DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Revised Procedures for the Announcement of Approvals and Denials of Premarket Approval Applications and Humanitarian Device Exemption Applications

Docket No. FDA- FDA-2019-N-3101

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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Office of Economics and Analysis
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I. Introduction and Summary

A. Introduction

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

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule will not impose any additional regulatory burden on the industry, we certify that the 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 an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

The benefit of this final rule is that it will result in cost savings to the Food and Drug Administration (FDA) from discontinuing publishing in the *Federal Register*, on a quarterly basis, a list of approvals and denials of medical device premarket approval applications (PMAs) and humanitarian device exemption applications (HDEs). Discontinuing publishing *Federal Register* notices with these approval and denial lists will eliminate duplication in announcing this information; information on these approvals and denials will continue being readily available to the public on FDA's home page on the Internet (https://www.fda.gov).

We estimate that this final rule will result in no additional costs to industry because the rule will not require performance of any additional tasks. The rule, therefore, will not impose any additional regulatory burden on the industry.

Table 1 summarizes the estimated benefits and costs of the final rule. Annualized over 10 years, the estimated benefits (*i.e.*, cost savings) of the final rule range from $0.008 million to $0.013 million at both 3 and 7 percent discount rate, with a primary estimate of $0.010 million. The present value of the estimated benefits (*i.e.*, cost savings) of the final rule ranges from $0.068 million to $0.111 million at a 3 percent discount rate and from $0.056 million to $0.091 million at a 7 percent discount rate. The annualized costs of the final rule are $0 at both 3 and 7 percent discount rate. The present value of costs of the final rule is also $0 at both 3 and 7 percent discount rate.

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

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year	$0.010	$0.008	$0.013	2020	7%	10 years	Benefits are cost savings
		$0.010	$0.008	$0.013	2020	3%	10 years	Benefits are cost savings
	Annualized Quantified							
	Qualitative							
Costs	Annualized Monetized $millions/year	$0	$0	$0	2020	7%	10 years	
		$0	$0	$0	2020	3%	10 years	
	Annualized Quantified							
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year							
	From/ To	From:			To:			
	Other Annualized Monetized $millions/year							
	From/To	From:			To:			
Effects	State, Local or Tribal Government: No significant effect Small Business: No significant effect Wages: N/A Growth: N/A							

C. Comments on the Preliminary Economic Analysis of Impacts

We published a proposed rule on December 17, 2019 (84 FR 68829), that would amend the medical device regulations by discontinuing the publication in the *Federal Register* after each quarter a list of PMA and HDE approvals and denials announced in that quarter. The proposed rule would also update Agency contact information and statutory references in certain sections of the PMA and HDE regulations for purposes of accuracy, clarity, and consistency. We received three public comments on the proposed

rule, one of which was outside the scope of the proposed rule. We respond to these comments in the preamble.

D. Summary of Changes

We retain the benefit and cost model used in the Preliminary Regulatory Impact Analysis (PRIA) for this Final Regulatory Impact Analysis. We update the dollar figures reported for the cost savings into the most recent year available (2020).

II. Final Economic Analysis of Impacts

A. Background

FDA's current process for announcing medical device PMA and HDE approvals and denials includes the following duplicate procedures. FDA posts PMA and HDE approval and denial notices on FDA's home page on the Internet (https://www.fda.gov). FDA also periodically publishes in the *Federal Register* a notice with a list of PMA and HDE approvals and denials. This duplication in providing information regarding PMA and HDE approvals and denials is a time and resource burden to FDA that can be eliminated without losing transparency of information to the public.

B. Need for Federal Regulatory Action

FDA's existing procedures for announcing PMA and HDE approvals and denials include duplication in providing information regarding PMA and HDE approvals and denials that does not carry the benefit of added efficiency. There is also inconsistency in

FDA's regulations relating to requesting copies of the current PMA approvals and denials document and copies of safety and effectiveness data (SSED) that does not carry the benefit of added efficiency. Current § 814.45(d)(2) states that these requests shall be sent to the Freedom of Information (FOI) Staff's address. However, current § 814.44(d)(2) states that such requests shall be sent to the Division of Dockets Management, which we are also referring to as "Dockets Management Staff" in this document. The market cannot self-correct such inefficiency without FDA amending the existing regulatory requirements for announcing PMA and HDE approvals and denials and for requesting copies of the current PMA approvals and denials document and copies of SSED.

C. Purpose of the Rule

The final rule will amend the current procedures for announcing PMA and HDE approvals and denials. Discontinuing periodically publishing in the *Federal Register* a notice with a list of PMA and HDE approvals and denials will allow FDA to eliminate excess costs related to duplication in announcing this information. The final rule will also revise § 814.44(d)(2), regarding requesting copies of the current PMA approvals and denials document and copies of SSED, to state that such requests must be sent to FOI Staff, rather than to the Dockets Management Staff. This will lead to consistency between § 814.44(d)(2) and § 814.45(d)(2) because the latter currently states that requests for copies of the current PMA approvals and denials document and copies of SSED shall be sent to FOI Staff. The final rule will also update outdated references to section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and replace them with references to section 515(d)(4), since section 515(d)(3) was redesignated as

515(d)(4) by section 202 of the Food and Drug Administration Modernization Act of 1997.

D. Baseline Conditions

a. Covered Entities and Products

The final rule will address the announcement procedures for approvals and denials of PMAs for Class III medical devices and for approvals and denials of HDEs for Humanitarian Use Devices (HUDs). We estimate that currently the medical device industry consists of about 39,000 establishments, including over 26,000 medical device manufacturers.[1] We also estimate that currently about 760 firms have one or more Class III medical devices and about 60 firms have HUDs on the U.S. market.[2] These entities are likely to be routinely interested in the announcements of PMA and HDE approvals and denials.

Other entities, such as entities who may use public resources for conducting biomedical, regulatory, and medical product research may also be routinely interested in information from the FDA on medical device approvals and denials. We believe, however, that medical device manufacturers and these other entities will not be affected by the final rule because they will continue obtaining the same information on PMA and HDE approvals and denials from FDA's home page on the Internet (https://www.fda.gov). The only entity that will be affected by the final rule is the FDA.

[1] FDA Registration and Listing Database, June 5, 2020.
[2] FDA Premarket Approvals (PMAs) and Humanitarian Device Exemption (HDE) Databases, May 2020.

b. Current Practices

Currently, interested entities can obtain information on PMA and HDE approvals and denials on FDA's home page on the Internet (https://www.fda.gov), and the information is typically available more quickly on FDA's home page than in the *Federal Register*. Entities can access this information on FDA's home page without the need to wait potentially weeks or months for the FDA to publish a *Federal Register* notice with a list of approvals and denials. Obtaining information on PMA and HDE approvals and denials in a timely matter may be important to interested entities for a variety of reasons, including because FDA considers the 30-day period for requesting reconsideration of an FDA action under § 10.33(b) for notices of PMA and HDE approval to begin on the day the notice is placed on the Internet. Accordingly, we believe that currently nearly all interested entities obtain this FDA notification of PMA and HDE approvals and denials on FDA's home page on the Internet (https://www.fda.gov) instead of the *Federal Register*.

We also believe that in addition to approval and denial notices for PMAs and HDEs, these entities already routinely use FDA's homepage on the Internet to find copies of SSED for PMAs and copies of summaries of safety and probable benefit (SSPB) for HDEs. Such additional information and data are currently available and will continue to be available on the Internet and through requests to the FDA's FOI Staff. Currently, FDA requires that any entity that is submitting a request for copies of the current PMA approvals and denials document and copies of SSED must submit a written request. These written requests are processed by the FOI Staff even if submitted through the Dockets Management Staff as specified by current § 814.44(d)(2). The annual number of

requests that are mailed or submitted in person to the Dockets Management Staff is negligible.

E. Benefits of the Rule

Eliminating duplication in the current process for announcing medical device PMA and HDE approvals and denials will result in time and cost savings to FDA. The final rule will allow the Agency to use its valuable resources more efficiently by reallocating them to other priorities.

We estimate that discontinuing publishing in the *Federal Register*, on a quarterly basis, a notice with a list of PMA and HDE approvals and denials will result in annual time savings of about 60 hours (between 40 and 80 hours) of FDA employees' time. FDA employees will no longer need to spend time preparing, reviewing, editing, coordinating and sending this quarterly notification document to the *Federal Register*. Using FDA's Fully Loaded Full Time Employee Cost Model for FY 2020, we estimate that the total cost of a full-time FDA employee's time is $133 per hour (in 2020 dollars) after adjusting for benefits and overhead. In addition, FDA will no longer need to pay a publication fee to the *Federal Register*. We estimate the saved publication fees to be about $2,500 per year.[3] Therefore, the total annual cost savings to FDA, which comes from the elimination of employee time needed and the elimination of *Federal Register* publication fees, are between $0.008 million and $0.013 million, with our best estimate of about $0.010 million (= $133 x 60 hours + $2,500).

[3] Based on the most current (2018) *Federal Register* publishing rates and the average 4-column length of a typical notice: https://www.gpo.gov/how-to-work-with-us/agency/circular-letters/new-federal-register-publishing-rates

We estimate that cost savings to FDA related to forwarding and coordinating requests for copies between the Dockets Management Staff and the FOI Staff will be negligible because the number of requests that are annually mailed or submitted in person through the Dockets Management Staff is negligible.

F. Costs of the Rule

We estimate that the medical device industry will not incur any costs because the final rule will not require performance of any additional tasks and, therefore, will not impose any additional regulatory burden on the industry. It is unlikely that entities in the medical device industry have no access to the Internet. In lieu of obtaining a list of PMA and HDE approvals and denials from the *Federal Register*, these entities will easily be able to continue obtaining PMA and HDE approval and denial information from FDA's home page on the Internet (https://www.fda.gov). Moreover, we believe that an interested entity is more likely to routinely seek this information on FDA's home page on the Internet than to wait for a list of PMA and HDE approvals and denials to become available weeks to potentially months later in the *Federal Register*. We also believe that interested entities already routinely seek information on SSED for PMAs and SSPB for HDEs on the Internet.

We estimate negligible additional costs to some entities that are accustomed to requesting copies of the current PMA approvals and denials document and copies of SSED for PMAs through the Dockets Management Staff. These entities will need to learn that their requests must be sent to the FOI Staff instead of the Dockets Management Staff, resulting in a one-time cost related to additional time needed to look up the new

address. Because the number of requests that are annually mailed or submitted in person through the Dockets Management Staff is negligible, we estimate negligible additional costs to these entities.

G. Distributional Effects

We do not expect any significant distributional effects because this final rule will not require performance of any additional tasks by the industry.

H. International Effects

We do not expect any significant effects on international trade because this final rule will not require performance of any additional tasks by the industry. This rule, therefore, will not impose any additional burden on foreign entities.

I. Uncertainty and Sensitivity Analysis

We are uncertain about the exact number of hours that FDA employees of different occupations and pay grades spend each year on preparing *Federal Register* notices that announce PMA and HDE approvals and denials. In our estimates, we use a range for the number of hours and use the average FDA-wide fully loaded full-time employee cost that includes benefits and overhead, as reported by the Office of Management and Budget.

J. Analysis of Regulatory Alternatives to the Rule

The alternative is to take no action. Under this alternative, FDA would continue the current practice of publishing quarterly lists of PMA and HDE approvals and denials in the *Federal Register* and also posting approval and denial notices for PMAs and HDEs on FDA's home page on the Internet (https://www.fda.gov). With this alternative, FDA would continue to pay employee time and publication fees to announce in the *Federal Register* information that is already readily available on the Internet.

III. Final 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 this final rule will not impose any additional regulatory burden on entities of any size, we certify that the final 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, serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

A. Description and Number of Affected Small Entities

We estimate that nearly all medical device manufacturers are small business, but we expect that they will not be affected by this final rule. This final rule will only affect the FDA.

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

We certify that this final rule will have no impact on small entities because it does not impose any additional regulatory burden on entities of any size. The only result will be cost savings to FDA.