Analysis available at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

List of Subjects in 21 CFR Part 169

Food grades and standards, Oils and fats, Spices and flavorings.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 169 is amended as follows:

PART 169—FOOD DRESSINGS AND FLAVORINGS

■ 1. The authority citation for part 169 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

§ 169.115 [Removed]

■ 2. Remove § 169.115.

Dated: January 6, 2022.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

[FR Doc. 2022–00494 Filed 1–12–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 814

[Docket No. FDA–2019–N–3101]

RIN 0910–AI10

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: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule 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). This final rule discontinues the publication in the **Federal Register** after each quarter of 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 taking 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 updating Agency contact information and statutory references in certain sections of the PMA and HDE regulations for purposes of accuracy, clarity, and consistency.

DATES: This rule is effective February 14, 2022.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT:

For information concerning the final rule as it relates to devices regulated by the Center for Biologics Evaluation and Research: Tami Belouin, 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 final 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. 2438, Silver Spring, MD 20993–0002, 301–796–6524.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Final Rule

FDA is amending 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 taking 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 updating Agency contact information and statutory references in certain PMA and HDE regulations for purposes of accuracy, clarity, and consistency.

B. Summary of the Major Provisions of the Final Rule

FDA is amending its regulations regarding the announcement procedures for the approval and denial of PMAs and HDEs. FDA is discontinuing 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 final 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 final rule is that it will 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 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. 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 and, therefore, will not impose any additional regulatory burden on the industry.

II. Background

A. Need for the Regulation

FDA is amending 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 taking this action to improve the efficiency of announcing approvals and denials of PMAs and HDEs and eliminate duplication in announcing this information. The final rule allows FDA staff to focus on other Agency priorities and utilize FDA staff resources more efficiently. FDA is also revising § 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 updating 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 making available on the internet and placing on public display SSED, 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**.

In the **Federal Register** of December 17, 2019 (84 FR 68829), FDA published a proposed rule entitled ''Revised Procedures for the Announcement of Approvals and Denials of Premarket Approval Applications and Humanitarian Device Exemption Applications'' to discontinue publishing in the **Federal Register** after each quarter a list of PMA and HDE approvals and denials announced in that quarter. We also proposed to update Agency contact information and statutory references in certain sections of the PMA and HDE regulations for purposes of accuracy, clarity, and consistency. After consideration of the comments received, we are now finalizing the proposed rule without change.

C. Summary of Comments to the Proposed Rule

We received comments on the proposed rule from individual submitters. We received one comment in support of the proposed rule and one comment against discontinuing the quarterly publication in the **Federal Register** of a list of approvals and denials of PMAs and HDEs. These comments are further summarized in section IV.

III. Legal Authority

We are issuing this final 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. Comments on the Proposed Rule and FDA Response

A. Introduction

We received comments on the proposed rule from individual submitters. We describe and respond to the comments in sections IV.B and C of this document. We have numbered each comment to help distinguish between different comments. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

B. Specific Comments and FDA Response

(Comment 1) One comment supported the proposed rule.

(Response 1) We acknowledge and appreciate the supportive comment.

(Comment 2) One comment opposed discontinuing the publication in the **Federal Register** after each quarter of a list of PMA and HDE approvals and denials announced in that quarter. The comment stated that the **Federal Register** provides a complete, archivable, and reviewable record of Federal Agency decisions, that the FDA website does not provide. The comment further noted that the quarterly **Federal Register** summary may be useful to persons searching for aggregate trends in FDA actions.

(Response 2) We do not believe the quarterly **Federal Register** notice is needed to provide an adequate record of PMA and HDE approvals and denials. The **Federal Register** notice merely summarizes the quarterly PMA and HDE approvals and denials; it does not provide information on those approvals and denials beyond what can be obtained in other formats on the FDA website. Additionally, we will continue to give the public notice of PMA and HDE approvals and denials by placing notices of approvals and denials on FDA's home page on the internet. These notices, along with certain supporting documentation, are also maintained and can be viewed online at *https://www.regulations.gov*.

Furthermore, we do not believe it is necessary to publish the quarterly **Federal Register** notices as a search tool for ''aggregate trends in FDA actions.'' We note that there are existing tools such as FDA's searchable PMA database (*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm*) and HDE database (*https://*

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm; https://www.fda.gov/vaccines-blood-biologics/approved-blood-products/premarket-approvals-and-humanitarian-device-exemptions-supporting-documents) that the public can utilize to search for information on PMA and HDE approvals over a certain period of time.

C. Comment Outside the Scope of This Rulemaking

(Comment 3) One comment questioned which products FDA evaluates before they are sold.

(Response 3) We decline to respond because this comment is outside the scope of this final rule.

V. Effective Date

This final rule will become effective 30 days after the date of its publication in the **Federal Register**.

VI. Economic Analysis of Impacts

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.

The benefit of this final rule is that it will result in cost savings to FDA from discontinuing publishing in the **Federal Register**, on a quarterly basis, a list of approvals and denials of PMAs and 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 (years)	
Benefits:							
Annualized Monetized $millions/year	$0.010	$0.008	$0.013	2020	7	10	Benefits are cost savings.
	0.010	0.008	0.013	2020	3	10	Benefits are cost savings.
Annualized Quantified.							
Qualitative.							
Costs:							
Annualized Monetized $millions/year	0	0	0	2020	7	10	
	0	0	0	2020	3	10	
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.

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 1) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

This final 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.

IX. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the 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 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.

X. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects 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. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

XI. 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, Regulatory Impact Analysis, Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis,'' 2020 (available at: *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations*).

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, 21 CFR part 814 is 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, 379k–1, 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: January 6, 2022.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

[FR Doc. 2022–00501 Filed 1–12–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 882 and 1270

[Docket No. FDA–2020–N–1519]

RIN 0910–AI41

Revocation of the Regulations for Human Tissue Intended for Transplantation and Human Dura Mater

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to revoke the regulations for human tissue intended for transplantation and human dura mater recovered prior to May 25, 2005. The revocation does not affect the regulations for human cells, tissues, and cellular and tissue-based products (HCT/Ps) recovered on or after May 25, 2005. The rule is being finalized because these regulations are obsolete or no longer necessary to achieve public health goals.

DATES: This rule is effective February 14, 2022.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the