finally, this proposed rule is a response to the mandate in the SIA to amend and finalize certain specified regulations concerning nonprescription sunscreen. We have reviewed currently available scientific information for sunscreen products and proposed an OTC sunscreen monograph that addresses outstanding safety and efficacy considerations.

C. Purpose of the Proposed Rule

a. Sunscreen Active Ingredients

After the Nonprescription Drugs Advisory Committee met to discuss sunscreen products, we established a new safety testing paradigm. We published a final guidance in 2016 (Ref. 7) that discusses the safety data we would require for additional OTC sunscreen active ingredients being evaluated under the SIA. Applying that approach to the 16 sunscreen active ingredients listed in the stayed sunscreen monograph, we concluded that we need data from the following studies or tests to decide whether sunscreen products containing each active ingredient could be GRASE:

- Human dermal irritation and sensitization studies
- Human dermal photosafety studies
- Human absorption studies/maximum usage trials (MUsT)
- Pediatric data (on a case-by-case basis)
- Dermal and systemic carcinogenicity studies
- Developmental and reproductive toxicity studies (DART)
- Toxicokinetics
- Postmarketing safety data

FDA scientists reviewed the available data in the clinical and non-clinical literature, data submissions to the monograph rulemaking, and adverse event reports for these 16 sunscreen active ingredients. We found enough data to conclude that the active ingredients titanium dioxide and zinc oxide are GRASE for use in sunscreen products and that trolamine salicylate and PABA are not GRASE for use in sunscreen products. We identified data gaps for the remaining 12 active ingredients, which are described in the preamble to the proposed rule.

As described in guidance (Ref. 7), we intend to exercise enforcement discretion with respect to the marketing of sunscreens containing the 16 active ingredients until the forthcoming final sunscreen monograph becomes effective. In this rulemaking, we propose that titanium dioxide and zinc oxide are GRASE for use in sunscreen products and that trolamine salicylate and PABA are not GRASE for use in sunscreen products. If the proposed rule were finalized as proposed, firms could therefore continue to market sunscreen products containing titanium

dioxide and zinc oxide, but we would require that firms discontinue marketing, reformulate, or seek approval of sunscreen products containing trolamine salicylate or PABA.

We propose that we do not have enough information to make a positive GRASE determination for the remaining 12 sunscreen active ingredients and therefore request that manufacturers or others submit safety data on these 12 active ingredients. The actions we take in the final rule on these active ingredients would depend on the data we receive in response to this proposed rule. For example, if we receive data supporting a positive GRASE determination for an active ingredient in response to the proposed rule, then, in the final rule, we would conclude that sunscreen products containing that active ingredient are GRASE and not misbranded, meaning that firms would be able to continue marketing sunscreen products containing the active ingredient.

Alternatively, if we receive data showing that we cannot consider sunscreen products containing a particular active ingredient to be GRASE, or if we do not receive sufficient data to support the safety of an active ingredient, then, in the final rule, we would conclude that sunscreen products containing that active ingredient are not GRASE. Following the publication of the final rule, we would require that firms discontinue marketing sunscreen products containing such active ingredients, reformulate their sunscreen products to avoid using those active ingredients, or seek approval of these sunscreen products.

By requesting additional data on the systemic effects of sunscreen active ingredients, including carcinogenicity and developmental toxicity studies, and by proposing that active ingredients with remaining safety questions not be included in a final sunscreen monograph, we would address the failure of the market for sunscreen products to adjust to the possible long-term health effects of sunscreen use.

b. Sunscreen Labeling

We also propose to update sunscreen labeling standards to ensure that labeling of sunscreen products clearly and accurately communicates safety and effectiveness information to consumers. First, the proposed rule, if finalized, would create standard formats for the PDP to make the labeling of sunscreen products consistent. The proposed rule includes type size, font type, and text alignment requirements for PDPs, and, consistent with other already applicable requirements, requires that firms include a statement of identity (SOI) as one of the major features of a PDP. An SOI would consist of a list of the sunscreen's active ingredients in alphabetical order, the word "sunscreen", and the dosage form. For example, the statement of identity for a sunscreen lotion containing titanium dioxide and zinc oxide would be "Titanium Dioxide, Zinc Oxide Sunscreen Lotion."

If finalized, the proposed rule would also standardize SPF labeling by creating SPF labeling ranges for sunscreen products with an SPF of 15 and above. Table 6 describes these SPF labeling ranges.

Table 6. Proposed SPF Labeling Ranges

Labeled SPF Value	Range of Determined SPF Values
15	15 to 19
20	20 to 24
25	25 to 29

30	30 to 39
40	40 to 49
50	50 to 59
60+	60 to 80

We also propose to introduce a maximum permitted labeled SPF value for sunscreen products. We would increase the maximum labeled SPF value to "SPF 60+" (from SPF 30+ in the stayed final monograph and SPF 50+ in our 2011 proposed rule on this topic). The proposed rule, if finalized, would also cap the determined SPF at 80 in sunscreen products. We would require that firms discontinue, reformulate, or seek NDA approval for any sunscreen product with a determined SPF above 80.

The proposed rule contains new broad spectrum requirements, described in Table 3, that, if finalized, would help to correct the market failure arising from incomplete information about protection against skin cancer and early skin aging. It would do so by requiring improved UVA protection in most sunscreen monograph products and better aligning products with consumer expectations about the protections provided by those products.

We also propose that all sunscreen products with an SPF of 15 and above meet the new broad spectrum requirements. We would require that firms discontinue marketing, reformulate, or seek approval for any sunscreen products with an SPF of 15 or above that would not meet the new broad spectrum requirements. We would also require that manufacturers asterisk the SPF and include the phrase "*See Skin Cancer/Skin Aging Alert" on the PDP of all sunscreen products with an SPF below 15.

c. Other Considerations

The proposed rule, if finalized, would revise and further clarify our expectations for sunscreen testing entities. The proposed rule would clarify that final formulation testing constitutes the "manufacture" of a drug. Therefore, manufacturers must test sunscreen products in an establishment that follows all applicable registration, recordkeeping, and current good manufacturing practices requirements. We expect that the proposed rule, if finalized, would increase compliance with these existing requirements among testing entities. We also propose to require that both testing entities and responsible persons maintain records of the final formulation testing they conduct or that is conducted on their behalf. Finally, the proposed rule includes provisions that aim to ensure the protection of human subjects in clinical final formulation testing. For example, the proposed rule would require oversight by a registered institutional review board, informed consent, and adequate monitoring of personnel.

In 2011, we identified the dosage forms that we considered eligible and ineligible for inclusion in the sunscreen monograph. At that time, we stated that sunscreen sprays were eligible but required further data to be determined GRASE and that sunscreen powders were not eligible for the monograph. In the current proposed rule, if finalized, powders would be eligible for the monograph, but we believe we need additional information before a we can make a positive GRASE determination. Sunscreen sprays would be GRASE, subject to certain requirements necessary to minimize potential risks from unintended inhalation and flammability.

These requirements for sunscreen sprays include particle size, flammability and drying time testing. We would require firms to discontinue, reformulate, or seek approval for any sunscreen sprays that meet a regulatory definition of "extremely flammable," that do not meet the proposed particle size restrictions, or that meet the definition of "flammable" or "combustible" and take 10 minutes or more to dry. The proposed rule also includes a requirement that firms use appropriate flammability labeling for any sunscreen sprays that meet a regulatory definition of "combustible" or "flammable." We would also require firms whose sunscreen products meet that definition of combustible or flammable to conduct drying time testing. The drying time labeling requirement for combustible or flammable monograph sunscreen sprays would depend on the results of drying time testing.

We reviewed the available data on insect repellent and sunscreen combinations. We propose that these products are not GRASE and would require that firms discontinue or seek approval for any insect repellent and sunscreen combinations.

The proposed rule contains other provisions that do not affect our analysis; we do not discuss them in this document. The preamble to this proposed rule describes all the provisions of the proposed rule in detail.

D. Baseline Conditions

1. Sunscreen Market

In our analysis, we use the sunscreen market in 2016 to characterize the baseline sunscreen market. We combined information from our drug registration and listing data with Information Resources, Incorporated (IRI) retail sales scanner data, Euromonitor sales data, and an in-depth internet search. In the technical appendix, we discuss in detail the methods and assumptions used to develop our market size and consumption estimates (Ref. 1). Also, you may refer to Table 3 for some of the key terms we use in this section. We request comments on all assumptions used to characterize the baseline sunscreen market.

In Table 7, we estimate the total number of branded and private label formulations, products, brands, and manufacturers in the sunscreen market. We identified 7,485 branded formulations on the market, representing 3,563 products from 1,129 product lines and 741 different brands.

To characterize the private label sunscreen market, we collected product and ingredient information on 25 private label brands from internet searches. However, based on the number of private label brands available in retail stores, we expect there are many more private label brands on the market. Moreover, IRI aggregates private label scanner data. We are therefore unable to characterize every private label sunscreen product. Instead, we use the characteristics of sunscreens in our private label sample to extrapolate to the characteristics of all private label sunscreens.

We use 2014 Universal Product Code (UPC)-level scanner data from IRI to develop a weight for each private label product in our sample. Private label UPCs account for 6.9 percent

of all UPCs in product categories[7] that may include products with sunscreen claims. To calculate the number of private label formulations, we assume that the 7,485 branded formulations represent 93.1 percent of the sunscreen market based on the scanner data. Thus, we would expect a total of 8,036 formulations inc the sunscreen market, including 551 private label formulations. Because we only identify 449 private label formulations in our product search, we weight our private label products so that each private label formulation in our sample represents 1.23 formulations (551 population private label formulations ÷ 449 sample private label formulations).

We found a total of 443 manufacturers of sunscreen products, with 22 manufacturers making both branded and private label sunscreen products. However, some manufacturers produce sunscreen products for multiple firms. In total, based on FDA registration and listing and Dun and Bradstreet data, we estimate that 902 firms market sunscreen products. For each formulation, we know the active ingredients, the SPF and broad spectrum information on the label, the dosage form, whether the product is a combination sunscreen-insect repellent, and the estimated consumption of that formulation.

Table 7. Number of Branded and Private Label Formulations, Products, Product Lines, Brands, Manufacturers, and Firms

	Branded	Private Label Sample	Private Label Population	Total [1]
Formulations	7,485	449	551	8,036
Products	3,563	420	515	4,078
Product Lines	1,129	48	59	1,188
Brands	741	25	31	772
Manufacturers	434	25	31	443
Firms	873	49	60	902

[1] We calculate totals as the sum of branded and private label population estimates.

In Table 8, we estimate the total consumption of sunscreen products by product category in 2016. While sunscreen-only products account for most sunscreen consumption, consumers also use sunscreen products daily in the form of colorless cosmetic sunscreen products and color cosmetic sunscreen products. Consumption of sunscreen products in 2016 ranged from about 1,080 million ounces to 1,743 million ounces.

Table 8. Estimated 2016 Consumption of Sunscreen Products by Category

Category	Formulations	Products	Product Lines	Consumption in 2016 (millions of ounces)		
				Lower Bound	Primary Estimate	Upper Bound
Sunscreen-Only	2,096	2,030	442	1,006.31	1,006.31	1,006.31
Colorless Cosmetic	1,104	1,081	404	69.36	381.47	693.58
Color Cosmetic	4,836	968	342	4.27	23.47	42.67
Total	8,036	4,078	1,188	1,079.94	1,411.25	1,742.55

[7] We used the following IRI product categories in our analysis: Sun Tan; Skin Care; Hand and Body Lotion; Facial Cosmetics; Eye Cosmetics; and Lip Cosmetics.

In Table 9, we estimate the number of products and annual consumption by active ingredient. Notably, we found no evidence that firms market sunscreen products containing the two active ingredients, PABA and trolamine salicylate, that we propose to designate as not GRASE because of affirmative evidence of safety risk. Most sunscreen formulations combine two or more of 8 active ingredients: avobenzone, homosalate, octocrylene, octinoxate, octisalate, oxybenzone, titanium dioxide, and zinc oxide. The most prevalent active ingredient on the market in terms of consumption is avobenzone.

Table 9. Number of Products and Annual Consumption by Active Ingredient

Active Ingredient	Products[a]	Estimated 2016 Consumption (millions of ounces)		
		Lower Bound[a]	Primary Estimate[a]	Upper Bound[a]
Avobenzone	1,641	841.65	1,040.21	1,238.77
Octisalate	1,791	756.53	971.33	1,186.13
Octocrylene	1,432	807.36	1,001.79	1,196.22
Homosalate	1,167	741.79	873.67	1,005.55
Oxybenzone	1,342	728.70	821.11	913.52
Octinoxate	1,940	168.52	304.42	440.32
Titanium Dioxide	1,427	114.49	173.71	232.93
Zinc Oxide	1,342	119.90	186.44	252.98
Ensulizole	88	5.58	25.61	45.64
Meradimate	20	2.63	14.10	25.58
Padimate O	31	11.16	11.47	11.79
Sulisobenzone	4	0.24	0.41	0.58
Aminobenzoic Acid (PABA)	0	0.00	0.00	0.00
Cinoxate	0	0.00	0.00	0.00
Dioxybenzone	0	0.00	0.00	0.00
Trolamine Salicylate	0	0.00	0.00	0.00

[a] If a product contains more than one active ingredient, then we include it in the number of products and the quantity consumed for all relevant rows.

The proposed rule, if finalized, would affect products with labeled SPFs above 60, including those with determined SPF values of 80 or above. Moreover, the proposed rule would affect products with an SPF of 15 or above that would not meet the new broad spectrum requirements and products with an SPF below 15 that make broad spectrum claims but would not meet the new broad spectrum requirements. Additionally, the proposed rule would affect sunscreen-insect repellent combinations, sunscreen sprays, and sunscreen powders. In Table 10, we estimate the number of products with these characteristics, and the annual consumption of such products.

Table 10. Number and Annual Consumption of Affected Products

Type of Sunscreen Product	Products	Estimated 2016 Consumption (millions of ounces)		
		Lower Bound	Primary Estimate	Upper Bound
Products containing ensulizole, meradimate, padimate O, or sulisobenzone	140	19.43	51.42	83.41

Products with labeled SPF between 60 and 80	88	109.36	110.52	111.68
Products with labeled SPF above 80	32	50.52	50.52	50.52
Products with SPF 15 and above that would not meet the new broad spectrum requirements	1,225	111.50	195.76	280.02
Products with SPF below 15 that make broad spectrum claims but would not meet the new broad spectrum requirements	20	5.82	6.03	6.24
Insect-repellent and sunscreen combinations	18	2.07	2.07	2.07
Spray dosage forms	520	384.39	384.70	385.00
Powder dosage forms	48	0.48	1.74	3.01

2. Assumptions about Data Submission

a. Active Ingredients Data Submission

In the preamble, we described the data gaps we have identified for 12 currently marketed active ingredients; as shown in Table 9, we have evidence that 2 of these 12 active ingredients are no longer marketed. Whether we would include an active ingredient in the final sunscreen monograph depends on:

- The data we receive on the active ingredient and
- Whether this data supports a positive GRASE determination for the active ingredient

In this prospective analysis, we do not know this information. Therefore, we must make assumptions about the types of data that we expect to receive and which active ingredients we would include in the final monograph.

For clarity, we consider one set of assumptions in our main analysis. Then, in the uncertainty analysis, we consider alternative sets of assumptions and their impacts on the benefits and costs of the proposed rule. The scenario in the main analysis is only one possible outcome, but we do not have enough information at this time to predict whether it reflects the most likely outcome of the proposed rule.

In our main analysis, we assume that we would only receive data for the 6 most prevalent active ingredients on the market: avobenzone, homosalate, octocrylene, octinoxate, octisalate, and oxybenzone (see Table 9). Approximately 88 percent of sunscreen consumption comes from products containing at least one of these active ingredients. Because of the high cost to reformulate the large number of affected products, we expect that firms have a strong incentive to provide us data on these active ingredients. We also assume that the data submitted for these active ingredients would demonstrate their safety for use in sunscreen products and, support a positive GRASE determination. Therefore, the final monograph would include 8 active ingredients: avobenzone, homosalate, octocrylene, octinoxate, octisalate, oxybenzone, titanium dioxide, and zinc oxide. We request comment on the assumptions in our main analysis.

Furthermore, we received comments from industry providing evidence that powder sunscreens are eligible for inclusion in the monograph, suggesting that firms also have incentives

to provide us safety and efficacy data on powder sunscreens. Therefore, we assume in our primary analysis that the final monograph would also include powder sunscreens.

We use the assumptions above throughout the main analysis. Then, we discuss three sets of alternative assumptions about the data we would receive for sunscreen active ingredients in the uncertainty section. First, we consider the scenario where firms submit data for only avobenzone and octocrylene and where that data supports a positive GRASE determination for those active ingredients. In this scenario, firms would incur lower ingredient testing costs, and the final monograph would include avobenzone, octocrylene, titanium dioxide, and zinc oxide only. Second, we consider the scenario where firms submit data for avobenzone, homosalate, octocrylene, octinoxate, octisalate, oxybenzone, and powder sunscreens, and where that data does not support a positive GRASE determination for those active ingredients or dosage forms. In this scenario, the final monograph would include titanium dioxide and zinc oxide only. Third, we consider the scenario where firms do not submit data for any active ingredients or dosage forms. In this scenario the final monograph would include titanium dioxide and zinc oxide only.

b. Deferrals

With a statutory timeline for publication of a final rule, some firms may need additional time to complete the necessary studies for active ingredients. In such cases, we would consider deferring action on an ingredient whose sponsors agree to submit the necessary data within a specified timeframe. Deferring action on a particular active ingredient could change the timeframe for a final decision on that active ingredient, however, we assume that deferring action would not change the overall outcome for the ingredient.

Some of the data that we believe we need to fill the data gaps for active ingredients involve studies that take several years to complete. Notably, carcinogenicity studies take two to three years, and may take up to 18 months thereafter to complete the full analysis. Therefore, throughout our main and uncertainty analyses, we assume that:

- If we receive data for an active ingredient, we would make a GRASE determination for that active ingredient 5 years after the publication of the final rule. This assumption implies that we would defer action on that active ingredient for 5 years.[8]
- If we do not receive data for an active ingredient or an adequate deferral request, we would make a GRASE determination for that active ingredient when the final rule publishes. This assumption implies that we would not defer action on that active ingredient.

A deferral would allow firms to distribute the costs of required studies over time. A deferral on a particular active ingredient or dosage form would also effectively make the compliance date for provisions related to that active ingredient or dosage form different from the compliance date for the rest of the proposed rule. It is possible that firms would need to reformulate products initially to comply with the proposed rule, and then reformulate products again after we make a GRASE determination for deferred active ingredients.

[8] In practice, we plan to defer action on an active ingredient for one year at a time. If the sponsor demonstrated that they were making progress after a year, then we expect to defer action for another year. When we refer to deferring action on an active ingredient, we mean deferring action one year at a time for five years.

In our main analysis, we assume that sponsors would consider many factors when deciding whether to conduct tests for the active ingredients used in their sunscreen products. We expect that sponsors would not commit resources to conduct the costly testing needed to submit data for an active ingredient unless they have a reasonable expectation that the data would support a positive GRASE determination for the active ingredient. In our uncertainty analysis, we relax this assumption, and consider the case where data submissions on deferred active ingredients and dosage forms do not support a positive GRASE determination, requiring a second round of reformulations after 5 years.

E. Benefits of the Proposed Rule

In our analysis of benefits and costs of the proposed rule, we assume that some firms may choose to discontinue sunscreen products rather than incur the costs to relabel or reformulate the products. Consumers of discontinued products could respond to the proposed rule by switching to alternative sunscreen products. Consumers of discontinued products could also stop using sunscreen products. Throughout our analysis, in our upper bound estimates, we assume that firms discontinue insect repellent and sunscreen combinations and sunscreens with an SPF above 80, and that consumers of these products switch to alternative sunscreen products.

To capture possible product discontinuation in our lower bound, we assume that firms also discontinue colorless cosmetic sunscreen products or color cosmetic sunscreen products in response to the proposed rule. While the proposed rule does not distinguish between cosmetic sunscreen products and sunscreen-only products, the market for cosmetic sunscreen products fundamentally differs from the market for sunscreen-only products. For cosmetic sunscreen products, like moisturizers and facial makeup, there are sunscreen-free alternative cosmetic products. In many cases, consumers would switch from a cosmetic sunscreen product to a sunscreen-free cosmetic product marketed by the same firm, allowing that firm to retain its market share if they discontinue the sunscreen product. In this case, consumers of discontinued cosmetic sunscreen products might stop using sunscreen products. For the lower bound estimates, we assume that consumers of discontinued cosmetic sunscreen products stop using sunscreen products.

1. Benefits of Active Ingredient Testing

We assume that we would not receive safety data for some active ingredients. Without submission of needed data, we would consider these active ingredients not GRASE for use in sunscreen products, and manufacturers could no longer include them in marketed sunscreen formulations without first obtaining approval of a new drug application. To the extent that these active ingredients represent a health risk to consumers, the proposed rule, if finalized, would benefit public health by removing these ingredients from the sunscreen market. We call these active ingredients "active ingredients about which safety questions remain." We do not know if these active ingredients pose health risks to consumers.

In this section, we estimate the average consumer's annual exposure to active ingredients about which safety questions remain. Without data on the magnitude of the health risks of these

active ingredients, we cannot monetize the potential benefits from reduced exposure to these active ingredients.

We assume that we would not receive data for the 4 least prevalent active ingredients currently on the market [9]: meradimate, padimate O, ensulizole, and sulisobenzone. As illustrated in Table 9, the market share of sunscreens containing these active ingredients is very small. The total consumption of sunscreens containing at least one of these active ingredients represents approximately 4 percent of all sunscreen consumption, suggesting that firms have little incentive to submit data to us for these active ingredients. From Table 10, we estimate that consumers used between 19.43 million ounces and 83.41 million ounces of sunscreen products containing at least one of these four active ingredients in 2016. If the proposed rule is finalized, firms would discontinue or reformulate these products, and the use of sunscreen products would no longer expose consumers to active ingredients about which safety questions remain.

2. Benefits of Broad Spectrum Testing and Labeling

The proposed requirements for broad spectrum testing and SPF labeling would generate public health benefits for consumers. However, the benefits from these requirements depend on how manufacturers and consumers respond to the proposed rule, if finalized. In this section, we discuss the potential impact of broad spectrum testing and SPF labeling independent of the potential reformulation for active ingredients included in the previous section.

a. Benefits from Increased Use of Broad Spectrum Sunscreen

We expect that the proposed rule, if finalized, would both increase overall use of broad spectrum sunscreen products and increase the magnitude of UVA protection in existing broad spectrum sunscreens without requiring consumers to change their behavior. While a broad spectrum sunscreen product protects against UVA and UVB radiation, and this radiation is a known human carcinogen (Ref. 8), we do not have enough information about the incremental public health impact of adding broad spectrum protection to a sunscreen product on the risk of skin cancer. We ask for comments on the assumptions used in this section regarding the quantification of the public health benefits of adding broad spectrum protection to a sunscreen product.

1. Sunscreen Products with SPF 15 or Above that Would Not Meet the New Broad Spectrum Requirements

We would require that all sunscreen products with an SPF of 15 or above meet the new broad spectrum requirement. Manufacturers could respond to the rule by reformulating sunscreen products with an SPF of 15 or above that do not meet the new broad spectrum requirement. In this case, consumers who continue buying reformulated sunscreens that meet the new broad spectrum requirement would benefit from the improved UVA protection provided by these sunscreens. Alternatively, manufacturers could respond to the rule by removing from the market any sunscreen product with an SPF of 15 or above that would not meet the new broad spectrum requirement. In response, consumers of these products could purchase an alternative sunscreen

[9] From Table 10, firms do not currently market sunscreens containing two ingredients with data gaps: cinoxate and dioxybenzone. Removing these ingredients from the sunscreen monograph therefore creates no benefits or costs.

product with SPF 15 or above that meets the new broad spectrum requirements. They could also purchase an alternative sunscreen product with an SPF below 15 that may not meet the new broad spectrum requirements.

We cannot predict with certainty which sunscreen products would meet the new broad spectrum requirements. In the technical appendix, we describe how we use available data to predict which of these sunscreen products would meet the new broad spectrum requirements (Ref. 1). From Table 10, we estimate that, in 2016, consumers used between 111.50 million ounces and 280.02 million ounces of sunscreen products with an SPF of 15 or above that would not meet the new broad spectrum requirements. If we account for discontinued products, in 2016 consumers used between 92.38 million ounces and 280.02 million ounces of sunscreen products with an SPF of 15 or above that firms would reformulate to meet the new broad spectrum requirements.

2. Sunscreen Products with SPF Below 15 that Meet the Current Broad Spectrum Requirement but Would Not Meet the New Broad Spectrum Requirement

We expect that some sunscreen products with an SPF below 15 would meet the current broad spectrum requirement, but would not meet the new broad spectrum requirements. Manufacturers could respond to the rule by reformulating these products. Consumers who would continue buying the reformulated sunscreen product would benefit from increased use of sunscreen product with improved UVA protection.

Manufacturers could also respond to the rule by removing from the market sunscreen products with an SPF below 15 that meet the current broad spectrum requirement but would not meet the new broad spectrum requirement. Consumers could purchase an alternative sunscreen product that may or may not provide broad spectrum protection. Consumers of these sunscreen products could also choose not to purchase an alternative sunscreen.

Alternatively, manufacturers could respond to the rule by relabeling sunscreen products with an SPF below 15 that would not meet the new broad spectrum requirement. Consumers who continue buying these relabeled sunscreen products that would not meet the new broad spectrum requirements would not benefit from increased use of broad spectrum sunscreen products.

From Table 10, we estimate that, in 2016, consumers used between 5.81 million and 6.24 million ounces of sunscreen products with an SPF below 15 that meet the current broad spectrum requirement, but would not meet the new broad spectrum requirements. If we account for discontinued products, in 2016 consumers used between 5.78 million ounces and 6.24 million ounces of sunscreen products with an SPF below 15 that firms would reformulate to meet the new broad spectrum requirements.

In total, we estimate that in 2016 consumers used between 98.16 million ounces and 286.26 million onces of sunscreen products that firms would reformulate to meet the new broad spectrum requirements.

b. Benefits from Improved SPF Labeling

Consumers may change their behavior in response to the SPF labeling of sunscreen products. Consumers who expect higher sun protection with higher SPF values may stay in the

sun longer and apply less sunscreen (Refs. 9, 10). Some consumers may assume that a higher SPF value means that it is safe to stay in the sun for longer periods, leading to extended sun exposure (Ref. 6). Variability in SPF values is also greater at high SPFs (Refs. 11, 12).

By requiring manufacturers of sunscreen products with a determined SPF between 60 and 80 to use the label "SPF 60+" and to discontinue any products with a determined SPF above 80, the proposed rule, if finalized, would reflect the lack of data showing additional clinical benefit provided by sunscreens with determined SPF values above 60 and reflect the inherent variability in the clinical SPF test.

We expect consumers would benefit from SPF labeling that more accurately represents the sun protection that they would receive from their sunscreen products. For example, because of the variability of determined SPF values at high SPF levels, under current regulations a consumer could use a sunscreen product with an SPF 80 label that has determined SPF results that are much lower. In this case, the consumer might expect greater protection from sunburn, skin cancer, and early skin aging from the SPF 80 sunscreen product and stay in the sun for longer than they would if the sunscreen had a lower SPF value. Under the proposed rule, if finalized, this consumer would have more accurate information about the level of sun protection in the sunscreen product, which may minimize the extent to which they risk greater exposure based on perceived benefits of the SPF 80 label.

From Table 10, we estimate that, in 2016, consumers used between 159.88 million and 162.20 million ounces of sunscreen products with potentially misleading SPF values. Although we lack data to predict the degree to which consumers would change their sun exposure and sunscreen application patterns in response to the proposed rule, if the proposed rule were finalized, we expect consumers would benefit from reduced use of sunscreen products with potentially misleading SPF values. The complex relationship between sunscreen use and reduced health risks from lower sun exposure makes it difficult to estimate the public health benefit of this provision of the proposed rule.

3. Benefits from Avoided Severe Burns

Consumers have reported several adverse events related to the flammability of spray sunscreens. In 2013, we issued a consumer update in response to five reports of consumers suffering significant burns requiring hospitalization while wearing sunscreen sprays near sources of flame (Ref. 13). Flammability testing, drying time testing, flammability labeling, and other requirements would allow consumers to avoid such adverse events, making sunscreen sprays safer for consumers. Assuming that, on average, consumers would avoid between 0 and 2 significant burns requiring hospitalization annually as a result of the proposed rule, we estimate the benefits of the reduced flammability of spray sunscreens using a quality-adjusted life years approach.

In Table 11, we present the baseline health-realted quality of life by age and sex, based on estimates from Hanmer et al. (2006) (Ref. 14). From the 2015 National Health Interview Survey, 39.61 percent of sunscreen users are males and 60.39 percent are females. Therefore, to obtain the average baseline health-related quality of life for a sunscreen user of a given age, we average the health-related quality life by age for males and females, weighted by the percent of sunscreen users of each sex. Using these estimates and the probability of surving to age t

conditional on surviving to age $t-1$,[10] the representative sunscreen user[11] *without* a severe burn has between 17.63 and 18.11 remaining quality-adjusted life years at a 3 percent discount rate and between 11.05 and 11.31 remaining quality-adjusted life years at a 7 percent discount rate, assuming a maximum life expectancy of 100 years.

Table 11. Baseline Health-Related Quality of Life by Sex and Age

Age Range	Males			Females			Weighted Average		
	Lower Bound	Primary Estimate	Upper Bound	Lower Bound	Primary Estimate	Upper Bound	Lower Bound	Primary Estimate	Upper Bound
Less than 30	0.92	0.93	0.93	0.91	0.91	0.92	0.91	0.92	0.93
30 to 39	0.91	0.92	0.93	0.89	0.89	0.90	0.90	0.90	0.91
40 to 49	0.88	0.89	0.89	0.86	0.86	0.87	0.86	0.87	0.88
50 to 59	0.85	0.86	0.87	0.83	0.83	0.85	0.84	0.84	0.86
60 to 69	0.83	0.84	0.85	0.80	0.81	0.82	0.81	0.82	0.83
70 to 79	0.79	0.80	0.82	0.76	0.77	0.78	0.77	0.78	0.80
Greater than 79	0.76	0.78	0.81	0.70	0.72	0.75	0.72	0.75	0.77

Miller et al. (2013) measure the reductions in health-related quality of life from severe burns requiring admittance to a burn center (Ref. 17). Table 12 presents Miller et al.'s estimates of the reduction in health-related quality of life from severe burns over time. Based on these estimates, in contrast to the representative sunscreen user without a severe burn, the representative sunscreen user with a severe burn has between 15.42 and 17.07 remaining quality-adjusted life years at a 3 percent discount rate and between 9.64 and 10.63 remaining quality-adjusted life years at a 7 percent discount rate. Therefore, we estimate that a severe burn reduces a sunscreen user's quality-adjusted life years by between 1.04 and 2.21 quality-adjusted life years at a 3 percent discount rate and by between 0.68 and 1.42 quality-adjusted life years at a 7 percent discount rate.

Table 12. Reductions in Health-Related Quality of Life from Severe Burns over Time

Time Since Burn	Lower Bound	Primary Estimate	Upper Bound
0 years	13.4%	16.8%	20.2%
1 year	7.0%	10.4%	13.8%
2+ years	5.3%	8.7%	12.1%

We use estimates of the value per quality-adjusted life-year from the Department of Health and Human Services (HHS) guidelines (Ref. 3) to estimate the willingness-to-pay to avoid a severe burn. In 2019, the value per quality-adjusted life year ranges from $0.24 million

[10] Estimates of the probability of surviving to age t, conditional on surviving to age $t-1$ from Centers for Disease Control and Prevention (CDC) Life Tables (Ref. 15)

[11] From the 2015 National Health Interview Survey, the average age of an adult sunscreen user is 46 (Ref.16).

to $0.78 million at a 3 percent discount rate, with a primary estimate of $0.51 million and from $0.40 million to $1.30 million at a 7 percent discount rate, with a primary estimate of $0.85 million. The willingness-to-pay to avoid a severe burn equals the value per quality-adjusted life year times the reduction in the number of quality-adjusted life years due to a severe burn. That is, the willingness-to-pay to avoid a severe burn in a given year is the value of the decrease in quality-adjusted life years in that year. For example, the willingness-to-pay to avoid a severe burn in year 2019 ranges from $0.25 million to $1.72 million at a 3 percent discount rate and from $0.27 million to $1.84 million at a 7 percent discount rate.

In Table 13, we estimate the total benefits from avoided severe burns, assuming the proposed rule, if finalized, would prevent between 0 and 2 severe burns annually. These benefits would begin in year 1, one year after the final rule publishes. The annualized benefits from avoided severe burns would range from $0.00 million to $3.62 million at a 3 percent discount rate and from $0.00 million to $3.72 million at a 7 percent discount rate.

Table 13. Total Benefits from Avoided Severe Burns over 20 years ($ million)

Value	Lower Bound	Primary Estimate	Upper Bound
Present Discounted Value of Benefits (3%)	$0.00	$13.44	$55.45
Present Discounted Value of Benefits (7%)	$0.00	$10.28	$42.15
Annualized Value of Benefits (3%)	$0.00	$0.88	$3.62
Annualized Value of Benefits (7%)	$0.00	$0.91	$3.72

4. Benefits from Avoided Particle Inhalation

Both spray and powder sunscreens could pose health risks from consumer inhalation of small particles. The proposed rule would address these risks by requiring particle size testing of sunscreen sprays. We also assume that we would include sunscreen powders in the final monograph and that we would require particle size testing of sunscreen powders. These provisions of the proposed rule would allow consumers to avoid health risks from the inhalation of small particles. In the absence of data on which sunscreen sprays and powders pose health risks due to the inhalation of small particles, we assume that all existing spray and powders sunscreens currently pose inhalation risks. We estimate that consumers used between 384.86 million ounces and 388.02 million ounces of sunscreens that could pose health risks from the inhalation of small particles in 2016.

5. Other Benefits

a. Recordkeeping

The proposed rule, if finalized, would clarify the responsibilities of responsible persons and testing entities. Some responsible persons and testing entities could come into compliance with applicable existing regulations, like current good manufacturing practices, which are designed to ensure the identity, strength, quality, and purity of drug products. We expect that improved compliance with applicable existing regulations would improve health outcomes for consumers.

The proposed rule would create necessary recordkeeping requirements and clarify existing recordkeeping obligations for responsible persons and testing entities. Better

recordkeeping would allow FDA and manufacturers to more quickly address problems with sunscreen products, like adverse events. For example, we often require records of sunscreen testing data to allow us to identify the cause of a safety or efficacy concern when a problem with a sunscreen product arises. Recordkeeping requirements would enable us to collect and review testing data compiled by responsible persons and testing entities to identify the source of a problem. This would avoid the need for FDA to re-test products itself to monitor compliance with regulatory requirements. Accordingly, better recordkeeping would improve FDA's inspections of sunscreen manufacturers by allowing us to more easily verify that marketed sunscreen products provide the protection that their labels claim they provide, and this could potentially lead to safer and more effective products

The proposed rule also includes provisions that, if finalized, would help ensure the protection of human subjects enrolled in clinical final formulation testing by requiring, among other things, oversight by a registered institutional review board, informed consent, and adequate monitoring of study personnel. These provisions would benefit human subjects who participate in formulation studies and would improve the reliability of sunscreen testing. Approval from a registered IRB and informed consent would also help ensure that testing entities treat human subjects ethically.

We lack information about the current practices of testing entities and responsible persons. We also do not know how the proposed rule, if finalized, would change the behaviors or outcomes for consumers and firms. We request comment and data regarding the quantification of the benefits of the recordkeeping requirements in the proposed rule for consumers, responsible persons, and testing entities.

b. Sunscreen-Insect Repellent Combinations

We have tentatively determined that consumers cannot use sunscreen-insect repellent combinations safely and effectively as sunscreens. In the proposed rule, we would require manufacturers to remove sunscreen-insect repellent combinations from the market. The expected benefits of removing these products from the market depends on how consumers respond to the proposed rule.

We assume that most consumers using insect repellent and sunscreen combination products require protection from insect bites and protection from the sun. In response to the proposed rule, if finalized, we expect that these consumers would replace their insect repellent and sunscreen combination products with separate insect repellent and a sunscreen product. If these consumers use these separate products concurrently, as if they were a sunscreen-insect repellent combination product, then they could still experience the negative health effects of using insect repellents in combination with sunscreens. If these consumers follow the instructions for use of insect repellent and sunscreens, then they would avoid some of the negative health effects of using insect repellents in combination with sunscreens.

Additionally, consumers may value the convenience of insect repellent and sunscreen combinations. Substituting separate insect repellents and sunscreens for these products may generate negative benefits for consumers. We ask for comment about how consumers would respond to removing sunscreen-insect repellent combinations from the market, and the value of sunscreen-insect repellent combinations to consumers.

c. *Negative Benefits from Possible Reduced Sunscreen Use*

As discussed previously, we expect that firms would discontinue some products in response to the proposed rule. In our upper bound estimates, we assume that firms discontinue insect repellent and sunscreen combinations, and sunscreens with an SPF above 80, and that consumers of these products switch to alternative sunscreen products. In our lower bound estimates, we assume that firms also discontinue colorless cosmetic sunscreen products or color cosmetic sunscreen products, and consumers of discontinued products would stop use of sunscreen products.

If consumers of discontinued products stop using sunscreen products, consumption of sunscreen products could fall in response to the proposed rule. Thus, these consumers would receive higher doses of UV radiation from exposure to the sun, increasing their risk of negative health effects like sunburn, skin cancer, and early skin aging. Any negative health effects from reduced consumption of sunscreens would create negative benefits for these consumers.

6. Sunscreen Transaction Cost Savings

a. Effort to Choose a Sunscreen Product

Choosing a sunscreen product can be a complex task. For example, Kong et al. (2015) found consumers evaluate many product features when buying a sunscreen product (Ref. 6). They also found that more than half of the consumers surveyed responded that they read the back of the label before buying a sunscreen product. The proposed labeling could change the effort consumers spend to make their buying decisions for a sunscreen product by affecting the physical effort required to locate active ingredient or efficacy information on the product label and the mental effort required to process this information once they find it. Some consumers consider sunscreen active ingredients when choosing a sunscreen. In another study, Xu et al. (2016) evaluated consumer reviews of top sunscreen products on Amazon and found that 17 percent of the reviews discussed active ingredients as positive attributes of sunscreens whereas 10 percent of the reviews discussed active ingredients as negative attributes of sunscreens.

b. Physical Effort

Both Kong et al. and Xu et al. show that consumers may use some information on the front label of the sunscreen product, such as SPF, broad spectrum, and water resistance. The proposed labeling would standardize the size and format of this information and enhance its prominence, making it easier to compare across products.

Kong et al. and Xu et al. show that consumers may also compare active ingredient information on the back of sunscreen product labels. To compare active ingredients when shopping in brick-and-mortar stores, consumers must physically pick up and turn over multiple products. On the internet, active ingredient information may be even more difficult to locate and compare. In general, consumers must visit each product's individual webpage to find active ingredient information, and this information is often not easily accessible. Some consumers may only look at the back of sunscreen product labels to view active ingredient information.

We expect that the proposed rule, if finalized, would reduce the physical effort required to choose a sunscreen product by standardizing the size and format of efficacy information,

creating time savings for consumers who consider efficacy information on the PDP when choosing a sunscreen. The proposed rule would also reduce the physical effort required to choose a sunscreen product by adding active ingredients to the PDP on the front of the container or package, creating time savings for consumers who only look at the back of sunscreen product labels to view active ingredient information. Finally, the proposed rule would require that that firms provide the dosage form of sunscreen products in a standard location on the PDP, creating time savings for consumer who consider dosage form information when choosing a sunscreen. These labeling changes would make it easier for consumers to compare sunscreen products by reducing the physical effort needed to choose a sunscreen product.

3. Mental Effort

Once consumers find information on the features of sunscreen products, they must spend mental effort to process the information and make a buying decision. We apply Sweller's cognitive load theory (Ref. 19) to predict how this mental effort could change in response to redesigned sunscreen product labels. When people use their knowledge to solve problems, they rely on their long-term memory. When faced with new information, people use their "working" memory, which has a limited capacity. Because of this limited capacity, high demands on working memory affect the quality of decision making and the time needed to solve complex problems. However, as people learn, they store information in their long-term memory, and decision making becomes more efficient.

Wilson and Wolf (2009) reviewed the literature on cognitive load in health communications, and propose that well-designed health communications make the information that is most relevant to the consumer clear and easily understood, while minimizing distracting information (Ref. 20). Kong et al. found that many consumers use information such as SPF, water resistance, and broad spectrum statements to choose a sunscreen product. The proposed type size and text alignment standards would make this information more prominent on sunscreen labels and more easily comparable across multiple sunscreens. In this way, the proposed rule, if finalized, would reduce the mental effort required to choose a sunscreen.

For consumers who are unfamiliar with sunscreen active ingredients, the proposed labeling changes could also increase the mental effort required to buy a sunscreen product. Under current regulations, active ingredient information is limited to the Drug Facts panel on the back of the sunscreen product. Kong et al. (2015) found that 20.9% of their sample never looked at the Drug Facts panel (Ref. 6). Including the active ingredients on the principal display panel could cause some consumers to look at active ingredient information for the first time. Such consumers could respond to this information in different ways.

Some consumers would ignore the active ingredient information. In this case, the consumer would not read or process the active ingredient information. We expect that these consumers would not spend any additional mental effort to make their buying decision.

Some consumers would read the active ingredient information, but choose not to incorporate it into their buying decision. In this case, the consumer would need to read and process the information. We expect that these consumers would spend some mental effort and take more time to make their decision. However, when buying sunscreen products in the future, these consumers might ignore the active ingredient information, reducing their mental effort.

Some consumers might read the active ingredient information and incorporate it into their sunscreen product choice. In this case, these consumers would need to read and process the information. Adding an additional product feature would make their sunscreen product buying decisions more complex and increase the mental effort required to make their decisions. However, we expect that over time consumers could learn more about sunscreen active ingredients and store this learned information in long-term memory as knowledge. Therefore, we expect that the increase in mental effort could fall over time.

c. Time to Choose a Sunscreen

Physical and mental effort both affect the time it takes to choose a sunscreen product and, consequently, sunscreen transaction costs. When physical or mental effort increases, it takes consumers more time to choose a sunscreen product, and sunscreen transaction costs increase. When physical or mental effort decrease, it takes consumers less time to choose a sunscreen product, and sunscreen transaction costs decrease.

While we expect that the physical effort to choose a sunscreen product would decrease in response to the proposed rule, we lack data to estimate the magnitude of this effect. In the regulatory impact analysis for the 1999 final rule establishing the Drug Facts panel, we assumed that the Drug Facts panel would save consumers 10 seconds each time they choose an over-the-counter drug product (Ref. 21). We ask for comment on whether our previous estimate of 10 seconds could serve as a proxy for the physical effort saved by the proposed sunscreen labeling.

We also lack data to estimate how the average consumer's mental effort would change in response to the redesigned sunscreen labels. We expect that the proposed rule, if finalized, could initially increase the mental effort required to make the buying decision for a sunscreen product. But, following cognitive load theory, we expect that the incremental change in the mental effort required to make a buying decision would fall over time. We ask for comment on how much time the changes to sunscreen labeling would cost consumers each time they buy a sunscreen due to changes in the mental effort required to choose a sunscreen.

To support the quantification of these cost savings, we specifically request experimental data on how much time consumers currently spend reading the sunscreen labeling in comparison to how much time consumers would spend reading the proposed sunscreen product labeling. We also ask for any quantified evidence of the change over time in the physical and mental effort required to purchase a sunscreen.

7. Summary of Benefits

The average consumer would benefit from increased use of sunscreen products with better protection from UVA radiation, reduced exposure to active ingredients about which safety questions remain, reduced use of sunscreen products with potentially misleading SPF values, reduced flammability of spray sunscreens, reduced particle inhalation from spray and powder sunscreens, and transaction cost savings. We also expect benefits from ingredient testing and recordkeeping by responsible persons and testing entities. We request comment on our estimates and on any potential benefits of the proposed rule not discussed in this analysis.

In Table 14, we summarize the total annual quantified benefits of the proposed rule, represented by the 2016 consumption of sunscreens. These benefits may overlap for individual consumers. For example, a consumer may use a sunscreen with both improved broad spectrum protection and less misleading SPF values.

Table 14. Annual Quantified Benefits of the Proposed Rule (millions of ounces)

Type of Benefit	Lower Bound	Primary Estimate	Upper Bound
Increased use of products with improved UVA protection	98.16	201.79	286.26
Less exposure to sunscreens containing active ingredients about which safety questions remain	19.43	51.42	83.41
Less exposure to sunscreens with potentially misleading sun protection information	159.88	161.04	162.20
Less exposure to spray and powder sunscreens posing inhalation risks	384.39	384.70	385.00

In Table 15, we estimate the total annualized monetized benefits of the proposed rule, if finalized, over 20 years. Annualized monetized benefits range from $0.00 million to $3.64 million at a 3 percent discount rate and from $0.00 million to $3.72 million at a 7 percent discount rate.

Table 15. Annualized Benefits of the Proposed Rule over 20 Years ($ millions)

	Lower Bound (3%)	Primary Estimate (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary Estimate (7%)	Upper Bound (7%)
Avoided Severe Burns	$0.00	$0.88	$3.62	$0.00	$0.91	$3.72
Total Benefits	$0.00	$0.88	$3.62	$0.00	$0.91	$3.72

F. Costs of the Proposed Rule

1. Administrative Costs

We expect that firms would incur administrative costs to read and understand the rule. Based on average read speed and the length of the preamble, we assume that employees in management positions would spend between 4.8 and 24 hours reading and understanding the rule per firm at a fully loaded wage of $142.12 per hour for employees in management positions (Table 4). We also assume that all 902 firms involved in the marketing of sunscreen products would need to read and understand the proposed rule. The cost to read and understand the rule would range from $682 per firm to $3,411 per firm.

We also expect that all 443 manufacturers would incur costs to update their manufacturing standard operating procedures (SOPs) in response to the proposed rule, if finalized. Using information from the Eastern Research Group (Ref. 22), we assume that employees in management positions would spend between 2.25 and 60 hours updating SOPs and that managerial clerks or assistants would spend between 0.75 and 20 hours updating SOPs, where the fully loaded labor cost is $142.12 for managers and $51.50 for managerial clerks or

assistants in 2019. The cost to update manufacturing SOPs would range from $358 to $9,557 per manufacturer.

The one-time cost to read and understand the proposed rule would range from $0.62 million to $3.08 million. The one-time costs to update manufacturing SOPs would range from $0.16 million to $4.23 million. The total, one-time administrative costs of the proposed rule would range from $0.77 million to $3.31 million. We expect that firms would incur these costs in year 0, the year the final rule publishes. The annualized administrative costs of the proposed rule, if finalized, would range from $0.05 million to $0.48 million at a 3 percent discount rate and from $0.07 million to $0.64 million at a 7 percent discount rate.

2. Cost to Fill Data Gaps for Active Ingredients and Powder Sunscreens

a. Cost to Fill Data Gaps for Active Ingredients

In Table 18, we estimate the costs of conducting the testing needed to fill the data gaps described in the preamble for each active ingredient. We expect that the total cost to conduct a test for an active ingredient includes the cost of the test itself and a coordination cost; we assume that the coordination increases the testing cost from 5 percent to 15 percent. We request comment on this assumption. The coordination costs includes costs for firms to coordinate with each other, and costs for firms to coordinate with FDA. Because of this coordination, we assume that we receive one set of data for each active ingredient in the data submission scenario.

Table 16. Costs of Safety Testing Studies per Active Ingredient ($)

Type of Test	Testing Cost			Coordination Cost			Total Cost		
	Lower Bound	Primary Estimate	Upper Bound	Lower Bound	Primary Estimate	Upper Bound	Lower Bound	Primary Estimate	Upper Bound
Irritation and Sensitization[a]	$5,281	$10,884	$16,486	$264	$1,088	$2,473	$5,545	$11,972	$18,959
Photosafety Studies[b]	$26,893	$47,062	$67,232	$1,345	$4,706	$10,085	$28,237	$51,769	$77,317
MUsT[a]	$182,931	$182,931	$182,931	$9,147	$18,293	$27,440	$192,078	$201,225	$210,371
Pediatric Studies[c]	$182,931	$182,931	$182,931	$9,147	$18,293	$27,440	$192,078	$201,225	$210,371
Dermal Carcinogenicity[d]	$1,832,440	$2,036,044	$2,239,649	$91,622	$203,604	$335,947	$1,924,062	$2,239,649	$2,575,596
Systemic Carcinogenicity[d]	$1,628,835	$1,679,736	$1,730,638	$81,442	$167,974	$259,596	$1,710,277	$1,847,710	$1,990,233
DART Studies[d]	$848,618	$914,143	$979,668	$42,431	$91,414	$146,950	$891,049	$1,005,557	$1,126,618
Toxicokinetics[d]	$81,442	$97,221	$113,000	$4,072	$9,722	$16,950	$85,514	$106,943	$129,951

[a] Source: Environmental Protection Agency (Refs. 23,24)

[b] Source: Eastern Research Group (Ref. 22)

[c] We assume that cost of pediatric studies is the same as the cost of a MUsT.

[d] Source: Expert elicitation of a contract research organization

We assume that firms would conduct all types of tests for homosalate, octocrylene, octinoxate, and octisalate. For avobenzone, we assume that firms would conduct all types of tests except for irritation, sensitization, and photosafety. For oxybenzone, we assume that firms would conduct all types of tests except sensitization and irritation. These scenarios assume that the MUsTs for these ingredients produce results that necessitate further studies. The total costs of conducting safety testing in this scenario range from $30.11 million to $37.84 million.

We assume that we would defer action on these six active ingredients for five years. Deferring action distributes the testing cost over time. As a result, firms would incur annual testing costs for five years, from years 0 to 4. Assuming that one-time costs are evenly distributed over 5 years, the annual costs of conducting safety testing range from $6.02 million to $7.57 million.

b. Cost to Fill Data Gaps for Powder Sunscreens

To make a GRASE determination for powder sunscreens, we require more information, like information about how consumers use powder sunscreens and information about effectiveness testing of powder sunscreens. We do not expect that providing this information would require firms to conduct additional safety testing for powder sunscreens. We expect that firms already have this information available for currently marketed products. Therefore, firms would incur administrative and coordination costs to gather information about powder sunscreens.

We assume that it would take between 15 and 25 hours to compile the information needed to support a GRASE determination for powder sunscreens and 5 hours for firms to coordinate the submission of this information. Using the fully loaded wage for medical scientists from Table 4, the administrative cost to submit information about powder sunscreens would range from $1,826 (20 hours × $91.28 per hour) to $2,738 (30 hours × $91.28 per hour). We assume that firms would incur these costs in year 0. We request comment on the availability of this data, and the time required to compile and submit the data to us.

The total annualized cost to fill data gaps for active ingredients and powder sunscreens would range from $1.85 million to $2.33 million at a 3 percent discount rate and from $2.33 to $2.93 million at a 7 percent discount rate.

3. Relabeling and Reformulation Costs

a. Relabeling Costs

If the proposed rule is finalized, we expect that firms would need to relabel products for multiple reasons. Based on our review of the labels of sunscreen products on the market, we expect firms to relabel all products that would remain on the market. In Table 17, we estimate the number of products and product lines by sunscreen category, excluding any insect repellent and sunscreen combinations, and any sunscreens with an SPF above 80.

Table 17. Relabeled Products and Product Lines by Product Category

Product Category	Products	Product Lines
Sunscreen-Only	1,979	435
Colorless Cosmetic	1,081	404

Color Cosmetic	968	342
Total[a]	4,028	1,181

[a]We expect that firms would discontinue 50 products (4,078 total products from Table 7 – 4,028 relabeled products) and 7 product-lines (1,188 total product-lines from Table 7 – 1,181 relabeled product-lines).

Using the number of relabeled products likely overestimates the number of relabeled units. First, many brands use similar labels for similar products that vary only in SPF value; we consider these products within a single product-line. For example, the label of Coppertone Sport SPF 30 is nearly identical to the label of Coppertone Sport SPF 50. Some relabeling costs, like analytical testing and market testing, would overlap for such products. Therefore, we expect firms would incur relabeling costs only once for such products. Second, some firms may choose to discontinue sunscreen products rather than relabeling the products. We expect that firms are more likely to discontinue colorless cosmetic sunscreen products or color cosmetic sunscreen products than sunscreen-only products. To capture the range in the number of relabeled units, we use the number of products (4,028) as our upper bound number of relabeled units, the number of product-lines (1,181) as our primary estimate, and the number of sunscreen-only product-lines (435) as our lower bound.

To estimate the per unit costs, we use a model developed by the Research Triangle Institute (Ref. 25), which estimates the relabeling cost using the cost of labor, materials, analytical testing, market testing, and discarded inventory per stock keeping unit (SKU). Because the proposed rule, if finalized, would require multiple changes, the model predicts that firms could not coordinate the required labeling changes for 100 percent of SKUs into their regularly scheduled labeling changes. In the relabeling cost model, the cost per relabeled unit ranges from $14,944 to $36,197. Given our estimates of the number of relabeled units and the cost per relabeled unit, the one-time relabeling costs range from $6.50 million to $145.80 million. The annualized costs would range from $0.41 million to $9.24 million at a 3 percent discount rate and from $0.54 million to $12.02 million at a 7 percent discount rate. We request comment on any other potential costs of relabeling sunscreen products in response to the proposed rule.

Complying with the new requirements for sunscreen labeling may require manufacturers to make other marketing claims on product labeling less prominent. Manufacturers and consumers may value this information. We request comment on the costs to manufacturers and consumers of reducing the prominence of marketing claims on sunscreen labeling.

b. Reformulation Costs

Under the proposed rule, if finalized, we expect that firms would reformulate products for three reasons[12]. First, firms would reformulate any product that includes an active ingredient not included in the final sunscreen monograph. Second, firms would reformulate some products to meet the new broad spectrum requirements. Third, firms would reformulate some spray sunscreen products and some powder sunscreen products based on flammability test results or

[12] Firms could also reformulate products with a determined SPF above 80. However, most firms marketing sunscreen products with an SPF above 80 sell a product in the same product-line that would use the SPF 60+ label. Therefore, we expect that most firms would remove these products from the market rather than reformulating.

particle size test results. We do not have adequate information to estimate which sunscreen spray products or powder sunscreen products would not meet the new flammability or particle size requirements. Therefore, we conservatively assume that firms would reformulate all sunscreen sprays and powders in response to the proposed rule. We estimate that firms would reformulate 1,750 products (Table 18).

Table 18. Reformulated Branded and Private Label Products by Product Category

Product Category	Branded [1]	Private Label Sample	Total Sample	Private Label Population	Total Population
Sunscreen-Only	605	137	742	168	773
Colorless Cosmetic	340	21	361	26	366
Color Cosmetic	587	20	607	25	612
Total	1,532	178	1,710	218	1,750

[1] Our sample of branded products equals the population of branded products.

However, using the total number of reformulated products likely overestimates the number of reformulated units. First, contract manufacturers produce many sunscreen products, and may sell these products to multiple entities. These products would appear as unique products in our data, but would represent a single reformulation. Second, some firms may choose to discontinue sunscreen products rather than reformulate. Similar to relabeling, we expect that firms would more likely discontinue colorless cosmetic sunscreen products or color cosmetic sunscreen products than sunscreen-only products.

To capture the range of reformulated units, we use the number of reformulated products (1,750) as the upper bound. We use the number of sunscreen products in our sample as the primary estimate (1,710). For this estimate, we do not account for any private label products that are not in our sample. By using the sample number of sunscreen products, we assume that any private label products not in our sample are duplicate formulations to the products in our sample. Finally, we use the number of sunscreen-only products in our sample (742) as the lower bound.

Using a report by the Eastern Research Group (Ref. 22), we estimate that reformulating a single unit costs between $182,917 and $361,198. The total one-time reformulation costs range from $135.72 million to $632.24 million. The annualized reformulation costs would range from $8.60 million to $40.06 million at a 3 percent discount rate and from $11.19 million to $52.13 million at a 7 percent discount rate.

4. Other Costs

a. Testing and Recordkeeping

In a 2010 report, the Eastern Research Group estimated that there are between 6 and 10 entities conducting SPF, broad spectrum, and water resistance testing in the market for sunscreen products (Ref. 22). We expect that some currently noncompliant responsible persons and testing entities would begin to comply with existing regulatory requirements that apply to their operations. The cost to comply with existing requirements would include the cost to register each establishment engaged in manufacturing and list their products. It could also include the costs to comply with applicable current good manufacturing practices, equipment maintenance standards.

Firms could also incur costs from the new requirements in the proposed rule, if finalized. Testing entities could incur costs to obtain approval from a registered IRB for clinical final formulation testing. The costs of obtaining IRB approval include the costs to develop procedures to ensure that testing meets IRB standards and the direct cost of submitting a study for IRB review. Responsible persons and testing entities could also incur costs to obtain required information from investigators and adequately monitor personnel. Finally, responsible persons and testing entities and could incur costs to retain records of sunscreen testing.

While we are aware that not all responsible persons and testing entities currently meet the requirements put forth in the proposed rule, we do not have enough information about current practices to estimate these costs. We request data and comments to help us estimate the costs of complying with the revised testing and recordkeeping requirements for responsible persons and testing entities, including minor modifications to testing protocols.

b. Testing of Spray and Powder Sunscreens

Assuming that we include powder sunscreens in the final monograph, manufacturers of spray and powder sunscreen products marketed under the monograph would need to perform particle size testing. Manufacturers of spray sunscreens marketed under the monograph would also need to perform flammability testing and, for certain sprays, drying time testing.

Table 19 shows the number of spray and powder sunscreens in the market, excluding any insect repellent and sunscreen combinations and any sunscreens with an SPF above 80. We estimate that 567 sunscreen sprays and 48 sunscreen powders would require testing to remain on the market.

Table 19. Branded and Private Label Spray and Powder Sunscreens by Product Category

Dosage Form	Product Category	Branded	Private Label Sample	Total Sample	Private Label Population	Total Population
Spray	Sunscreen-Only	348	116	464	142	490
	Colorless Cosmetic	7	0	7	0	7
	Color Cosmetic	0	0	0	0	0
	Total	355	116	471	142	497
Powder	Sunscreen-Only	2	0	2	0	2
	Colorless Cosmetic	4	0	4	0	4
	Color Cosmetic	42	0	42	0	42
	Total	48	0	48	0	48
Total	Sunscreen-Only	350	116	466	142	492
	Colorless Cosmetic	11	0	11	0	11
	Color Cosmetic	42	0	42	0	42
	Total	403	116	519	142	545

However, using the total number of spray and powder sunscreens products likely overestimates the number of tested units. First, contract manufacturers produce many sunscreen products, and may sell these products to multiple entities. These products would appear as

unique products in our data, but would represent a single tested unit. Second, some firms may choose to discontinue sunscreen products rather than conduct particle size, flammability, or drying time testing. As with relabeling and reformulating, we expect that firms would more likely discontinue colorless cosmetic sunscreen products or color cosmetic sunscreen products than sunscreen-only products.

To capture the range of tested spray units, we use the number of spray products (497) as the upper bound. We use the number of sunscreen products in our sample as the primary estimate (471). For this estimate, we do not account for any private label products that are not in our sample. By using the sample number of sunscreen products, we assume that any private label products not in our sample are duplicate formulations to the products in our sample. Finally, we use the number of sunscreen-only products in our sample (464) as the lower bound.

To capture the range of tested powder units, we use the number of powder products (48) as the upper bound. We use the number of sunscreen products in our sample as the primary estimate (48). For this estimate, we do not account for any private label products that are not in our sample. By using the sample number of sunscreen products, we assume that any private label products not in our sample are duplicate formulations to the products in our sample. Finally, we use the number of sunscreen-only products in our sample (2) as the lower bound.

Manufacturers of monograph spray and powder sunscreens would perform particle size testing on each lot of a spray or powder sunscreen to ensure those lots meet new particle size standards. Using information from the EPA, we estimate that particle size testing costs $1,697 per lot (Ref. 26), and that this cost includes the cost of sampling the lot. We assume that manufacturers release between 1 and 5 lots of each product annually. We request comment on this assumption. The annual cost of particle size testing for spray sunscreens would range from $0.79 million to $4.22 million. These costs would begin in year 1. The annual cost of particle size testing for powder sunscreens would range from $0.00 million to $0.41 million. These costs would begin in year 5, after we make a final GRASE determination for powder sunscreens.

Under the proposed rule, if finalized, manufacturers of monograph spray sunscreens would perform flammability testing on each batch of a spray sunscreen. Based on an internet search of chemical testing laboratories, we expect that flammability testing would cost $860 per batch. We assume that manufacturers release between 1 and 5 batches of each product annually. We request comment on this assumption. The annual cost of flammability testing for spray sunscreens would range from $0.40 million to $2.14 million, and these costs would begin in year 1.

Finally, under the proposed rule, manufacturers of monograph sunscreens would perform drying time testing on each lot of a spray formulation that meets a regulatory definition of either “flammable or “combustible” when the flammability test is conducted. In the absence of data on the cost of drying time testing for sunscreen manufacturers, we assume that drying time testing costs the same as flammability testing. We request comment on this assumption. The annual cost of drying time testing for spray sunscreens would range from $0.40 million to $2.14 million, and these costs would begin in year 1.

The total annual testing costs would range from $1.49 million to $8.32 million. The annualized testing costs would range from $1.48 million to $9.34 million at a 3 percent discount rate and from $1.45 million to $9.09 million at a 7 percent discount rate.

5. Summary of Costs

In Table 20, we estimate the total annualized quantified costs of the proposed rule, if finalized, over 20 years. Annualized quantified costs range from $12.40 million to $60.42 million at a 3 percent discount rate and from $15.57 million to $75.84 million at a 7 percent discount rate.

Table 20. Annualized Costs of the Proposed Rule over 20 Years ($ millions)

Type of Cost	Lower Bound (3%)	Primary Estimate (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary Estimate (7%)	Upper Bound (7%)
Administrative Costs	$0.05	$0.22	$0.48	$0.07	$0.29	$0.64
Costs to Fill Data Gaps	$1.85	$2.09	$2.33	$2.33	$2.62	$2.93
Relabeling Costs	$0.41	$1.85	$9.24	$0.54	$2.40	$12.02
Reformulation Costs	$8.60	$28.90	$40.06	$11.19	$37.61	$52.13
Testing of Sprays and Powders	$1.49	$4.74	$8.32	$1.45	$4.62	$8.12
Total Costs	$12.40	$37.79	$60.42	$15.57	$47.55	$75.84

In Table 21, we estimate the undiscounted costs of the proposed rule over 20 years. Firms would incur most costs of the proposed rule in year 1, in which they would reformulate and relabel sunscreen products.

Table 21. Undiscounted Costs of the Proposed Rule over 20 Years ($ millions)

Year	Lower Bound	Primary Estimate	Upper Bound
0	$6.80	$10.09	$14.88
1	$149.83	$497.13	$794.51
2	$7.61	$11.85	$16.47
3	$7.61	$11.85	$16.47
4	$7.61	$11.85	$16.47
5 - 19	$1.59	$5.07	$8.90

6. Net Benefits of the Proposed Rule

In Table 22, we estimate the net benefits of the proposed rule, if finalized, over 20 years. The present value of the net benefits would range from -$840.41 million to -$128.23 million at a 3 percent discount rate and from -$859.67 million to -$134.38 million at a 7 percent discount rate. The annualized net benefits would range from -$60.42 million to -$8.78 million at a 3 percent discount rate and from -$75.84 million to -$11.85 million at a 7 percent discount rate.

Table 22. Net Benefits[13] of the Proposed Rule over 20 Years ($ millions)

	Lower Bound (3%)	Primary Estimate (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary Estimate (7%)	Upper Bound (7%)
Present Value of Total Benefits	$0.00	$13.44	$55.45	$0.00	$10.28	$42.15
Present Value of Total Costs	$183.68	$558.84	$890.41	$176.53	$538.99	$859.67
Present Value of Net Benefits	($890.41)	($545.40)	($128.23)	($859.67)	($528.71)	($134.38)
Annualized Total Benefits	$0.00	$0.88	$3.62	$0.00	$0.91	$3.72
Annualized Total Costs	$12.40	$37.79	$60.42	$15.57	$47.55	$75.84
Annualized Net Benefits	($60.42)	($36.91)	($8.78)	($75.84)	($46.64)	($11.85)

G. Distributional Effects

1. Sunscreen-Insect Repellent Combinations

We anticipate that firms manufacturing sunscreen-insect repellent combinations would discontinue these products in response to the proposed rule, if finalized. We assume that the markets for sunscreens and insect repellents would absorb the market share of any discontinued products.

We found two types of sunscreen brands marketing a sunscreen and insect repellent combination. First, some sunscreen brands solely market insect repellent and sunscreen combinations. Thus, we expect these brands to exit the market. Second, some brands market insect repellent and sunscreen combinations in addition to marketing sunscreen products. These brands already market sunscreen-only versions of their insect repellent/ sunscreen combinations. These brands would discontinue their insect repellent and sunscreen combinations and consumers would purchase separate sunscreens and insect repellents. Manufacturers of sunscreen-insect repellent combinations would lose profits, but manufacturers of sunscreens and manufacturers of insect repellents would gain profits. Thus, we expect that the insect repellent provisions of the proposed rule, if finalized, would result only in between-product transfers.

2. Sunscreens with SPF above 80

We assume that firms would discontinue products with an SPF above 80 in response to the proposed rule, if finalized. We assume that the market for sunscreen would absorb the market share of these discontinued products, resulting in between-product transfers. That is, manufacturers of sunscreens with an SPF above 80 would lose profits, but manufacturers of other sunscreens would gain profits.

3. Other Discontinued Products

[13] The lower bound net benefits equal the lower bound benefits minus the upper bound costs. The upper bound net benefits equal the upper bound benefits minus the lower bound costs.

In our lower bound estimates throughout our analysis, we assume that firms would discontinue colorless and color cosmetic sunscreen products in response to the proposed rule, and that consumers of these products would not switch to alternative sunscreen products. If consumers of these discontinued products switch to alternative colorless or color products without sunscreen, then the proposed rule would create between-product transfers. Manufacturers of discontinued products would lose profits, and manufacturers of alternative products would gain profits.

If consumers of discontinued products do not switch to alternative products, then the proposed rule would have additional costs. Manufacturers of discontinued products would lose profits, but other manufacturers would not gain profits.

H. International Effects

Our analysis includes the costs to both foreign and domestic manufacturers in the sunscreen industry because the proposed rule, if finalized, would apply to any foreign or domestic manufacturer marketing sunscreens products in the United States. We assume that manufacturers, rather than labelers, would bear most of the costs of complying with the proposed rule[14]. We estimate that 52 percent of the 443 sunscreen manufacturers in the market are foreign manufacturers. We expect that, on average, foreign manufacturers would not incur disproportionately higher costs than domestic manufacturers. We request comment on the international effects of the proposed rule.

I. Uncertainty and Sensitivity Analysis

1. Industry Submits Data for 2 Active Ingredients

The active ingredients and dosage forms included in the final sunscreen monograph will depend on two things:

- Which active ingredients and dosage forms firms submit data for
- Whether this data supports a positive GRASE finding for sunscreens using the active ingredients and dosage form

In the primary analysis, we assumed that firms would submit data for the six most prevalent active ingredients currently on the market– avobenzone, homosalate, octocrylene, octinoxate, octisalate, and oxybenzone – and for powder sunscreens. We also assumed that this data would support a positive GRASE finding for all of these active ingredients and powder sunscreens. In this section, we consider a scenario in which firms only submit data for two active ingredients: avobenzone and octocrylene. Avobenzone is the most prevalent active ingredient on the market. Octocrylene is an active ingredient commonly used to photostabilize avobenzone. As in the primary analysis, we assume that the data would support a positive GRASE determination for these active ingredients.

[14] While we expect that sunscreen labelers would face some administrative costs to comply with the proposed rule, the cost per labeler is low.

In this scenario, we assume that the final monograph would include 4 active ingredients – avobenzone, octocrylene, titanium dioxide, and zinc oxide - and would not include powder sunscreens.

We summarize the annual quantified benefits in Table 23 and we summarize the annualized monetized benefits in Table 24. In this scenario, the benefits of increased use of products with improved UVA protection would be slightly lower because firms would discontinue powder sunscreens in year 1. The benefits of less exposure to sunscreens containing active ingredients about which safety questions remain would be higher because more active ingredients would be nonmonograph in this scenario.

Table 23. Annual Quantified Benefits when Industry Submits Data for 2 Active Ingredients (millions of ounces)

Type of Benefit	Lower Bound	Primary Estimate	Upper Bound
Increased use of products with improved UVA protection	98.16	201.79	286.26
Less exposure to sunscreens containing active ingredients about which safety questions remain	984.47	1,273.60	1,562.73
Less exposure to sunscreens with potentially misleading sun protection information	159.88	161.04	162.20
Less exposure to spray and powder sunscreens posing inhalation risks	384.86	386.44	388.02

Table 24. Annualized Benefits over 20 years when Industry Submits Data for 2 Active Ingredients ($ millions)

	Lower Bound (3%)	Primary Estimate (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary Estimate (7%)	Upper Bound (7%)
Avoided Severe Burns	$0.00	$0.88	$3.62	$0.00	$0.91	$3.72
Total Benefits	$0.00	$0.88	$3.62	$0.00	$0.91	$3.72

In Table 25, we summarize the annualized costs of the proposed rule if industry submits data for 2 active ingredients. The safety testing costs would be lower because firms would submit data for fewer active ingredients and dosage forms. The relabeling costs and spray testing costs would be lower because firms would discontinue powder dosage forms. The reformulation costs would be higher because more products would contain nonmonograph active ingredients.

Table 25. Annualized Costs over 20 years when Industry Submits Data for 2 Active Ingredients ($ millions)

Type of Cost	Lower Bound (3%)	Primary Estimate (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary Estimate (7%)	Upper Bound (7%)
Administrative Costs	$0.05	$0.22	$0.48	$0.07	$0.29	$0.64
Costs to Fill Data Gaps	$0.62	$0.69	$0.77	$0.78	$0.87	$0.97
Relabeling Costs	$0.41	$1.83	$9.13	$0.53	$2.38	$11.88

Reformulation Costs	$17.57	$53.94	$75.01	$22.86	$70.20	$97.61
Testing of Sprays	$1.48	$4.51	$7.94	$1.45	$4.40	$7.75
Total Costs	$20.13	$61.20	$93.33	$25.69	$78.14	$118.85

In Table 26 we estimate the net benefits of the proposed rule if industry submits data for 2 active ingredients. Our primary estimate of the present value of net benefits equals -$924.30 million at a 3 percent discount rate and -$875.52 million at a 7 percent discount rate. Our primary estimate of the annualized value of net benefits equals -$60.32 million at a 3 percent discount rate and -$77.24 million at a 7 percent discount rate.

Table 26. Net Benefits over 20 years when Industry Submits Data for 2 Active Ingredients ($ millions)

	Lower Bound (3%)	Primary Estimate (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary Estimate (7%)	Upper Bound (7%)
Present Value of Total Benefits	$0.00	$13.44	$55.45	$0.00	$10.28	$42.15
Present Value of Total Costs	$308.46	$937.74	$1,430.18	$291.17	$885.79	$1,347.27
Present Value of Net Benefits	($1,430.18)	($924.30)	($253.01)	($1,347.27)	($875.52)	($249.03)
Annualized Total Benefits	$0.00	$0.88	$3.62	$0.00	$0.91	$3.72
Annualized Total Costs	$20.13	$61.20	$93.33	$25.69	$78.14	$118.85
Annualized Net Benefits	($93.33)	($60.32)	($16.51)	($118.85)	($77.24)	($21.97)

2. Data Submissions are Not Sufficient

In the primary analysis, we assumed that firms would submit data for six active ingredients – avobenzone, homosalate, octocrylene, octinoxate, octisalate, and oxybenzone – and for powder sunscreens. We also assumed that this data would support a positive GRASE finding for all of these active ingredients and dosage forms. In this section, we consider a scenario in which firms submit data for the avobenzone, homosalate, octocrylene, octinoxate, octisalate, oxybenzone, and powder dosage forms, but that none of this data would support a positive GRASE determination for the active ingredients or dosage forms after five years.

In this scenario, the only active ingredients in the final monograph would be titanium dioxide and zinc oxide. The final monograph would not include powder sunscreens. Because we would have deferred action on avobenzone, homosalate, octocrylene, octinoxate, octisalate, and oxybenzone, firms would undergo two rounds of reformulation and relabeling:

1. In year 1, firms would reformulate products to meet the new broad spectrum requirements and would relabel products to comply with new labeling requirements.

2. In year 5, firms would reformulate products to remove any nonmonograph active ingredients and would relabel products to include the new active ingredients on the PDP and the Drug Facts panel.

We summarize the annual quantified benefits in Table 27 and we summarize the annualized monetized benefits in Table 28. The benefits of the proposed rule would increase after we make a final GRASE determination for active ingredients. In this scenario, the benefits of increased use of products with improved UVA protection would be lower because firms would discontinue powder sunscreens and some consumers of these products may stop using sunscreens in response. The benefits of less exposure to sunscreens containing active ingredients about which safety questions remain would be higher because more active ingredients would be nonmonograph in this scenario.

Table 27. Annual Quantified Benefits when Data Submissions would not Support a Positive GRASE Determination (millions of ounces)

Type of Benefit	Before GRASE Determination			After GRASE Determination		
	Lower Bound	Primary Estimate	Upper Bound	Lower Bound	Primary Estimate	Upper Bound
Increased use of products with improved UVA protection	98.16	201.79	286.26	98.16	201.79	286.26
Less exposure to sunscreens containing active ingredients about which safety questions remain	19.43	51.42	83.41	984.47	1,273.60	1,562.73
Less exposure to sunscreens with potentially misleading sun protection information	159.88	161.04	162.20	159.88	161.04	162.20
Less exposure to spray and powder sunscreens posing inhalation risks	384.86	386.44	388.02	384.86	386.44	388.02

Table 28. Annualized Benefits over 20 years when Data Submissions would not Support a Positive GRASE Determination ($ millions)

	Lower Bound (3%)	Primary Estimate (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary Estimate (7%)	Upper Bound (7%)
Avoided Severe Burns	$0.00	$0.88	$3.62	$0.00	$0.91	$3.72
Total Benefits	$0.00	$0.88	$3.64	$0.00	$0.91	$3.72

Furthermore, this scenario could generate negative benefits for consumers. Although some consumers prefer sunscreens containing titanium dioxide and zinc oxide (Ref. 18), some formulations using these active ingredients may leave a whitish cast on the skin. Some consumers may find the cosmetic characteristics of such sunscreens containing titanium dioxide or zinc oxide undesirable. Consequently these consumers may reduce or discontinue their use of sunscreens in response to the proposed rule, potentially increasing their risk of sunburn, skin cancer, or early skin aging.

In Table 29, we estimate the relabeling and reformulation costs before the GRASE determination, in year 1, and after the GRASE determination, in year 5. Because the second

round of relabeling would require only a minor labeling change, the relabeling costs per unit would be lower in year 5 than in year 1. We estimate the cost of a minor labeling change using our labeling cost model (Ref. 25).

Table 29. Relabeling and Reformulation Costs when Data Submissions would not Support a Positive GRASE Determination

	Before GRASE Determination			After GRASE Determination		
	Lower Bound	Primary Estimate	Upper Bound	Lower Bound	Primary Estimate	Upper Bound
Relabeled Units	435	1,181	4,028	1,522	3,208	3,295
Relabeling Cost per Unit ($)	$14,943	$24,699	$36,197	$9,553	$9,553	$9,553
Total Relabeling Cost ($m)	$6.50	$29.17	$145.80	$14.54	$30.65	$31.48
Reformulated Units	718	1,653	1,692	1,522	3,208	3,295
Reformulation Cost per Unit ($)	$182,917	$266,735	$361,198	$182,917	$266,735	$361,198
Total Reformulation Cost ($m)	$131.33	$440.91	$611.08	$278.40	$855.69	$1,190.20

In Table 30, we summarize the annualized costs of this scenario. The relabeling and reformulation costs would be higher because more products would contain nonmonograph active ingredients and because firms would reformulate some products twice. The particle size testing costs would be lower because firms would discontinue powder dosage forms.

Table 30. Annualized Costs over 20 years when Data Submissions would not Support a Positive GRASE Determination ($ millions)

Type of Cost	Lower Bound (3%)	Primary Estimate (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary Estimate (7%)	Upper Bound (7%)
Administrative Costs	$0.05	$0.22	$0.48	$0.07	$0.29	$0.64
Costs to Fill Data Gaps	$1.85	$2.09	$2.33	$2.33	$2.62	$2.93
Relabeling Costs	$1.23	$3.57	$11.01	$1.45	$4.33	$14.00
Reformulation Costs	$23.99	$76.10	$105.71	$28.34	$90.17	$125.24
Testing of Sprays	$1.48	$4.51	$7.94	$1.45	$4.40	$7.75
Total Costs	$28.61	$86.49	$127.47	$33.63	$101.82	$150.56

In Table 31 we show the net benefits of this scenario. Our primary estimate of the present value of net benefits equals -$1,311.92 million at a 3 percent discount rate and -$1,143.92 million at a 7 percent discount rate. Our primary estimate of the annualized value of net benefits equals -$85.61 million at a 3 percent discount rate and -$100.91 million at a 7 percent discount rate.

Table 31. Net Benefits of the Proposed Rule over 20 Years when Data Submissions would not Support a Positive GRASE Determination ($ millions)

	Lower Bound (3%)	Primary Estimate (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary Estimate (7%)	Upper Bound (7%)
Present Value of Total Benefits	$0.00	$13.44	$55.45	$0.00	$10.28	$42.15
Present Value of Total Costs	$438.39	$1,325.36	$1,953.36	$381.25	$1,154.20	$1,706.72
Present Value of Net Benefits	($1,953.36)	($1,311.92)	($382.95)	($1,706.72)	($1,143.92)	($339.10)
Annualized Total Benefits	$0.00	$0.88	$3.62	$0.00	$0.91	$3.72
Annualized Total Costs	$28.61	$86.49	$127.47	$33.63	$101.82	$150.56
Annualized Net Benefits	($127.47)	($85.61)	($24.99)	($150.56)	($100.91)	($29.92)

3. No Data Submissions

In the primary analysis, we assumed that firms would submit data for six active ingredients – avobenzone, homosalate, octocrylene, octinoxate, octisalate, and oxybenzone – and for powder sunscreens. We also assumed that this data would support a positive GRASE finding for all of these active ingredients and dosage forms. In this section, we consider a scenario in which firms do not submit data for any active ingredients or dosage forms. In this scenario, the only active ingredients in the final monograph would be titanium dioxide and zinc oxide. The final monograph would not include powder sunscreens.

We summarize the annual quantified benefits in Table 32 and we summarize the annualized monetized benefits in Table 33. In this scenario, the benefits of increased use of products with improved UVA protection would be lower because firms would discontinue powder sunscreens and some consumers of these products may stop using sunscreens in response. The benefits of less exposure to sunscreens containing active ingredients about which safety questions remain would be higher because more active ingredients would be nonmonograph in this scenario.

Table 32. Annual Quantified Benefits when We Receive No Data Submissions (millions of ounces)

Type of Benefit	Lower Bound	Primary Estimate	Upper Bound
Increased use of products with improved UVA protection	98.16	201.79	286.26
Less exposure to sunscreens containing active ingredients about which safety questions remain	984.47	1,273.60	1,562.73
Less exposure to sunscreens with potentially misleading sun protection information	159.88	161.04	162.20
Less exposure to spray and powder sunscreens posing inhalation risks	384.86	386.44	388.02

Table 33. Annualized Benefits over 20 years when We Receive No Data Submissions ($ millions)

	Lower Bound (3%)	Primary Estimate (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary Estimate (7%)	Upper Bound (7%)
Avoided Severe Burns	$0.00	$0.88	$3.62	$0.00	$0.91	$3.72
Total Benefits	$0.00	$0.88	$3.64	$0.00	$0.91	$3.72

As discussed in the previous uncertainty section, this scenario could generate negative benefits for consumers. Although some consumers prefer sunscreens containing titanium dioxide and zinc oxide (Ref. 18), some formulations using these active ingredients may leave a whitish cast on the skin. Some consumers may find the cosmetic characteristics of such sunscreens containing titanium dioxide or zinc oxide undesirable. Consequently these consumers may reduce or discontinue their use of sunscreens in response to the proposed rule, potentially increasing their risk of sunburn, skin cancer, or early skin aging.

In Table 34, we summarize the annualized costs of this scenario. The reformulation costs would be higher because more products would contain nonmonograph active ingredients. The particle size testing costs would be lower because firms would discontinue powder dosage forms.

Table 34. Annualized Costs over 20 years when We Receive No Data Submissions ($ millions)

Type of Cost	Lower Bound (3%)	Primary Estimate (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary Estimate (7%)	Upper Bound (7%)
Administrative Costs	$0.05	$0.22	$0.48	$0.07	$0.29	$0.64
Costs to Fill Data Gaps	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Relabeling Costs	$0.41	$1.83	$9.13	$17.66	$55.03	$76.51
Reformulation Costs	$17.66	$55.03	$76.51	$1.48	$4.51	$7.94
Testing of Sprays	$1.48	$4.51	$7.94	$0.00	$0.00	$0.00
Total Costs	$19.60	$61.58	$94.05	$19.21	$59.83	$85.09

In Table 31 we show the net benefits of this scenario. Our primary estimate of the present value of net benefits equals -$930.25 million at a 3 percent discount rate and -$881.58 million at a 7 percent discount rate. Our primary estimate of the annualized value of net benefits equals -$60.71 million at a 3 percent discount rate and -$77.77 million at a 7 percent discount rate.

Table 35. Net Benefits of the Proposed Rule over 20 Years when We Receive No Data Submissions ($ millions)

	Lower Bound (3%)	Primary Estimate (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary Estimate (7%)	Upper Bound (7%)
Present Value of Total Benefits	$0.00	$13.44	$55.45	$0.00	$10.28	$42.15

Present Value of Total Costs	$300.42	$943.68	$1,441.23	$283.75	$891.86	$1,358.29
Present Value of Net Benefits	($300.42)	($930.25)	($1,385.78)	($283.75)	($881.58)	($1,316.14)
Annualized Total Benefits	$0.00	$0.88	$3.62	$0.00	$0.91	$3.72
Annualized Total Costs	$19.60	$61.58	$94.05	$25.03	$78.68	$119.83
Annualized Net Benefits	($19.60)	($60.71)	($90.43)	($25.03)	($77.77)	($116.11)

4. Benefits of Avoided Skin Cancer Breakeven Analysis

In our primary analysis, we estimated that in 2016 consumers used between 98.16 million ounces and 286.26 million onces of sunscreen products that would reformulate to meet the new broad spectrum requirements. Given that the average consumer used between 3.33 ounces and 5.38 ounces,[15] we estimate that between 29 and 53 million consumers would benefit from using sunscreens with improved protection against UVA radiation. Because exposure to broad spectrum UV causes skin cancer (Ref. 12), we expect that the public health benefits of the new broad spectrum requirements would be significant.

To estimate the gain in public health from improved broad spectrum protection presents many challenges. First, skin cancers can develop years after exposure to UV radiation. Second, the relationship between sunscreen use and exposure to UV radiation depends on how consumers use sunscreens and characteristics of different sunscreen formulations. Third, UV radiation exposure varies significantly between consumers. For example, UV radiation varies geographically, by time of day, and by time of year.

In this section we estimate the number of cases of skin cancer we would need to avoid for the benefits of the proposed rule to equal the costs of the proposed rule. First, we estimate the willingness-to-pay to avoid the three types of skin cancer – melanoma, basal cell carcinoma, and squamous cell carcinoma – using a quality-adjusted life years approach.

In our analysis of the benefits from avoided severe burns, we estimated that the representative sunscreen user has between 17.63 and 18.11 quality-adjusted life years at a 3 percent discount rate and between 11.05 and 11.31 quality-adjusted life years at a 7 percent discount rate. In this section, we also consider the reduction in the quality-adjusted life years of the representative sunscreen user due to skin cancer.

As mentioned above, skin cancers can develop years after exposure to UV radiation. The average age of a melanoma diagnosis is 63 (Ref. 27) and the average age of a basal cell carcinoma or squamous cell carcinoma diagnosis is 64 (Ref. 28). We assume that using sunscreens with improved protection against UVA radiation today would reduce the risk of developing skin cancer later in life. We estimate the value of this risk reduction by estimating

[15] We estimate the average sunscreen consumption per consumer by dividing the total sunscreen consumption in 2016 from Table 9 by the population in 2016.

how much a 46-year-old representative sunscreen user is willing to pay to avoid skin cancer later in life.

In Table 36, we estimate the health-related quality of life reduction for patients with skin cancer at the time of diagnosis by the type of skin cancer. Because skin cancer frequently reoccurs and because treating skin cancers often creates scarring, we assume that reductions in the health-related quality of life from skin cancer last a life time. Assuming that these reductions begin at age 63 for melanoma and at age 64 for basal cell carcinoma and squamous cell carcinoma, we estimate the number of quality-adjusted life years for the representative sunscreen user. Basal cell carcinoma reduces the number of a quality-adjusted life years for a consumer by between 0.00 and 0.04 quality-adjusted life years at a 3 percent discount rate and between 0.00 and 0.01 quality-adjusted life years at a 7 percent discount rate. Melanoma reduces the number of quality-adjusted life years of a consumer by between 0.02 and 0.80 quality-adjusted life years at a 3 percent discount rate and between 0.01 and 0.29 quality-adjusted life years at a 7 percent discount rate. Squamous cell carcinoma decreases the number of quality-adjusted life years by between 0.00 and 0.41 quality-adjusted life years at a 3 percent discount rate and between 0.00 and 0.14 quality-adjusted life years at a 7 percent discount rate.

Table 36. Reductions in Health-Related Quality of Life by Type of Skin Cancer

Type of Skin Cancer	Lower Bound	Primary Estimate	Upper Bound
Basal Cell Carcinoma[b]	0.0%	0.1%	0.7%
Melanoma[a]	0.4%	2.9%	12.6%
Squamous Cell Carcinoma[b]	0.0%	1.0%	6.9%

[a] Ref. 29
[b] Ref. 30

In 2019, the value per quality-adjusted life year ranges from $0.24 million to $0.79 million at a 3 percent discount rate, with a primary estimate of $0.52 million. The value per quality-adjusted life year in 2019 ranges from $0.40 million to $1.32 million at a 7 percent discount rate, with a primary estimate of $0.86 million. Based on these estimates, in Table 37, we estimate how much the representative sunscreen user would be willing to pay in 2019 to avoid future skin cancer, by type of skin cancer.

Table 37. Willingness to Pay to Avoid Skin Cancer in 2019, by Type of Skin Cancer ($)

	Lower Bound (3%)	Primary Estimate (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary Estimate (7%)	Upper Bound (7%)
Basal Cell Carcinoma	$0	$3,050	$32,563	$0	$1,790	$19,083
Melanoma	$6,120	$95,675	$640,108	$3,704	$57,823	$386,275
Squamous Cell Carcinoma	$0	$30,498	$325,634	$0	$17,900	$190,829

From Table 22, the annualized net costs (this is the inverse of the annualized net benefits) of the proposed rule range from -$60.42 million to -$8.78 million at a 3 percent discount rate.

The annualized net costs of the proposed rule would range from -$75.84 million to -$11.85 million at a 7 percent discount rate.

Finally, we estimate the annual number of avoided cases of each type of skin cancer required for the annualized benefits of the proposed rule to equal the annualized costs of the proposed rule. We assume that skin cancer benefits from the proposed rule begin in year 1. That is, the average sunscreen user would begin to benefit from improved broad spectrum protection in year 1, reducing their risk of skin cancer later in life. The lower bound breakeven point equals the lower bound net costs divided by the upper bound willingness-to-pay to avoid skin cancer. The upper bound breakeven point equals the upper bound net costs divided by the lower bound willingness-to-pay to avoid skin cancer. Table 38 shows the results of our breakeven analysis.

Table 38. Annual Avoided Cases of Skin Cancer Required for the Annualized Benefits to Equal the Annualized Costs of the Proposed Rule

	Lower Bound (3%)	Primary Estimate (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary Estimate (7%)	Upper Bound (7%)
Basal Cell Carcinoma	1,813	11,827	N/A[a]	1,683	11,055	N/A[a]
Melanoma	92	377	310	86	352	1,400
Squamous Cell Carcinoma	181	1,183	N/A[a]	168	1,105	N/A[a]

[a]The lower bound willingness-to-pay to avoid skin cancer is $0.

At a 3 percent discount rate, the primary estimate of the annualized costs of the proposed rule would equal the annualized benefits of the proposed rule if we avoided 11,827 cases of basal cell carcinoma each year, 377 cases of melanoma each year, or 1,183 cases of squamous cell carcinoma each year. At a 7 percent discount rate, the primary estimate of the annualized costs of the proposed rule would equal the annualized benefits of the proposed rule if we avoided 11,055 cases of basal cell carcinoma each year, 352 cases of melanoma each year, or 1,105 cases of squamous cell carcinoma each year.

To contextualize these estimates, we compare the breakeven points to the incidence of each form of skin cancer in 2012 (Refs. 31-33). At a 7 percent discount rate, the primary estimate of the annualized costs of the proposed rule would equal the annualized benefits if we avoided 0.25 percent of cases of basal cell carcinoma each year, 0.51 percent of cases of melanoma each year, or 0.10 percent of cases of squamous cell carcinoma each year.

5. Possible Changes in Consumer and Producer Surplus

In our analysis, we assume that the supply and demand for sunscreen products would not change in response to the proposed rule, if finalized. If supply or demand change in response to the proposed rule, if finalized, it could affect the consumer or producer surplus in the sunscreen market, creating additional benefits or costs of the proposed rule.

The proposed rule, if finalized, could increase the perceived value of sunscreen products by giving consumers greater confidence in the safety and effectiveness of sunscreen products and improving the quality of sunscreen products. Increases in perceived value would increase the demand for sunscreen products. However, the proposed rule could also affect the non-sun

protection characteristics of sunscreen products, like cosmetic characteristics, feel characteristics, or ease of use. These changes could increase or decrease demand.

The proposed rule, if finalized, could make it easier for new entrants to compete in the sunscreen market by making sunscreen products and their labels more homogenous. Increased entry would increase the supply of sunscreen products. The proposed rule could also decrease supply by increasing the marginal production costs of sunscreens if active ingredients on the final sunscreen monograph are more expensive than active ingredients on the stayed sunscreen monograph but not on the final sunscreen monograph.

We do not have enough information to predict the direction or magnitude of changes in demand and supply in response to the proposed rule, if finalized. If total surplus (the sum of consumer surplus and producer surplus) increases in response to the proposed rule, this analysis would underestimate the benefits of the rule. If total surplus decreases in response to the proposed rule, this analysis would underestimate the cost of the rule. Finally, if the proposed rule would increase consumer surplus but decrease producer surplus, or if the proposed rule would increase producer surplus but decrease consumer surplus, the proposed rule would result in additional transfers.

6. Additional Uncertainty

We request comments about any potential benefits or costs of the proposed rule not included in this analysis. We additionally request information on any potential unintended effects of the proposed rule. For example, we primarily consider the costs to sunscreen manufacturers, and we are uncertain of the costs to testing entities, responsible persons, and active ingredient manufacturers. We also request comment about the affect of the proposed rule on the total available supply of sunscreen products.

J. Analysis of Regulatory Alternatives to the Proposed Rule

1. FDA Conducts All Active Ingredient Testing

The proposed rule, if finalized, could cause the removal of some safe active ingredients from the sunscreen market simply because firms do not submit data for those active ingredients. If we conducted all safety testing for all 12 sunscreen active ingredients with data gaps, then we would only remove ingredients with evidence showing affirmatively that they are not GRASE for use in sunscreens from the monograph, as opposed to ingredients that are found not be GRASE for use in sunscreens because of insufficient data. Though we do not have enough information to estimate the benefits and costs of this alternative, we expect that this alternative is less stringent than the proposed rule.

In this alternative, the ingredient testing costs would decrease relative to the primary analysis because FDA would not incur costs to coordinate with industry on testing. However, FDA would also incur formulation development costs for use in testing, costs to source active ingredients in small quantities, and costs to administer contracts. The costs of this alternative to manufacturers would depend on the result of safety testing. For example, if we determine that all 12 active ingredients are GRASE for use in sunscreens, then manufacturers would reformulate fewer products and the cost to firms would be lower than under the proposed rule. Because we would

know the risk associated with each active ingredient, the public health benefits of removing any ingredient would be positive rather than nonnegative.

2. Delayed Compliance Date

As an alternative, we could also delay the compliance date for the rule. If we delay the compliance date, manufacturers would incur administrative costs in year one, but they wouldn't incur safety testing, relabeling, reformulation, flammability testing, or particle size testing costs until the new compliance date. In Table 39, we estimate the annualized costs if we delay the compliance date by one, two, three, four, or five years.

Table 39. Annualized Costs with Delayed Compliance Date over a 20 Year Time Horizon ($ millions)

Length of Delay in Compliance Date	Lower Bound (3%)	Primary Estimate (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary Estimate (7%)	Upper Bound (7%)
No Delay (2020)	$12.40	$37.79	$60.42	$15.57	$47.55	$75.84
One Year (2021)	$12.04	$36.57	$58.42	$14.67	$44.51	$70.91
Two Years (2022)	$11.68	$35.39	$56.48	$13.84	$41.68	$66.30
Three Years (2023)	$11.34	$34.24	$54.60	$13.05	$39.02	$61.99
Four Years (2024)	$11.01	$33.13	$52.77	$12.32	$36.55	$57.97
Five Years (2025)	$10.78	$32.33	$51.49	$11.73	$34.55	$54.77

However, delaying the compliance date would also delay benefits and cost savings from the proposed rule. In Table 40, we estimate the annualized benefits if we delay the compliance deadline by one, two, three, four, or five years.

Table 40. Annualized Benefits with Delayed Compliance Date over a 20 Year Time Horizon ($ millions)

Length of Delay in Compliance Date	Lower Bound (3%)	Primary Estimate (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary Estimate (7%)	Upper Bound (7%)
No Delay (2020)	$0.00	$0.88	$3.62	$0.00	$0.91	$3.72
One Year (2021)	$0.00	$0.82	$3.39	$0.00	$0.83	$3.41
Two Years (2022)	$0.00	$0.77	$3.17	$0.00	$0.76	$3.11
Three Years (2023)	$0.00	$0.72	$2.96	$0.00	$0.69	$2.84
Four Years (2024)	$0.00	$0.67	$2.75	$0.00	$0.63	$2.57
Five Years (2025)	$0.00	$0.62	$2.54	$0.00	$0.57	$2.33

In Table 41, we estimate the annualized net benefits if we delay the compliance date by one, two, three, four, or five years. Delaying the compliance date by five years results in the highest net benefits across these alternatives at a 3 percent discount rate and at a 7 percent discount rate.

Table 41. Annualized Net Benefits with Delayed Compliance Date over a 20 Year Time Horizon ($ millions)

Length of Delay in Compliance Date	Lower Bound (3%)	Primary Estimate (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary Estimate (7%)	Upper Bound (7%)
No Delay (2020)	($60.42)	($36.91)	($8.78)	($75.84)	($46.64)	($11.85)
One Year (2021)	($58.42)	($35.75)	($8.64)	($70.91)	($43.68)	($11.27)
Two Years (2022)	($56.48)	($34.62)	($8.51)	($66.30)	($40.92)	($10.72)
Three Years (2023)	($54.60)	($33.53)	($8.38)	($61.99)	($38.33)	($10.21)
Four Years (2024)	($52.77)	($32.46)	($8.26)	($57.97)	($35.92)	($9.74)
Five Years (2025)	($51.49)	($31.72)	($8.24)	($54.77)	($33.98)	($9.41)

III. Initial Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed would impose significant costs which could result in exits by small entities, we find that the proposed rule would have a significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this document, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

In this section, we consider the effect of the proposed rule, if finalized, on small businesses by estimating the average cost per small, domestic firm. To estimate this cost, we make three key assumptions. We welcome comments and data on these assumptions.

We assume that manufacturers would bear all costs of relabeling and reformulating sunscreen products and contract manufacturers would not pass on relabeling and reformulation costs to their clients, sunscreen labelers. We also assume that only large manufacturers would incur costs to provide active ingredient testing data. We expect that large manufacturers would be more likely to have the resources needed to conduct ingredient testing. Also, because large manufacturers generally sell more sunscreen products, we expect that large manufacturers would have more incentive to ensure that an active ingredient stays in the sunscreen monograph than small manufacturers.

Finally, we assume that the proposed rule would only affect manufacturers in the Pharmaceutical Preparations Manufacturing industry (North American Industry Classification System (NAICS) Code 325412) and manufacturers in the Toilet Preparations Manufacturing industry (NAICS Code 325620). By matching registration data with Dun and Bradstreet data on firm NAICS codes, we find that, though these two industries are the most common, sunscreen manufacturers can belong to many different industries. We focus our analysis on pharmaceutical preparations manufacturers and toilet preparations manufacturers for simplicity. By making this assumption, we assume that pharmaceutical preparations manufacturers and toilet preparations manufacturers are representative of sunscreen manufacturers in other industries.

A. Description and Number of Affected Small Entities

The Small Business Administration defines a small business in the Pharmaceutical Preparations Manufacturing industry as a business with 1,250 or fewer employees (Ref. 34). A small business in the Toilet Preparations Manufacturing industry has 1,250 or fewer employees (Ref. 34). Using registration and listing data and Dun and Bradstreet data, we estimate that 179 of the 434 manufacturers in the sunscreen industry are small, domestic firms per the Small Business Administration's definition of a small business.

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

1. Average Costs to Small Manufacturers

In Table 42, we estimate the average number of relabeled and reformulated units at each small, domestic manufacturer. We also estimate the average number of tested spray units and testing powder units at each small, domestic manufacturer.

Table 42. Reformulated Units, Relabeled Units, Tested Spray Units, and Tested Powder Units from Small, Domestic Manufacturers

	All Small, Domestic Manufacturers			Average per Small, Domestic Manufacturer		
	Lower Bound	Primary Estimate	Upper Bound	Lower Bound	Primary Estimate	Upper Bound
Relabeled Units	210	610	2,115	1	3	11
Reformulated Units	379	917	947	2	5	5
Tested Spray Units	237	237	261	1	1	1
Tested Powder Units	1	20	20	0.01	0.11	0.11

Using the information in Table 42, we can estimate the stream of costs to small, domestic manufacturers over 20 years. On average, the year 1 costs to small domestic manufacturers would range from $392,673 to $2,269,102. The annualized costs to small domestic manufactures would range from $28,737 to $166,086 at a 3 percent discount rate and from $36,073 to $208,621 at a 7 percent discount rate.

Table 43. Average Costs to Small, Domestic Manufacturers over 20 Years ($)

Year	Lower Bound	Primary Estimate	Upper Bound
0	$1,041	$5,509	$12,968
1	$392,673	$1,405,024	$2,269,102
2	$4,343	$13,024	$23,912
3	$4,343	$13,024	$23,912
4	$4,343	$13,024	$23,912
5	$4,352	$13,578	$24,835
6	$4,352	$13,578	$24,835
7	$4,352	$13,578	$24,835
8	$4,352	$13,578	$24,835
9	$4,352	$13,578	$24,835
10	$4,352	$13,578	$24,835

11	$4,352	$13,578	$24,835
12	$4,352	$13,578	$24,835
13	$4,352	$13,578	$24,835
14	$4,352	$13,578	$24,835
15	$4,352	$13,578	$24,835
16	$4,352	$13,578	$24,835
17	$4,352	$13,578	$24,835
18	$4,352	$13,578	$24,835
19	$4,352	$13,578	$24,835
Present Discounted Value of Costs (3%)	$440,359	$1,549,391	$2,545,071
Present Discounted Value of Costs (7%)	$408,912	$1,444,901	$2,364,839
Annualized Costs (3%)	$28,737	$101,110	$166,086
Annualized Cost Savings (7%)	$36,073	$127,466	$208,621

To determine the magnitude of these costs relative to expected revenue, we use data from the Survey of U.S. Businesses (Ref. 35). We compare the average expected year 1 revenue to the average expected year 1 compliance costs, as well as the average expected annualized revenue to the average expected annualized compliance costs over 20 years.

In Table 44, we estimate the one-time compliance costs as a percent of revenue for small firms in the pharmaceuticals preparations manufacturing industry. In Table 45, we estimate the annualized compliance costs as a percent of revenue for small firms in the pharmaceuticals preparations manufacturing industry. Both tables suggest that the proposed rule would have a significant impact on small businesses in the pharmaceutical preparations manufacturing industry.

Table 44. One-Time Compliance Costs as a Percentage of Revenue for the Pharmaceutical Preparations Manufacturing Industry ($ millions)

	Firm Size	Lower Bound	Primary Estimate	Upper Bound
Year 1 Revenue	0-19 Employees	$8.88	$8.88	$8.88
	20-99 Employees	$19.59	$19.59	$19.59
	100-499 Employees	$115.32	$115.32	$115.32
Year 1 Costs	All Small Firms	$0.39	$1.41	$2.27
Year 1 Costs as % of Year 1 Revenue	0-19 Employees	4.42%	15.82%	25.56%
	20-99 Employees	2.00%	7.17%	11.58%
	100-499 Employees	0.34%	1.22%	1.97%

Table 45. Annualized Compliance Costs as a Percentage of Revenue for the Pharmaceutical Preparations Manufacturing Industry ($ millions)

	Firm Size	Lower Bound (3%)	Primary Estimate (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary Estimate (7%)	Upper Bound (7%)
Annualized Revenue	0-19 Employees	$8.88	$8.88	$8.88	$8.88	$8.88	$8.88
	20-99 Employees	$19.59	$19.59	$19.59	$19.59	$19.59	$19.59
	100-499 Employees	$115.32	$115.32	$115.32	$115.32	$115.32	$115.32
Annualized Costs	All Small Firms	$0.03	$0.10	$0.17	$0.04	$0.13	$0.21
Annualized Costs as % of Annualized Revenue	0-19 Employees	0.32%	1.14%	1.87%	0.41%	1.44%	2.35%
	20-99 Employees	0.15%	0.52%	0.85%	0.18%	0.65%	1.06%
	100-499 Employees	0.02%	0.09%	0.14%	0.03%	0.11%	0.18%

In Table 46, we estimate the one-time compliance costs as a percent of revenue for small firms in the toilet preparations manufacturing industry. In Table 47, we estimate the annualized compliance costs as a percent of revenue for small firms in the toilet preparations manufacturing industry. Both tables suggest that the proposed rule would have a significant impact on small businesses in the toilet preparations manufacturing industry.

Table 46. One-Time Compliance Costs as a Percentage of Revenue for the Toilet Preparations Manufacturing Industry ($ millions)

	Firm Size	Lower Bound	Primary Estimate	Upper Bound
Year 1 Revenue	0-19 Employees	$1.53	$1.53	$1.53
	20-99 Employees	$16.04	$16.04	$16.04
	100-499 Employees	$52.21	$52.21	$52.21
Year 1 Costs	All Small Firms	$0.39	$1.41	$2.27
Year 1 Costs as % of Year 1 Revenue	0-19 Employees	25.70%	91.97%	148.53%
	20-99 Employees	2.45%	8.76%	14.15%
	100-499 Employees	0.75%	2.69%	4.35%

Table 47. Annualized Compliance Costs as a Percentage of Revenue for the Toilet Preparations Manufacturing Industry ($ millions)

	Firm Size	Lower Bound (3%)	Primary Estimate (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary Estimate (7%)	Upper Bound (7%)
Annualized Revenue	0-19 Employees	$1.53	$1.53	$1.53	$1.53	$1.53	$1.53
	20-99 Employees	$16.04	$16.04	$16.04	$16.04	$16.04	$16.04
	100-499 Employees	$52.21	$52.21	$52.21	$52.21	$52.21	$52.21
Annualized Costs	All Small Firms	$0.03	$0.10	$0.17	$0.04	$0.13	$0.21
	0-19 Employees	1.88%	6.62%	10.87%	2.36%	8.34%	13.66%

Annualized Costs as % of Annualized Revenue	20-99 Employees	0.18%	0.63%	1.04%	0.22%	0.79%	1.30%
	100-499 Employees	0.06%	0.19%	0.32%	0.07%	0.24%	0.40%

2. Exits of Small Firms

Table 44 through Table 47 indicate that the compliance costs for the average small, domestic manufacturer may make up a significant share of their revenue. As a result, some manufacturers could exit the sunscreen market rather than comply with the proposed rule (if finalized) or seek NDAs. These manufacturers could discontinue their sunscreen products and continue marketing other, non-sunscreen products. In this case, the cost to the manufacturer would be the lost profits from the sale of sunscreen products. These manufacturers could also go out of business. In this case, the cost to the manufacturer would be the total lost profits. In our analysis, we cannot distinguish between manufacturers that would discontinue their sunscreen products and manufacturers that would go out of business.

To estimate the number of manufacturers that would exit the sunscreen market in response to the proposed rule if finalized, we use the Small Business model developed by the Eastern Research Group (Ref. 36). The model uses data from the Statistics of Small Businesses (Ref. 35) and assumes that revenue within each employment size category has a normal distribution among firms. We input the one-time and recurring costs of the proposed rule into the model using a 20-year time horizon and both 3 percent and 7 percent discount rates. A firm would exit if their pre-tax costs are greater than their revenues. In Table 48, we present the outputs of the small business model. We expect that between 1.56 and 9.58 percent of all sunscreen manufacturers in the Pharmaceutical Preparation Manufacturing industry would exit the market in response to the proposed rule, if finalized, at a 3 percent discount rate, while between 2.19 percent and 12.40 percent would exit at a 7 percent discount rate. We expect that between 0.70 and 5.03 percent of all sunscreen manufacturers in the Toilet Preparation Manufacturing industry would exit the market in response to the proposed rule, if finalized, at a 3 percent discount rate, while between 1.05 percent and 6.78 percent would exit at a 7 percent discount rate.

Table 48. Exits in the Sunscreen Market (% of all sunscreen manufacturers in that industry)

Industry	Lower Bound	Primary Estimate	Upper Bound
Pharmaceutical Preparation Manufacturing (3%)	1.56%	5.52%	9.58%
Pharmaceutical Preparation Manufacturing (7%)	2.19%	7.50%	12.40%
Toilet Preparation Manufacturing (3%)	0.70%	2.69%	5.03%
Toilet Preparation Manufacturing (7%)	1.05%	3.63%	6.78%

C. Alternatives to Minimize the Burden on Small Entities

We could reduce the burden on small businesses by delaying the compliance date for small businesses. If we delay the compliance date for small businesses, small businesses would incur administrative costs in year 0, but they wouldn't incur relabeling, reformulation,

flammability testing, drying time testing, or particle size testing costs until the new compliance date. In Table 49, we estimate the annualized costs to small businesses if we delay the compliance date by one, two, three, four, or five years. Delaying the compliance date would reduce the burden of the proposed rule on small entities by delaying relabeling, formulation, flammability testing, drying time testing, and particle size testing costs to the new compliance date.

Table 49. Annualized Costs to Small Businesses with Delayed Compliance Date over a 20 Year Time Horizon ($)

Length of Delay in Compliance Date	Lower Bound (3%)	Primary Estimate (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary Estimate (7%)	Upper Bound (7%)
No Delay (2020)	$28,737	$101,110	$166,086	$36,073	$127,466	$208,621
One Year (2021)	$27,745	$97,716	$160,428	$33,621	$118,884	$194,539
Two Years (2022)	$26,782	$94,421	$154,935	$31,329	$110,864	$181,379
Three Years (2023)	$25,848	$91,222	$149,601	$29,186	$103,368	$169,080
Four Years (2024)	$24,940	$88,116	$144,423	$27,184	$96,363	$157,585
Five Years (2025)	$24,303	$85,834	$140,742	$25,587	$90,635	$148,347

We choose not to delay the compliance date for small businesses to maximize the public health benefits of the proposed rule. Small businesses make up most of the sunscreen market. Delaying the compliance date for small businesses would delay the implementation of the proposed rule for most marketed sunscreens, reducing the health benefits of the proposed rule.

D. Summary

Based on this analysis, the proposed would impose significant costs which could result in exits by small entities. Therefore, we find that the proposed rule would have a significant economic impact on a substantial number of small entities.

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