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-2019-N-3101

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 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 proposed rule, if finalized, would not impose any additional regulatory burden on the industry, 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 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 $154 million, using the most current (2018) 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

The benefit of this proposed rule, if finalized, is that it would result in cost savings to 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 would eliminate duplication in announcing this information; information on these approvals and denials would continue being readily available to the public on FDA's home page on the Internet (https://www.fda.gov).

We estimate that this proposed rule, if finalized, would result in no additional costs to industry because the rule would not require performance of any additional tasks. This proposed rule, therefore, would not impose any additional regulatory burden on the industry.

Table 1 summarizes the estimated benefits and costs of the proposed rule, if finalized. Annualized over 10 years, the estimated benefits (*i.e.* cost savings) of the proposed rule, if finalized, would 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 proposed rule, if finalized, would range 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 proposed rule, if finalized, would be $0 at both 3 and 7 percent discount rate. The present value of costs of the proposed rule, if finalized, would also be $0 at both 3 and 7 percent discount rate.

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	$0.010	$0.008	$0.013	2018	7%	10 years	Benefits are cost savings
		$0.010	$0.008	$0.013	2018	3%	10 years	Benefits are cost savings
	Annualized Quantified							
	Qualitative							
Costs	Annualized Monetized $millions/year	$0	$0	$0	2018	7%	10 years	
		$0	$0	$0	2018	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							

In line with Executive Order 13771, in Table 2 we discuss annualized and present values of costs and cost savings over an infinite time horizon. The present value of the net costs would be $0 at both 3 and 7 percent discount rate. The total annualized cost

savings would range from $0.008 million to $0.013 million at both 3 and 7 percent discount rates.

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

Item	Primary Estimate (7%)	Lower Estimate (7%)	Upper Estimate (7%)	Primary Estimate (3%)	Lower Estimate (3%)	Upper Estimate (3%)
Present Value of Costs	$0	$0	$0	$0	$0	$0
Present Value of Cost Savings	$0.143	$0.114	$0.186	$0.333	$0.267	$0.433
Present Value of Net Costs	($0.143)	($0.114)	($0.186)	($0.333)	($0.267)	($0.433)
Annualized Costs	$0	$0	$0	$0	$0	$0
Annualized Cost Savings	$0.010	$0.008	$0.013	$0.010	$0.008	$0.013
Annualized Net Costs	($0.010)	($0.008)	($0.013)	($0.010)	($0.008)	($0.013)

Note: Net costs are calculated as costs minus cost savings. Values in parentheses denote net negative costs (i.e. cost-savings).

We request comments on any assumptions and estimates presented in this Preliminary Regulatory Impact Analysis (PRIA).

II. Preliminary 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. Market Failure Requiring 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 summaries 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 issuing another regulation that amends the existing 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 Proposed Rule

The purpose of this proposed rule, if finalized, is to 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 would allow FDA to eliminate excess costs related to duplication in announcing this information. This proposed rule, if finalized, would 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 would 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. This proposed rule would also update outdated references to section 515(d)(3) of the 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

This proposed rule, if finalized, would 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 18,000[1] medical device manufacturers, including about 700 firms that have one or more Class III medical devices on the U.S. market and about 50 firms that have HUDs on the U.S. market.[2] These firms are likely to be routinely interested in the announcements of PMA and HDE approvals and denials.

[1] Dun and Bradstreet, Inc., 2014
[2] FDA Medical Device Registration Database, 2018

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 would not be affected by this proposed rule, if finalized, because they would continue obtaining the same information on PMA and HDE approvals and denials from FDA's home page on the Internet (https://www.fda.gov). We request comment on this assumption.

The only entity that would be affected by this proposed rule, if finalized, is the FDA.

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 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 request comment on this assumption.

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 SSPB for HDEs. Such additional information and data are currently available and would 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 Proposed Rule

Eliminating duplication in the current process for announcing medical device PMA and HDE approvals and denials would result in time and cost savings to FDA. If finalized, this proposed rule would 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 would result in annual time savings of about 60 hours (between 40 and 80 hours) of FDA employees' time. FDA employees would no longer need to spend time preparing, reviewing, editing, coordinating and sending this quarterly notification document to the *Federal Register*.

The compensation of a full-time FDA employee is $129 per hour (in 2018 dollars) after adjusting for benefits and overhead. In addition, FDA would no longer need to pay a publication fee to the *Federal Register*. We estimate that 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, would be between $0.008 million and $0.013 million, with our best estimate of about $0.010 million (= $129 x 60 hours + $2,500).

We estimate that cost savings to FDA related to forwarding and coordinating requests for copies between the Dockets Management Staff and the FOI Staff would 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 Proposed Rule

We believe that the medical device industry would not incur any costs because the proposed rule, if finalized, would not require performance of any additional tasks and, therefore, would 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 would 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

[3] Based on the 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

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. If this proposed rule is finalized, these entities would 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 proposed rule, if finalized, would not require performance of any additional tasks.

H. International Effects

We do not expect any significant effects on international trade because this proposed rule, if finalized, would not require performance of any additional tasks. This proposed rule, therefore, would 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 wage rate that includes benefits and overhead, as reported by the Office of Management and Budget.

J. Analysis of Regulatory Alternatives to the Proposed Rule

The alternative would be to take no action. Under this alternative, FDA would continue the current practice of publishing 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. 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 this proposed rule, if finalized, would not impose any additional regulatory burden on entities of any size, 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, serves as the Preliminary 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 would not be affected by this proposed rule, if finalized. This proposed rule, if finalized, would only affect the FDA.

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

We expect that this proposed rule, if finalized, would have no impact on small entities because it does not impose any additional regulatory burden on entities of any size. If this proposed rule is finalized, the only result will be cost savings to FDA.