DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Medical Devices; General and Plastic Surgery Devices; Classification of Certain Solid Wound Dressings, Wound Dressings Formulated as a Gel, Creams, or Ointment, and Liquid Wound Washes

Docket No. FDA–2023–N–3392

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

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Table of Contents

List of Tables

I. Introduction and Summary

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, 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, 13563, and 14094 direct us to assess all benefits, costs, and transfers 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). Rules are "significant" under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they "have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of [the Office of Information and Regulatory Affairs (OIRA)] for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities." OIRA has determined that this proposed rule is not a significant regulatory action under Executive Order 12866 Section 3(f)(1).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the costs of the proposed rule primarily accrue to larger firms, we propose to certify that the proposed rule will not 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 estimates of anticipated impacts, 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 $177 million, using the most current (2022) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

This proposed rule, if finalized, would classify certain types of currently unclassified wound dressings and liquid wound washes containing antimicrobials and/or other chemicals: solid dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes. FDA is proposing to classify wound dressings and liquid wound washes containing medically important antimicrobials *(i.e.*, antimicrobial drugs that are important for therapeutic use in humans and associated with a high level of antimicrobial resistance (AMR) concern)[1] into class III, for which FDA is separately proposing to require the filing of a premarket approval application (PMA). FDA has determined that general controls and special controls together are insufficient to provide reasonable assurance of safety and effectiveness for such wound dressings and liquid wound washes. In addition, FDA is proposing to classify wound dressings and liquid wound washes containing antimicrobials with a medium or low level of AMR concern into class II subject to general and special controls. FDA is publishing this proposed rule

1 Table 1 of the World Health Organization's (WHO) 2018 publication "Critically important antimicrobials for human medicine: 6th edition" (https://www.who.int/publications/i/item/9789241515528) has a list of all classes of medically important antimicrobials. For the purposes of this proposed order, an antimicrobial is considered medically important if, and only if, it falls within any of these classes regardless of the level of importance specified by the WHO (*i.e.*, critically important, highly important, or important).

based, in part, on the recommendations of the General and Plastic Surgery Devices Panel regarding the classification of certain types of wound dressings and liquid wound washes.

To estimate costs and benefits associated with the proposed rule, if finalized, we assume that the appropriate baseline is the current state of the US with unclassified wound dressings and liquid wound washes containing antimicrobials and/or other chemicals. We then compare the likely impacts of the proposed rule against this baseline. The quantifiable benefits of the proposed rule, if finalized, accrue to manufacturers of wound dressings and liquid wound washes and FDA. These benefits are the result of clarifications in the 510(k)-submission process, specifically defined regulatory classification and published special controls. This additional clarity in requirements should result in fewer additional information submissions to FDA. We estimate annualized cost savings ranging from approximately $1.12 million to $6.31 million at a 3 percent discount rate, and approximately $1.14 million to $6.42 million at a 7 percent discount rate. Our primary annualized estimates are approximately $2.66 million at a 3 percent discount rate and $2.71 million at a 7 percent discount rate. The primary estimates of the present value of total cost savings in the 10 years following any final rule that may be issued based on this proposed rule are $24.55 million at a 3 percent rate of discount and $19.02 million at a 7 percent rate of discount. If the proposed rule is finalized, society may experience welfare gains from reductions in AMR due to the rule. These welfare gains would be in the form of decreased mortality, morbidity, and medical costs. Unfortunately, the magnitude of these potential benefits is difficult to forecast and we do not quantify these impacts in the analysis. We summarize quantified benefits in Table 1.

The costs of the proposed rule, if finalized, are associated with costs to industry for reading and understanding the rule, preparing and submitting PMAs, and other costs related to the PMA process and maintaining the class III designation. FDA also incurs costs from reviewing PMAs, annual and supplemental reports, and inspection activities. When annualized over a period of 10 years, we estimate these costs range from approximately $0.72 million to $1.25 million at a 3 percent discount rate, and approximately $0.65 million to $1.17 million at a 7 percent discount rate. Our primary annualized estimates are approximately $0.92 million at a 3 percent discount rate and $0.85 million at a 7 percent discount rate. The primary estimates of the present value of total costs in the 10 years following any final rule that may be issued based on the proposed rule are approximately $7.23 million at a 3 percent discount rate and $6.48 million at a 7 percent discount rate. These values are summarized in Table 1.

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

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year	$2.71	$1.14	$6.42	2022	7%	10 years	
		$2.66	$1.12	$6.31	2022	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Costs	Annualized Monetized $millions/year	$0.92	$0.72	$1.25	2022	7%	10 years	
		$0.85	$0.65	$1.17	2022	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year					7%		
						3%		
	From/To	From:			To:			
	Other Annualized Monetized $millions/year	$0.30	$0.19	$0.58	2022	7%	10 years	
		$0.28	$0.18	$0.56	2022	3%	10 years	
	From/To	From: Industry			To: FDA			

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Effects	State, Local or Tribal Government: None Small Business: None Wages: Growth:							

II. Preliminary Economic Analysis of Impacts

A. Background

Currently, solid wound dressings, wound dressings formulated as a gel, cream, or ointment, and liquid wound washes that contain antimicrobials and/or other chemicals are unclassified devices. Until an unclassified device type is formally classified by regulation, marketing of new devices within this device type requires FDA clearance of a 510(k). As described below, these devices are generally subject to premarket review through the 510(k) pathway and are cleared for marketing if their intended use and technological characteristics are "substantially equivalent" to devices that were in commercial distribution prior to the passage of the Medical Device Amendments on May 28, 1976.

After the enactment of the 1976 amendments, FDA commenced to identify and classify all preamendments devices in accordance with the Federal Food Drug & Cosmetic Act (FD&C Act). As part of this effort, FDA completed the classification process for four types of wound dressings as class I medical devices. These types are nonresorbable gauze/sponge for external use, hydrophilic wound dressings, occlusive wound dressings, and hydrogel wound dressings and burn dressings. However, wound dressings and liquid wound washes that contain antimicrobials and/or other chemicals were not included in these prior actions and are not separately classified to date.

Consistent with the FD&C Act, FDA convened multiple General and Plastic Surgery Devices Panel meetings regarding the classification of wound dressings (held on November 27, 1998; August 25 and 26, 2005; and September 20 and 21, 2016. From these meetings, FDA understands that wound dressings and liquid wound washes containing medically important antimicrobials pose higher AMR risk than other wound dressings and liquid wound washes. The proposed rule would establish the identification, classification, and regulatory controls for certain wound dressings, including solid wound dressings, wound dressings formulated as a gel, cream, or ointment, and liquid wound washes that contain antimicrobials and/or other chemicals. This rule would enhance existing FDA efforts to slow the spread of AMR and ensure safe and effective use of antimicrobials in wound dressings and liquid wound washes.

B. Need for Federal Regulatory Action

FDA is proposing to classify wound dressings and liquid wound washes that are currently unclassified and contain antimicrobials and/or other chemicals. The proposed rule is intended to safeguard public health by slowing the spread and development of AMR. To accomplish these aims, FDA is proposing to classify wound dressings and liquid wound washes containing medically important antimicrobials into class III. Wound dressings and liquid wound washes designated as class III would require the filing of a PMA. Solid wound dressings containing antimicrobials acting as a protectant with a medium or low level of AMR concern are proposed for classification into class II. Wound dressings formulated as a gel, cream, or ointment and liquid wound washes containing antimicrobials acting as a preservative with a medium or low level of AMR concern are also proposed for classification into class II.

The proposed rule addresses a source of market failure associated with the use of these products. The use of a wound dressing or liquid wound wash covered by this proposed rule potentially imposes a cost on society in the form of increased prevalence of AMR. Because medical providers and their patients primarily focus on the private benefits and costs associated with the use of a wound dressing or wash, they fail to fully account for the contribution of their use of these products to AMR prevalence in society. This is known as a negative externality. A consequence of a negative externality is that wound dressings or liquid wound washes may be used too frequently, given that the private benefits and costs of their use do not incorporate the additional social costs of AMR. Federal regulatory actions, such as this proposed rule, may help alleviate this market failure by limiting or changing the use of wound dressings and liquid wound washes containing antimicrobials.

C. Purpose of the Proposed Rule

The proposed rule is intended to classify certain wound dressings and liquid wound washes containing antimicrobials and/or other chemicals into either class III or class II, to identify and implement appropriate controls needed to provide reasonable assurance of safety and effectiveness for these devices. This includes controls designed to evaluate and address the level of AMR concern associated with utility of antimicrobials for preservative and protectant roles within these wound dressings and liquid wound washes, to slow the spread and development of AMR. In so doing, the proposed rule will better align the use of these wound dressings and liquid wound washes with their social costs.

D. Baseline Conditions

The impact of the proposed rule, if finalized, will depend on the number of affected entities and currently marketed products. To estimate the effects of the proposed rule, if finalized, we first identify the pre-regulation baseline prior to implementation of the regulation. Our estimates of the effects of the proposed regulation will be compared to the approximated baseline. We use the most recent and complete years of data as our baseline.

1. Number of covered products and entities

The proposed rule, if finalized, is intended to classify certain wound dressings and liquid wound washes into class III and class II There are approximately 538 wound dressings that will be affected by the proposed rule, if finalized.[2] Of these, FDA subject matter experts expect 1 will be classified as class III. The remaining 537 wound dressings and liquid wound washes are expected to be class II. Table 2 summarizes these anticipated classifications.

Table 2—Baseline Number of Products and Firms by Expected Classification

Category	Class III	Class II	Total
Products	1	537	538
Firms	1	245	246

Next, we estimate the number of entities affected by the proposed classification regulation using registration and listing information. Based on FDA registration and listing data, we estimate that there are approximately 246 medical device firms that manufacture wound dressings and liquid wound washes covered by this rule. The

[2] This number is based on data from FDA registration and listing information. See https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrl/textsearch.cfm.

distribution of these firms across expected classification(s) is also shown in Table 2. We expect that 1 firm will have wound dressings and liquid wound washes that are class III and 245 firms will have class II wound dressings and liquid wound washes.

2. Estimates of annual 510(k) submissions and approvals

Since 2017, FDA received between 35 and 60 510(k) submissions annually with an average of approximately 47 submissions.[3] Of these, it cleared between 10 and 30 submissions each year. FDA clears roughly 21 submissions on average annually for wound dressings and liquid wound washes considered as part of this classification regulation. We assume that future product submission and market authorization rates will remain the same as the current pre-regulatory baseline. These values are summarized in Table 3.

Table 3—Recent Annual 510(k) Submissions and Clearances for Covered Products

Calendar Year	Submitted 510(k)s	Cleared 510(k)s
2017	60	30
2018	46	27
2019	51	20
2020	35	18
2021	44	10
Average	47	21
Minimum	35	10
Maximum	60	30

To calculate the annual number of submitted and market authorized products expected to be in each classification category, we multiply the baseline values for annual submissions and market authorizations by the percentage of baseline products expected to be classified in each product category. For instance, in Table 2, nearly 100 percent of

[3] These values come from registration and listing data from 2017 to 2021. Primary values represent the average across each of these years of data, and not a simple average of the lower and upper bounds.

baseline FRO products are expected to be classified as class II (537 / 538 = 0.998). Multiplying this percentage by the minimum, average, and maximum values of annual submissions and approvals described in Table 3, we estimate that between approximately 35 and 60 products will be submitted for clearance as class II products each year. Of these, we expect approximately 10 to 30 clearances annually. Fewer products will be submitted and authorized as class III. The expected value of class III submissions and approvals is less than 1, with primary estimates of roughly 0.09 products submitted and 0.04 approved on average. These values are summarized in Table 4.

Table 4—Expected Annual Submissions and Market Authorizations by Expected Classification

	Expected Classification	**Lower Estimate**	**Primary Estimate**	**Upper Estimate**
Annual Submissions	Class III	0.07	0.09	0.11
	Class II	34.93	47.11	59.89
Annual Approvals	Class III	0.02	0.04	0.06
	Class II	9.98	20.96	29.94

E. Benefits of the Proposed Rule

1. Cost-savings from a reduction in submissions necessitating requests for additional information

Due to a lack of clear guidelines, such as a defined regulatory classification and published special controls, applicants may submit a 510(k) submission that is lacking information required for the submission's review or that includes excessive information (*e.g.*, performance claims and test reports) that exceed the utility of the 510(k) pathway, necessitating requests for additional information by CDRH. FDA estimates that the

majority of 510(k) submissions for the product codes within the scope of this classification action (upwards of 90%) are placed on Refuse to Accept (RTA) hold to address administrative issues such as a lack of data critical for substantive review. The number of 510(k) submissions that are placed on RTA hold has some uncertainty as some are voluntarily withdrawn at this juncture. Once the 510(k) submissions have been accepted for substantive review, roughly 60 percent have major deficiencies that requires additional testing before the device is able to be cleared. Using our earlier estimates of annual submissions, we estimate FDA reviews between 21 (35 submissions x 0.60 = 21) and 36 (60 submissions x 0.60 = 36) 510(k) submissions requiring additional information each year. The primary value is approximately 28 submissions annually. FDA estimates the average number of 510(k) submissions requiring additional information would be reduced by 70 percent, or by 15 (21 submissions x 0.70 = 15) to 25 (36 submissions x 0.70 = 25) submissions. The primary estimate of the reduction in 510(k) submissions requiring additional information is approximately 20.

Cost-savings from the reduction in 510(k) submissions requiring additional information reflect fewer 510(k) resubmissions and reduced review time for FDA staff. We estimate the cost-savings to industry and FDA by multiplying the reduction in submissions each year by estimated values of 510(k) preparation and review costs. In the baseline, medical device firms submit 510(k) submissions to FDA to receive clearance to market a new or modified product. These submissions are costly for industry to prepare and for FDA to review. We estimate that these submissions will cost between $64,000 and $255,000 in 2022 dollars (Eastern Research Group, 2012). The primary cost estimate is $127,000.

To calculate the cost-savings to industry from the reduction in incomplete 510(k) submissions requiring additional information, we multiply the average preparation and submission cost to prepare a 510(k) by the annual reduction in the number of 510(k) submissions requiring additional information. This results in a range of estimated cost-savings. The values range from approximately $0.94 million to $6.41 million, with a primary estimate of roughly $2.27 million. These estimates are summarized in Table 5.

Table 5—Cost-Savings from Fewer 510(k) Submissions Requiring Additional Information

	Low Annual Submissions	**Middle Annual Submissions**	**High Annual Submissions**
Preparation and Submission Savings	$0.94	$2.52	$6.41
FDA Review and Response Savings	$0.29	$0.40	$0.50

Note: Dollar values in millions of 2022 dollars.

For cost-savings accruing to FDA, we multiply the average 510(k) review cost by the estimated annual reductions in the number of 510(k) submissions requiring additional information. We estimate that it will cost $20,000 to review each 510(k) submission, in 2022 dollars (Geiger, 2005). This value incorporates costs needed to review the file, consult with others within the agency, work with the sponsor of the product to resolve any identified issues, document the review, and receive internal concurrence from leadership. We multiply this value by the estimated range of 510(k) submissions requiring additional information. The estimated cost-savings range from approximately $0.29 million to $0.50 million with primary value of $0.40 million. These estimates are summarized in Table 6.

2. Potential benefits left unquantified

There are benefits associated with the proposed rule that we do not quantify or monetize. These benefits are difficult to predict and any impacts on social welfare are uncertain. One potential source of public health benefits is avoided illness and death. The proposed rule is intended to promote public health by reducing unwarranted exposure to antimicrobials, including medically important antimicrobials that may directly contribute to the development and spread of AMR. By ensuring a more prudent antimicrobial usage in wound dressings, this may reduce mortality, decrease infections and associated sequelae, and lower medical spending. Unfortunately, the potential magnitude of these effects is uncertain and we lack sufficient data to make a prediction. If the proposed rule leads to a reduction in the spread of AMR, then the estimated benefits of the proposed rule in this analysis may be underestimated.

3. Summary of benefits

Table 6 summarizes the cost-savings associated with the proposed rule. Over the 10-year period following publication of any final rule that may be issued based on the proposed rule, the primary estimates of the present value of these savings are approximately $22.73 million at a 3 percent rate of discount and $19.02 million at a 7 percent rate of discount. Present values range from $9.57 million to $53.86 million at a 3 percent discount rate, and $8.01 million to $45.07 million at a 7 percent discount rate. The annualized values of the primary estimates are approximately $2.66 million and $2.71 million in cost savings per year at 3 and 7 percent rates of discount, respectively. Annualized values range from $1.12 million to $6.31 million at a 3 percent rate of discount, and $1.14 million to $6.42 million at a 7 percent rate of discount.

Table 6—Total Cost-Savings in 10-Year Period Following Rule Publication

	Discount Rate	**Low**	**Primary**	**High**
Present Value of Benefits	3%	$9.57	$22.73	$53.86
	7%	$8.01	$19.02	$45.07
Annualized Value of Benefits	3%	$1.12	$2.66	$6.31
	7%	$1.14	$2.71	$6.42

Note: Dollar values in millions of 2022 dollars.

F. Costs of the Proposed Rule

1. Costs to industry to read and understand the proposed rule

Manufacturers incur a one-time cost to read and understand the proposed rule. As recommended by guidance from the Department of Health and Human Services, we assume a reading speed of between 200 and 250 words per minute (Office of the Assistant Secretary for Planning and Evaluation, 2016). For simplicity, we take the midpoint of this range, 225 words per minute, as our primary estimate of reading time. The proposed rule consists of over 27,000 words. This implies that approximately 122 minutes, roughly 2 hours, are needed to read and understand the proposed rule (27,000 words / 225 words per minute = 122 minutes). Estimates of reading time based on a reading speed of 200 and 250 words per minute range from approximately 137 to 110 minutes, respectively.

We use these estimates to calculate the monetary costs associated with reading and understanding the proposed rule. To do so, we use information on hourly wages. We assume that 1 lawyer reads and interprets the proposed rule for their firm. The mean hourly wage for lawyers in the medical equipment and supplies manufacturing industry, as reported by the US Bureau of Labor Statistics, is $103.20 in 2022 dollars (US Bureau of Labor Statistics, 2022). We double this wage to account for the value of benefits and

overhead. This fully-loaded hourly wage is $206.39. For each firm, the cost to read and understand the proposed rule is just over $420($206.39 per hour x 122 minutes = $420). Across all 246 manufacturers, the total cost is approximately $103,300 ($368 per firm x 246 firms = $103,300). The high and low reading speed estimates are approximately $93,000 and $116,200. We assume that firms incur this cost immediately after publication of the proposed rule, if finalized. These estimates are summarized in Table 7.

Table 7—Costs to Read and Understand the Rule

	Low	**Primary**	**High**
One-time Costs to Industry	$92,955	$103,283	$116,193

Note: Dollar values in 2022 dollars.

2. Costs from class III classification

a. Cost related to PMAs and associated reports

Manufacturers of solid wound dressings, wound dressings formulated as a gel, cream, or ointment, and liquid wound washes containing medically important antimicrobials (*i.e.*, antimicrobial drugs that are important for therapeutic use in humans and associated with a high level of AMR, which is the ability of a microorganism to resist the effects of an antimicrobial) will incur additional costs because of the proposed rule. These costs accrue to firms of products designated as class III, thus requiring a PMA. This will affect both currently marketed products and any future products that firms seek to market as class III. For industry, costs include resources necessary to prepare and submit PMAs, prepare and submit annual and supplemental reports, and labor burdens related to facility inspections. For FDA, costs include resources to review and respond to PMAs, review and respond to annual and supplemental reports, and to inspect facilities.

FDA previously estimated that the cost to industry to prepare and submit a PMA was $1 million in 2008 (Food and Drug Administration, 2008). Adjusted to 2022 dollar values, this amount is roughly $1.27 million. Because FDA expects 1 currently marketed product to be classified as class III, the total cost to industry to prepare and submit a PMA for this product is approximately $1.27 million ($1.27 million x 1 products = $1.27 million). More recent data suggests that PMA submission costs are higher, roughly $2.21 million in 2022 dollars (Sertkaya, DeVries, Jessup, & Beleche, 2022). We take the average of these two values as our primary estimate of $1.74 million. These estimates are summarized in Table 9.

Manufacturers of products in the future will incur an incremental cost because of the proposed rule. These firms, under baseline conditions in absence of the rule, submit a 510(k) submission to market their product. Consequently, the incremental cost of a PMA is the cost of that application less the cost to prepare and submit a 510(k). Using the primary estimate of 510(k) preparation and submission costs in a preceding section, we estimate this value as roughly $1.61 million ($1.74 million - $127,000 = $1.61 million). Combined with our expected number of future class III submissions from Table 4, we estimate that ongoing annual costs to industry will have a primary value of over $141,900. The lower and upper bounds are $78,800 and $218,500, respectively. These estimates are also summarized in Table 8.

Table 8—Costs to Industry from PMAs

	Low Annual Submissions	**Middle Annual Submissions**	**High Annual Submissions**
Expected One-time Costs for Currently Marketed Products*	$1.27	$1.74	$2.21

Expected Ongoing Costs for Future Products^	$78,778	$141,868	$218,525

* Dollar values in millions of 2022 dollars.
^ Dollar values in 2022 dollars.

Firms marketing a class III product must also comply with annual reporting requirements. To maintain marketing approval, these reports require the manufacturer to submit information summarizing changes to the product, results of unpublished investigations and studies, and reports in the scientific literature regarding the device. Lacking direct evidence of the cost to prepare and submit annual reports, we assume the ratio of user fee to preparation cost is the same for annual reports as for the PMA itself. This yields an estimate of the cost to prepare and submit an annual report of approximately $61,100.[4]

To calculate the total cost to industry due to annual reports, we multiply this value by the expected number of class III devices on the market in each year after the effective date of the proposed rule, if finalized. The number of products in each year is calculated using the value from the previous year and adding the expected number of approvals in the class III category, shown above in Table 4.[5] In the first year after the effective date of the proposed rule, if finalized, we estimate the primary total cost to industry to prepare and submit an annual report is roughly $63,400. By the tenth year after publication, this estimate rises to nearly $84,900 due to the increase in the expected number of class III products. The low and high estimates range from approximately $62,200 to $64,500 in

[4] The fiscal year 2023 user fees for a PMA and annual report submission are $441,547and $15,454, respectively. We estimate that the cost to prepare and submit a PMA is $1.74 million. The user fee to cost ratio is 0.25 ($441,547/ $1.74 million = 0.25). To yield this same ratio value of 0.25, the cost to industry to prepare and submit an annual report is $$61,100 ($15,454/ $61,100 = 0.25).
[5] We assume that products do not exit the market.

the first year and $72,400 to $95,100 in the tenth year. These estimates are summarized in Table 9.

Table 9—Costs to Industry from Annual Reports for Class III Products

Years After Publication	Low Approvals		Primary Approvals		High Approvals	
	No. of Reports	Costs	No. of Reports	Costs	No. of Reports	Costs
1	1.0	$62,192	1.0	$63,441	1.1	$64,462
2	1.0	$63,327	1.1	$65,824	1.1	$67,867
3	1.1	$64,462	1.1	$68,207	1.2	$71,272
4	1.1	$65,597	1.2	$70,591	1.2	$74,676
5	1.1	$66,732	1.2	$72,974	1.3	$78,081
6	1.1	$67,867	1.2	$75,357	1.3	$81,486
7	1.1	$69,002	1.3	$77,741	1.4	$84,890
8	1.1	$70,137	1.3	$80,124	1.4	$88,295
9	1.2	$71,272	1.4	$82,507	1.5	$91,700
10	1.2	$72,407	1.4	$84,890	1.6	$95,105

Note: Dollar values in 2022 dollars.

Manufacturers of class III products may also incur supplemental reporting costs in the future. Supplements to an existing PMA are required whenever a firm wishes to make a change that affects the safety or effectiveness of a currently marketed device. Such changes may include new indications for use, labeling changes, or a change in packaging. Based on data internal to the agency, we estimate that each PMA receives nearly 3.5 supplements each year.[6] We use this value as an upper bound estimate of the number of supplemental reports submitted for each device annually. We assume that the primary estimate is 1 supplemental report per device annually, and that the lower bound is 0.5 reports. This lower bound is meant to represent a scenario where not all class III wound dressing devices receive a supplemental report in a given year.

[6] This is based on a subset of PMAs for cardiovascular devices between 2005 and 2010.

As with annual reports, we lack information of the cost to prepare and submit a supplemental report. Consequently, we again assume that the ratio of user fee to preparation cost is the same for supplemental reports as it is for the PMA. This results in an estimate of approximately $87,200.[7] To calculate the total cost to industry due to supplemental reports, we multiply this value by the expected number of class III devices on the market in each year after publication of the proposed rule, if finalized. We then multiply by the estimated number of supplements per device in each year. For instance, in the first year after publication of the final rule, our primary estimate of supplemental reporting cost is roughly $90,600. By the tenth year after publication, this estimate rises to over $121,200 due to the increase in the expected number of supplemental reports. The low and high estimates range from approximately $44,400 to $315,600 in the first year and $59,000 to $359,300 in the tenth year. These estimates are summarized in Table 10.

Table 10—Costs to Industry from Supplemental Reports for Class III Products

Years After Publication	**Low Approvals**		**Primary Approvals**		**High Approvals**	
	No. of Reports	Costs	No. of Reports	Costs	No. of Reports	Costs
1	0.5	$44,387	1.0	$90,556	3.6	$315,609
2	0.5	$46,007	1.1	$93,958	3.7	$320,469
3	0.5	$47,627	1.1	$97,360	3.7	$325,329
4	0.6	$49,247	1.2	$100,762	3.8	$330,189
5	0.6	$50,867	1.2	$104,164	3.8	$335,049
6	0.6	$52,487	1.2	$107,566	3.9	$339,909
7	0.6	$54,107	1.3	$110,968	4.0	$344,769
8	0.6	$55,727	1.3	$114,370	4.0	$349,629
9	0.7	$57,347	1.4	$117,772	4.1	$354,489
10	0.7	$58,967	1.4	$121,174	4.1	$359,349

Note: Dollar values in 2022 dollars.

[7] The methodology is the same as for annual reports. However, the user fee for supplemental reports is calculated as a weighted average because there are different types of supplemental reports, each associated with a different user fee. The weights in the weighted-average calculation represent the percentage of the total for each type of supplemental report.

FDA will also experience additional PMA costs because of the proposed rule, if finalized. We estimate that it will cost FDA approximately $781,100 to review each application. This is based on a 2005 estimate of $563,000, which we adjust to 2022 dollar values (Geiger, 2005). Because FDA expects 1 currently marketed product to be classified as class III, the total cost to the agency to review a PMA is approximately $843,600. This estimate is summarized in Table 11.

The agency will also spend resources reviewing future PMAs. Using our expected number of future class III applications from Table 4, we estimate that ongoing annual costs to FDA will have a primary value of almost $74,000. The lower and upper bounds are approximately $54,900 and $94,100, respectively. These estimates are also summarized in Table 12.

Table 11—Costs to FDA from PMAs

	Low annual applications	**Primary annual applications**	**High annual applications**
Expected One-time Costs for Currently Marketed Products		$843,638	
Expected Ongoing Costs for Future Products	$54,883	$74,014	$94,086

Note: Dollar values in 2022 dollars.

FDA must also review and respond to annual and supplemental reports submitted by industry. Our estimate of the cost to review an annual or supplemental report is $22,100. This value is based on a 2005 estimate of $14,700, which we adjust to 2022 dollar values (Geiger, 2005). For annual reports, we use this estimate to calculate agency review costs. We multiply the value by the expected number of class III devices on the market in each year after publication of the proposed rule, if finalized. In the first year

after publication of the final rule, our primary estimate of annual report review costs is roughly $22,900, By the tenth year after publication, this estimate is nearly $30,700. The low and high estimates range from approximately $22,500 to $23,300 in the first year and $26,200 to $34,400 in the tenth year. These estimates are summarized in Table 12.

Table 12—Costs to FDA from Annual Reports for Class III Products

Years After Publication	**Low Approvals**		**Primary Approvals**		**High Approvals**	
	No. of Reports	Costs	No. of Reports	Costs	No. of Reports	Costs
1	1.0	$22,464	1.0	$22,915	1.1	$23,283
2	1.0	$22,874	1.1	$23,775	1.1	$24,513
3	1.1	$23,283	1.1	$24,636	1.2	$25,743
4	1.1	$23,693	1.2	$25,497	1.2	$26,973
5	1.1	$24,103	1.2	$26,358	1.3	$28,202
6	1.1	$24,513	1.2	$27,219	1.3	$29,432
7	1.1	$24,923	1.3	$28,079	1.4	$30,662
8	1.1	$25,333	1.3	$28,940	1.4	$31,892
9	1.2	$25,743	1.4	$29,801	1.5	$33,122
10	1.2	$26,153	1.4	$30,662	1.6	$34,351

Note: Dollar values in 2022 dollars.

Agency review costs for supplemental reports are calculated by multiplying $20,400 by the expected number of class III devices on the market in each year after rule publication. We then multiply by the estimated number of supplements per device in each year. In the first year after publication of the final rule, our primary estimate of supplemental report review costs is roughly $22,900, By the tenth year after publication, this estimate is nearly $30,600. The low and high estimates range from approximately $11,200 to $79,900 in the first year and $14,900 to $90,900 in the tenth year. These estimates are summarized in Table 13.

Table 13—Costs to FDA from Supplemental Reports for Class III Products

Years After Publication	Low Approvals		Primary Approvals		High Approvals	
	No. of Reports	Costs	No. of Reports	Costs	No. of Reports	Costs
1	0.5	$11,232	1.0	$22,915	3.6	$79,862
2	0.5	$11,642	1.1	$23,775	3.7	$81,092
3	0.5	$12,052	1.1	$24,636	3.7	$82,322
4	0.6	$12,462	1.2	$25,497	3.8	$83,551
5	0.6	$12,871	1.2	$26,358	3.8	$84,781
6	0.6	$13,281	1.2	$27,219	3.9	$86,011
7	0.6	$13,691	1.3	$28,079	4.0	$87,241
8	0.6	$14,101	1.3	$28,940	4.0	$88,471
9	0.7	$14,511	1.4	$29,801	4.1	$89,700
10	0.7	$14,921	1.4	$30,662	4.1	$90,930

Note: Dollar values in 2022 dollars.

b. Cost of inspections

As part of the PMA process, FDA field personnel may inspect the manufacturing facilities belonging to the manufacturer. These inspections are costly for both industry and the agency. We assume that industry costs are twice as large as for FDA. Firms must prepare for the inspection and perform practice runs, as well as host the inspection itself (Eastern Research Group, 2012). These costs are estimated to be $127,500 for FDA and $254,900 for each firm. We estimate that initial one-time inspections of the 1 currently marketed wound dressings expected to be classified as class III will cost $127,000 for the agency and $254,900 for industry. In addition, we estimate that ongoing inspection costs for future PMA submissions will have a primary expected value of approximately $11,200 for the agency and $22,400 for industry. These values are calculated by multiplying the expected number of applications from Table 4 by the inspection cost estimates. We summarize the total inspection costs in Table 14.

Table 14—Costs to Related to Facility Inspections

	Affected Entity	Low Annual Applications	Primary Annual Applications	High Annual Applications
Expected One-time Costs to Firms of Currently Marketed Products	Industry		$254,933	
	FDA		$127,466	
Expected Ongoing Costs to Firms of Future Products	Industry	$16,585	$22,366	$28,431
	FDA	$8,292	$11,183	$14,216

Note: Dollar values in 2022 dollars.

3. Relabeling costs

The proposed rule, if finalized, will likely induce many firms to modify the labeling of their products. FDA estimates that 90 percent of currently marketed products covered by this rule will update their labeling. We take this as our primary estimate of the number of products that will undergo a change in labeling. Because this value is ultimately uncertain, we use 85 percent and 95 percent of currently marketed wound dressings and liquid wound washes as our lower and upper bounds, respectively.

To estimate industry relabeling costs, we use the FDA Labeling Cost Model developed by RTI International (RTI International, 2015). This model uses data provided by FDA to estimate the cost of a labeling change for specific types of products, minor to extensive labeling changes, and different compliance periods. The estimates we present

in this section correspond to a minor labeling change for adhesive bandages (medicated, nonmedicated, liquid, powder), medical wraps, and first aid gauze and tape.[8]

One-time relabeling costs are shown in Table 15. These costs are incurred immediately after the proposed rule, if finalized, becomes effective. Estimates from the model range from approximately $304 to $2,600 per device, with a primary estimate of $1,100 per device. Aggregating across all wound dressings and liquid wound washes, the total one-time relabeling costs range from approximately $515,700 to $576,400. The primary estimate is $546,100.

Table 15—One-time Relabeling Costs to Industry

	Low	**Primary**	**High**
Percent of Baseline Products	85%	90%	95%
Number of Affected Products	457	484	511
Total Relabeling Costs	$515,714	$546,050	$576,386

Note: Dollar values in 2022 dollars.

4. Summary of costs

Table 16 summarizes costs related to reading and understanding the proposed rule, the class III designation, and relabeling costs, if the rule is finalized.[9] These costs begin to accrue after any final rule based on this proposed rule becomes effective. Both FDA and industry are expected to incur costs from the proposed rule upon finalization. The total present value of our cost estimates range from approximately $5.55 million to $10.03 million at a 3 percent rate of discount, with a primary estimate of $7.24 million. For the 7 percent rate of discount, the present value of costs range from roughly $5.03 million to $8.78 million with a primary value of $6.49 million. The primary annualized

[8] A minor labeling change has a specific definition in this model. This change is defined as a one-color change that does not require a redesign of the labeling itself.

[9] We do not expect the loss of information from fewer 510(k) submissions to result in additional social costs. FDA does not expect this information would be valuable for managing public health risk or accomplishing the other regulatory goals of the rule, if finalized.

values of these costs in the 10 years following rule publication are approximately $0.85 million at a 3 percent rate of discount and $0.92 million at a 7 percent rate of discount. The annualized cost estimates range in value from $0.65 million to $1.18 million at a 3 percent rate of discount, and $0.72 million to $1.25 million at a 7 percent rate of discount.

Table 16—Total Costs in 10-Year Period Following Publication of the Final Rule

	Discount Rate	**Low**	**Primary**	**High**
Present Value of Costs	3%	$5.55	$7.24	$10.03
	7%	$5.03	$6.49	$8.78
Annualized Value of Costs	3%	$0.65	$0.85	$1.18
	7%	$0.72	$0.92	$1.25

Note: Dollar values in millions of 2022 dollars.

G. Distributional Effects

We do not anticipate that the proposed rule, if finalized, will result in differential impacts across varying income, ethnic, geographic, gender, or age groups. This is primarily because we only estimate benefits and costs accruing to FDA and industry. However, patients receiving medical care and other consumers of wound dressings and liquid wound washes covered by this proposed classification action may be affected by this proposed rule. These impacts could come in the form of improved transparency in product labeling leading to more informed purchases and decreased AMR prevalence and associated reductions in morbidity, and medical spending. Because access to medical care changes substantially across varying income, ethnic, geographic, gender, and age groups, these unquantified public health impacts may not be evenly distributed.

H. Transfers Caused by the Proposed Rule

The proposed rule, if finalized, will generate transfers in the form of user fee payments from industry to FDA. These user fees are the result of covered products

receiving the class III designation and associated PMA applications. For currently marketed products, one-time transfer fees are incurred in the first year after final rule publication. This includes fees for the PMA application itself, as well as any associated annual and supplemental reports.[10] In subsequent years, we multiply these fees against the expected number of new PMA applications, annual reports, and supplemental reports. The expected number of applications are described above in Table 4. User fees generated by new PMA applications are calculated after subtracting corresponding 510(k) user fees that would have occurred in the baseline. Transfers in each year after final rule publication are found in Table 17.

Table 17- User Fee Transfers from Industry to FDA in 10-Year Period after Publication

Years after Publication	Low	Primary	High
1	$614,029	$671,234	$905,316
2	$71,781	$131,083	$366,882
3	$83,433	$155,553	$401,839
4	$95,085	$180,023	$436,796
5	$106,738	$204,493	$471,753
6	$118,390	$228,963	$506,710
7	$130,042	$253,433	$541,667
8	$141,695	$277,902	$576,623
9	$153,347	$302,372	$611,580
10	$164,999	$326,842	$646,537

Note: Dollar values in 2022 dollars.

Table 18 summarizes transfers related to the PMA process if the rule is finalized. The total present value of our transfer estimates range from approximately $1.52 million to $4.80 million at a 3 percent rate of discount, with a primary estimate of $2.42 million. For the 7 percent rate of discount, the present value of transfers range from roughly $1.35

[10] User fees for fiscal year 2023 are found on: https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa

million to $4.10 million with a primary value of $2.09 million. The primary annualized values of these costs in the 10 years following rule publication are approximately $0.28 million at a 3 percent rate of discount and $0.30 million at a 7 percent rate of discount. The annualized cost estimates range in value from $0.18 million to $0.56 million at a 3 percent rate of discount, and $0.19 million to $0.58 million at a 7 percent rate of discount.

Table 18- Total User Fee Transfers

	Discount Rate	Low	Primary	High
Present Value of Costs	3%	$1.52	$2.42	$4.80
	7%	$1.35	$2.09	$4.10
Annualized Value of Costs	3%	$0.18	$0.28	$0.56
	7%	$0.19	$0.30	$0.58

Note: Dollar values in millions of 2022 dollars.

I. International Effects

We do not anticipate that the proposed rule, if finalized, will substantially impact imports of covered products. The costs associated with this rule represent a small fraction of revenue for firms in this industry.

J. Analysis of Regulatory Alternatives to the Proposed Rule

1. Remove class III designation and classify affected products as class II

In this section, we assume that the proposed rule does not classify certain wound dressings and liquid wound washes as class III. Rather, the proposed rule would designate these products as class II. Costs related to PMAs and subsequent reporting requirements would be eliminated under this scenario. The only remaining quantified costs would come from resources needed to read and understand the rule and relabeling.

Total benefits and costs under this scenario are summarized in Table 17. Panel A of Table 18 shows the total estimated cost savings under this regulatory alternative. These

values are identical to those from the main analysis. Panel B shows the combined estimates of costs related to reading and understanding the rule and relabeling. Relative to the main analysis, the ratio of quantified benefits to costs is larger if the class III designation is eliminated. As above, however, we do not estimate potential public health impacts from slowing the spread and development of AMR due to the proposed rule in this analysis. It is possible that eliminating the class III designation from the rule may affect these potential benefits.

Table 19—Cost-savings and Costs from Removing Class III Designation for Covered Wound Dressings and Liquid Wound Washes

	Discount Rate	**Low**	**Primary**	**High**
Panel A: Cost-savings				
Present Value of Cost-savings	3%	$9.57	$22.73	$53.86
	7%	$8.01	$19.02	$45.07
Annualized Value of Cost-savings	3%	$1.12	$2.66	$6.31
	7%	$1.14	$2.71	$6.42
Panel B: Costs				
Present Value of Costs	3%	$0.59	$0.63	$0.68
	7%	$0.57	$0.61	$0.65
Annualized Value of Costs	3%	$0.07	$0.07	$0.08
	7%	$0.08	$0.09	$0.09

Note: Dollar values in millions of 2022 dollars.

2. 510(k) Exemption for specific wound dressings and washes

Next, we consider as an alternative where certain liquid wound washes are exempted from 510(k) requirements. These include liquid wound washes containing antimicrobial(s) with a low level of AMR concern and liquid wound washes containing water or saline only, which do not contain antimicrobials with a medium to high level of AMR concern. For these products, under the alternative considered, FDA assumes that a

510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of this wound dressing type. As a result, additional cost-savings from avoided 510(k) submissions would accrue to industry and FDA. The agency estimates that 15 products would be exempt from the 510(k) process under this alternative.

Total benefits and costs under this scenario are summarized in Table 18. Panel A shows the total estimated cost-savings under this regulatory alternative. These values reflect cost-savings from both reductions in 510(k) submissions requiring additional information and avoided submissions due to the exemption. Panel B shows the total estimated costs from the main analysis. These cost estimates are identical to those in the main analysis. Relative to the main analysis, the ratio of quantified benefits to costs is larger when the exemption for certain class II products is added to the rule.

Table 20—Cost-savings and Costs from Including a 510(k) Exemption for Specific Wound Dressings and Washes

	Discount Rate	**Low**	**Primary**	**High**
Panel A: Cost-savings				
Present Value of Cost-savings	3%	$9.94	$23.61	$55.93
	7%	$8.32	$19.75	$46.80
Annualized Value of Cost-savings	3%	$1.17	$2.77	$6.56
	7%	$1.18	$2.81	$6.66
Panel B: Costs				
Present Value of Costs	3%	$5.55	$7.24	$10.03
	7%	$5.03	$6.49	$8.78
Annualized Value of Costs	3%	$0.65	$0.85	$1.18
	7%	$0.72	$0.92	$1.25

Note: Dollar values in millions 2022 dollars.

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 costs of the proposed rule will primarily accrue to large firms, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this document and the Preamble of the proposed rule, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

A. Description and Number of Affected Small Entities

We find that most firms affected by this rule are classified as small. The North American Industry Classification System (NAICS) code that best matches the affected industry is 339113.[11] For this code, the Small Business Administration (SBA) defines firms with 750 or fewer employees as small (US Small Business Administration, 2019). We compare this threshold with firm data from the Economic Census (US Census Bureau, 2021). Based on these data, shown in Table 19, there were 1,651 firms under NAICS code 339113 in 2017. All but 64 of these establishments had fewer than 750 employees. This implies that 1,587 firms in 2017 were small under the SBA standard.

Table 21—Distribution of Firms under NAICS 339113 by Number of Employees

Number of Employees	Number of Firms in NAICS 339113	Percent of Total Establishments	Total Revenues
Less than 5	625	38%	$411.97
5 to 9	323	20%	$542.89
10 to 19	231	14%	$755.16
20 to 99	277	17%	$2,562.64
100 to 749	131	8%	$5,486.84
Greater than 749	64	4%	$33,478.28

[11] This code covers manufacturers of surgical appliances and supplies, including bandages and dressings.

Total	1,651	100%	$43,237.78

Note: Dollar values in millions 2022 dollars.

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

The proposed rule will not have a significant impact on a substantial number of small entities. Table 20 shows information on firm revenue. Based on data from the 2017 Economic Census, the average revenue per firm under NAICS code 339113 is approximately $26.19 million in 2022 dollars (US Census Bureau, 2021). Using the total costs from the main analysis, the overall average cost per manufacturer affected by the proposed rule ranges from approximately $2,600 to $4,800, with a primary estimate of $3,400.[12] As a percentage of average revenue per firm, these costs do not exceed 1 percent.

Table 20—Comparison of Proposed Rule Costs with Firm Revenues

Number of Employees	Average Revenue per Firm*	Low: Avg. Cost per Covered Entity^	Low: Cost as % of Average Revenue	Primary: Avg. Cost per Covered Entity^	Primary: Cost as % of Average Revenue	High: Avg. Cost per Covered Entity^	High: Cost as % of Average Revenue
Less than 5	$0.66	$2,644	0.40%	$3,449	0.52%	$4,778	0.72%
5 to 9	$1.68	$2,644	0.16%	$3,449	0.21%	$4,778	0.28%
10 to 19	$3.27	$2,644	0.08%	$3,449	0.11%	$4,778	0.15%
20 to 99	$9.25	$2,644	0.03%	$3,449	0.04%	$4,778	0.05%
100 to 749	$41.88	$2,644	0.01%	$3,449	0.01%	$4,778	0.01%
Greater than 749	$523.10	$2,644	0.00%	$3,449	0.00%	$4,778	0.00%
Total	$26.19	$2,644	0.01%	$3,449	0.01%	$4,778	0.02%

* Dollar values in millions of 2022 dollars.
^ Dollar values in 2022 dollars.

[12] Based on cost estimates using the 3 percent rate of discount.

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