4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 814

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

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to amend the medical device regulations regarding the procedures for the announcement of approvals and denials of premarket approval applications (PMAs) and humanitarian device exemption applications (HDEs). We are proposing to discontinue publishing in the *Federal Register* after each quarter a list of PMA and HDE approvals and denials announced in that quarter. We will continue to post approval and denial notices for PMAs and HDEs on FDA's home page on the internet and will also continue to make available on the internet and place on public display summaries of safety and effectiveness data (SSED) for PMAs and summaries of safety and probable benefit (SSPB) for HDEs. FDA is proposing to take this action to improve the efficiency of announcing approvals and denials of PMAs and HDEs and to eliminate duplication in the current process for announcing this information. We are also proposing to update Agency contact information and statutory references in certain sections of the PMA and HDE regulations for purposes of accuracy, clarity, and consistency.

DATES: Submit either electronic or written comments on the proposed rule by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-N-3101 for "Revised Procedures for the Announcement of Approvals and Denials of Premarket Approval Applications and Humanitarian Device Exemption Applications." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The

second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: *For information concerning the proposed rule as it relates to devices regulated by the Center for Biologics Evaluation and Research*: Jessica Walker Udechukwu, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

For information concerning the proposed rule as it relates to devices regulated by the Center for Devices and Radiological Health: Joshua Nipper, Center for Devices and Radiological Health,

Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993-0002, 301-796-6524.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Proposed Rule

FDA is proposing to amend its medical device regulations regarding the procedures for the announcement of approvals and denials of PMAs and HDEs to discontinue the quarterly publication in the *Federal Register* of a list of approvals and denials of both PMAs and HDEs. FDA will continue to post approval and denial notices for PMAs and HDEs on FDA's home page on the internet (https://www.fda.gov) and will also continue to make available on the internet and place on public display SSED for PMAs and SSPB for HDEs. FDA is proposing to take this action to improve the efficiency of announcing approvals and denials of PMAs and HDEs and eliminate duplication in the current process for announcing this information. We are also proposing to update Agency contact information and statutory references in certain of the PMA and HDE regulations for purposes of accuracy, clarity, and consistency.

B. Summary of the Major Provisions of the Proposed Rule

FDA is proposing to amend its regulations regarding the announcement procedures for the approval and denial of PMAs and HDEs. FDA is proposing to discontinue publishing in the *Federal Register* after each quarter a list of PMA and HDE approvals and denials announced for that quarter. We will continue to post approval and denial notices for PMAs and HDEs on FDA's home page on the internet, and we will also continue to make SSED for PMAs and SSPB for HDEs available on the internet and place them on public display.

C. Legal Authority

FDA is issuing this proposed rule under sections 515, 520(h), 520(m), and 701(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360e, 360j(h), 360j(m), and 371(a)).

D. 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 medical device PMA and HDE approvals and denials. Annualized over 10 years, the estimated benefits (i.e., cost savings) to FDA 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. This proposed rule, if finalized, would result in no costs to industry because the rule would not require performance of any additional tasks and, therefore, would not impose any additional regulatory burden on the industry.

II. Background

A. Need for the Regulation

FDA is proposing to amend its medical device regulations regarding the procedures for the announcement of approvals and denials of PMAs and HDEs to discontinue the quarterly publication in the *Federal Register* of a list of approvals and denials of both PMAs and HDEs. FDA is proposing to take this action to improve the efficiency of announcing approvals and denials of PMAs and HDEs and eliminate duplication in announcing this information. The proposed rule, if finalized, would allow FDA staff to focus on other Agency priorities and utilize FDA staff resources more efficiently. FDA is also proposing to revise § 814.44(d)(2) (21 CFR 814.44(d)(2)) to be consistent with § 814.45(d)(2) (21 CFR 814.45(d)(2)), which states that requests for copies of the current PMA approvals and denials document and copies of SSED must be sent in writing to FDA's Freedom of Information Staff. In addition, FDA is proposing to update outdated references to section 515(d)(3) of the FD&C Act in the PMA (§§ 814.40 (21 CFR 814.40), 814.44, and 814.45) and HDE (§ 814.118 (21 CFR 814.118)) regulations.

B. History of the Rulemaking

Section 515(d)(4) of the FD&C Act permits an interested person to obtain review of an order approving a PMA in accordance with section 515(g) of the FD&C Act. The statute does not require the Agency to publish the approval of a PMA in the *Federal Register*; however, FDA issued in the *Federal Register* of July 22, 1986 (51 FR 26342) a final rule that provided, among other things, that notice of approval of a PMA, notice of an order denying approval of a PMA, and notice of an order withdrawing approval of a PMA will be published in the *Federal Register*. In the *Federal Register* of June 26, 1996 (61 FR 33232), FDA issued a final rule prescribing, among other things, the procedures for submitting HDEs, HDE amendments, and HDE supplements, and the criteria for FDA review and approval of HDEs. Furthermore, the final rule of June 26, 1996, provided that the notice of approval of an HDE be published in the *Federal Register* in accordance with the rules and policies applicable to PMAs submitted under 21 CFR 814.20. That final rule also provided that, if FDA issues an order denying approval of an HDE, FDA will comply with the same notice and disclosure provisions required for PMAs under § 814.45(b) and (d), as applicable.

In the *Federal Register* of January 30, 1998 (63 FR 4571), FDA issued a final rule discontinuing the publication of individual PMA approvals and denials in the *Federal Register*. The final rule provided that FDA would notify the public of PMA approvals and denials by posting them on FDA's home page on the internet, by placing SSED on the internet and in FDA's Dockets Management Branch, and by publishing in the *Federal Register* after each quarter a list of the PMA approvals and denials announced in that quarter. FDA stated that it believed that this procedure would expedite public notification of these actions because announcements could be placed on the internet more quickly than they could be published in the

Federal Register, and FDA believed that the internet would be accessible to more people than the *Federal Register*.

III. Legal Authority

We are issuing this proposed rule under the authority of sections 515, 520(h), and 520(m) of the FD&C Act, which set forth requirements for device premarket approval, release of detailed summaries of information respecting the safety and effectiveness of devices, and humanitarian device exemptions, and under section 701(a) of the FD&C Act, which provides FDA the authority to issue regulations for the efficient enforcement of the FD&C Act.

IV. Description of the Proposed Rule

We are proposing to amend 21 CFR part 814 to revise the PMA and HDE approval and denial announcement procedures.

FDA would discontinue publishing in the *Federal Register* after each quarter a list of PMA and HDE approvals and denials announced in that quarter (see proposed revisions to §§ 814.44, 814.45, and 814.116). FDA will continue to give the public notice of PMA and HDE approvals and denials by placing notices of approval and denial on FDA's home page on the internet. Notices of PMA and HDE approval will continue to include a notice of opportunity for interested persons to request review. FDA considers the 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices of PMA and HDE approval to begin on the day the notice is placed on the internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day filing period. In addition, we will continue to make available on the internet and place on public display SSED and SSPB.

We are also proposing to revise § 814.44(d)(2), regarding requests for copies of the current PMA approvals and denials document and copies of SSED, to state that such requests

must be sent to the Freedom of Information Staff, rather than to the Division of Dockets Management. We are proposing this revision because these requests are currently handled by the Freedom of Information Staff. Revised § 814.44(d)(2) would be consistent with current § 814.45(d)(2).

In addition, FDA is proposing to update outdated references to section 515(d)(3) of the FD&C Act in the PMA (§§ 814.40, 814.44, and 814.45) and HDE (§ 814.118) regulations. FDA is proposing to make this update because section 515(d)(3) of the FD&C Act was redesignated as section 515(d)(4) by section 202 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115).

V. Proposed Effective Date

FDA is proposing that any final rule based on this proposed rule become effective 30 days after the date of its publication in the *Federal Register*.

VI. Preliminary Economic Analysis of Impacts

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 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 $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 Benefits and Costs

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 medical device PMA and HDE approvals and denials. 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 no additional benefits beyond these cost savings to FDA.

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							

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
	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.--Executive Order 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 have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 1) and at https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.

VII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the proposed rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

IX. Consultation and Coordination with Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

X. Reference

The following reference is on display at the Dockets Management Staff (see ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at https://www.regulations.gov. FDA has verified the website address, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. FDA/Economics Staff, "Revised Procedures for the Announcement of Approvals and Denials of Premarket Approval Applications and Humanitarian Device Exemption Applications, Preliminary Regulatory Impact Analysis, Preliminary Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis," 2019 (available at: https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm).

List of Subjects in 21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 814 be amended as follows:

PART 814--PREMARKET APPROVAL OF MEDICAL DEVICES

1. The authority citation for part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c-360j, 360bbb-8b, 371, 372, 373, 374, 375, 379, 379e, 381.

§ 814.40 [Amended]

2. In § 814.40, remove "515(d)(3)" and add in its place "515(d)(4)"

§ 814.44 [Amended]

3. Amend § 814.44 as follows:

a. In the fourth sentence in paragraph (d)(1), remove "515(d)(3)" and add in its place "515(d)(4)" and remove the sixth sentence;

b. In paragraph (d)(2), remove "Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852" and add in its place "Freedom of Information Staff's address listed on the Agency's website at https://www.fda.gov."; and

c. In paragraphs (e)(2)(ii) and (f)(2), remove "515(d)(3)" and add in its place "515(d)(4)".

§ 814.45 [Amended]

4. Amend § 814.45 as follows:

a. In paragraph (d)(1), remove the third sentence and

b. In paragraph (e)(3), remove "515(d)(3)" and add in its place "515(d)(4)".

5. In § 814.116 revise the fourth sentence in paragraph (b) to read as follows:

§ 814.116 Procedures for review of an HDE.

(b) * * * The notice of approval of an HDE will be placed on the FDA's home page on the internet (https://www.fda.gov) in accordance with the rules and policies applicable to PMAs submitted under § 814.20. * * *

§ 814.118 [Amended]

6. In § 814.118(c)(3), remove "515(d)(3)" and add in its place "515(d)(4)".

Dated: December 9, 2019.

Brett P. Giroir,
Acting Commissioner of Food and Drugs.

[FR Doc. 2019-27045 Filed: 12/16/2019 8:45 am; Publication Date: 12/17/2019]