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 E.O. 13132. We have 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 E.O. 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 E.O. 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 E.O. and, consequently, a tribal summary impact statement is not required.

XI. Reference

The following reference is on display in 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 addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA Final Regulatory Impact Analysis, ''Regulation Requiring an Approved New Drug Application for Drugs Sterilized by Irradiation,'' available at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 310 is amended as follows:

PART 310—NEW DRUGS

■ 1. The authority citation for part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 360hh–360ss, 361(a), 371, 374, 375, 379e, 379k–1; 42 U.S.C. 216, 241, 242(a), 262.

■ 2. In § 310.502, revise paragraph (a) introductory text and remove and reserve paragraph (a)(11) to read as follows:

§ 310.502 Certain drugs accorded new drug status through rulemaking procedures.

(a) The drugs listed in this paragraph (a) have been determined by rulemaking procedures to be new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act. An approved new drug application under section 505 of the Federal Food, Drug, and Cosmetic Act and part 314 of this chapter is required for marketing the following drugs:

* * * * *

Dated: December 9, 2019.

Brett P. Giroir,

Acting Commissioner of Food and Drugs.

[FR Doc. 2019–27046 Filed 12–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 807, 812, and 814

[Docket No. FDA–2018–N–0628]

RIN 0910–AH48

Medical Device Submissions: Amending Premarket Regulations That Require Multiple Copies and Specify Paper Copies To Be Required in Electronic Format

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is issuing a final rule amending requirements for medical device premarket submissions to remove paper and multiple copies and replace them with requirements for a single submission in electronic format. This action would reduce the number of copies in electronic format required, thus improving and making more efficient the FDA's premarket submission program for medical devices.

DATES: This rule is effective January 15, 2020.

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.

FOR FURTHER INFORMATION CONTACT: Diane Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G609, Silver Spring, MD 20993, 301–796–6559, email: *Diane.Garcia@fda.hhs.gov.*

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XII. References

I. Executive Summary

A. Purpose of the Final Rule

FDA is issuing this final rule to amend regulations on medical device premarket submissions to remove requirements for paper and multiple copies and replace them with requirements for a single submission in electronic format to improve the FDA's medical device premarket submission program and create a more efficient submission program. Because a medical device premarket submission in electronic format is easily reproducible, the requirement for multiple copies, whether in electronic format or paper form, is no longer necessary. FDA believes it is beneficial to the public to limit any burden and expense to

submitters caused by requiring additional copies.

B. Summary of the Major Provisions of the Final Rule

Under this final rule, FDA is amending its regulations on medical device submissions to remove requirements for paper and multiple copies and replace them with requirements for a single submission in electronic format. This requirement for a single submission in electronic format applies to all submission types enumerated in section 745A(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379k–1); under this final rule, FDA is only amending those regulations that specifically mention paper and/or multiple copies of regulatory submissions and are not consistent with this final rule. Therefore, this final rule will amend regulations for the following submission types: Premarket Notification (510(k)) submissions (21 CFR 807.90); Confidentiality of Information Certifications (21 CFR 807.95); Investigational Device Exemption (IDE) applications (21 CFR 812.20); Premarket Approval Applications (PMAs) (21 CFR 814.20); PMA supplements (21 CFR 814.39); and Humanitarian Device Exemption (HDE) Applications (21 CFR 814.104). These regulations cover both Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) regulated devices. Submissions in electronic format include eCopies, submissions created and submitted on CD, DVD, or flash drive and mailed to FDA, and eSubmissions, submission package produced by an electronic submission template.

This final rule will also amend sections of the regulations that identify FDA's mailing address for submissions and replace those addresses with a website address for CDRH and CBER that provides the current mailing addresses.

C. Legal Authority

FDA is issuing this final rule from the same authority under which FDA initially issued these regulations: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360h–360j, 360c–360j, 360bbb–8b, 371, 372, 373, 374, 375, 379, 379e, 381, 382, 393; 42 U.S.C. 216, 241, 262, 263b–263n, 264, 271. In addition, section 745A of the FD&C Act provides FDA authority with respect to electronic format for submissions and any appeals, and section 701(a) of the FD&C Act (21 U.S.C. 371(a)) grants FDA general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act.

D. Costs and Benefits

The final rule amends device regulations describing the number of copies firms must submit with a premarket presubmission or submission. The final rule also amends all device regulations containing a reference to the specific form of a submission to require a submission in electronic format. The final rule will produce cost savings for firms without imposing any additional regulatory burdens for submissions or affecting the Agency's ability to review submissions. Firms will incur minimal administrative costs to read and understand the rule. We expect the economic impact of this regulation to be a total net costs savings yielding positive net benefits.

We estimate that the final rule will result in annualized benefits of $1.76 million at a 3 percent discount rate and $1.76 million at a 7 percent discount rate, over 10 years. We also estimate that the final rule will result in annualized costs of $0.75 million at a 3 percent discount rate and $0.87 million at a 7 percent discount rate, over 10 years.

II—TABLE OF ABBREVIATIONS/COMMONLY USED ACRONYMS IN THIS DOCUMENT

Term, abbreviation, or acronym	What it means
510(k)	Premarket Notification.
Agency	Food and Drug Administration.
CFR	Code of Federal Regulations.
eCopy	Submissions created and submitted on CD, DVD, or flash drive and mailed to FDA.
eSubmissions	Submission package produced by an electronic submission template.
EO	Executive Order.
FD&C Act	Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*
FDA	Food and Drug Administration.
FDARA	FDA Reauthorization Act of 2017 (Pub. L. 115–52).
FDASIA	Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144).
HDE	Humanitarian Device Exemption.
IDE	Investigational Device Exemption
PMA	Premarket Approval Application.

II. Background

A. Need for the Regulation/History of the Rulemaking

On February 24, 2017, E.O. 13777, ''Enforcing the Regulatory Reform Agenda'' was issued. One of the provisions in the E.O. requires Agencies to evaluate existing regulations and make recommendations to the Agency head regarding their repeal, replacement, or modification, consistent with applicable law. As part of this initiative, FDA is updating regulations as specified in this final rule.

FDA's current medical device regulations that require multiple copies and paper submissions predate the authority provided to FDA in the FD&C Act to require submissions in electronic format (see 21 CFR parts 807, 812, and 814 and section 745A of the FD&C Act).

The FD&C Act was amended by the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144) (see section 745A(b) of the FD&C Act and section 1136 of FDASIA). The amendments in FDASIA provided that after FDA issued guidance on the submission of electronic copies (eCopies), the submission of eCopies would be required for presubmissions and submissions and any supplements to these presubmissions and submissions for medical devices. (For sections requiring submission, see sections 510(k), 513(f)(2)(A), 515(c), (d) and (f), 520(g) and (m), and 564 of the FD&C Act (21 U.S.C. 360(k), 360c(f)(2)(A), 360e(c), (d) and (f), 360j(g) and (m), and 360bbb–3 or section 351 of the Public Health Service Act (42 U.S.C. 262).) Congress granted explicit statutory authorization to FDA to implement eCopy requirements by providing through guidance the standards and criteria for waivers and exemptions (section 745(b)(1) and (2) of the FD&C Act).

On January 2, 2013, FDA published the guidance entitled ''eCopy Program for Medical Device Submissions'' (eCopy guidance). The issuance of the eCopy guidance marked the beginning of the eCopy program. The 2013 guidance was superseded by an updated guidance of the same title issued on December 3, 2015. The eCopy guidance recommends that one paper copy should be submitted, and that any additional copies required under the regulations be submitted as eCopies. While the eCopy guidance did not change the overall number of copies required for any submission, the guidance states that eCopies should be provided in lieu of some of the paper copies. The guidance also outlines other requirements for eCopies. The eCopy

guidance provides instructions for the processing and technical standards for eCopies based on FDA's experience with the program (Ref. 1).

In 2017, the FD&C Act was amended by the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115–52) (see section 745A(b)(3) of the FD&C Act and section 207 of FDARA). The amended provisions in the FD&C Act require presubmissions and submissions (the same types of submissions as required eCopies), any supplements to such presubmissions or submissions for devices, and any appeals of action taken with respect to such presubmissions or submissions, including devices under the Public Health Service Act, to be submitted solely in electronic format as specified by FDA in guidance (section 745A(b)(3) of the FD&C Act).

FDA is amending current medical device regulations that require multiple copies and paper submissions to improve the efficiency of the review process by allowing immediate availability of an electronic version for review, rather than relying solely on the paper version. Because a submission in electronic format is easily reproducible, the requirement for multiple copies (whether in electronic format or paper form) is no longer necessary. Furthermore, FDA believes it is beneficial to the public to limit any burdens and expenses to submitters caused by requiring additional copies.

In the **Federal Register** of September 13, 2018 (83 FR 46444), FDA issued a proposed rule entitled ''Medical Device Submissions: Amending Premarket Regulations That Require Multiple Copies and Specify Paper Copies To Be Allowed in Electronic Format'' and requested public comments by December 12, 2018.

FDA believes this rule will result in meaningful burden reduction while allowing the Agency to achieve our public health mission and fulfill statutory obligations.

B. Summary of Comments to the Proposed Rule

In response to the proposed rule, FDA received 14 comments—from industry organizations, individuals, and anonymous. The comments on the proposed rule were all generally supportive of the proposed amendments regarding submissions in electronic format. Commenters expressed that premarket submissions in electronic format will make the process more efficient, faster, lower the costs, and promote innovation as well as speed up accessibility for patient care. Commenters also noted that the submissions in electronic format will reduce paper, errors and allow storage and easy access to submissions. One of the commenters suggested including additional regulations for submissions in electronic format and recommended corresponding changes to the proposed amendments.

C. General Overview of the Final Rule

FDA is issuing this final rule to amend regulations for medical device premarket submissions to remove the requirements for multiple copies of submissions and to instead require a single submission in electronic format. The revised submissions include premarket notification submissions (510(k) submissions) (§ 807.90); confidentiality of information certification (§ 807.95); investigational device exemption applications (§ 812.20); PMAs (§ 814.20), including PMA supplements (§ 814.39); and humanitarian device exemption applications (§ 814.104). This final rule also affects submissions for CBER regulated devices.

This final rule will also amend the regulations that identify FDA's mailing addresses for submissions by replacing those addresses with website addresses for CDRH and CBER that provide the current mailing addresses.

The submission of an eCopy is separate and distinct from FDA's electronic submission programs (eSubmitter), which include the CDRH's 510(k) eSubmissions Pilot Program (79 FR 24732, May 1, 2014). Nevertheless, FDA considers both eCopies, submissions created and submitted on a CD, DVD, or flash drive and mailed to FDA, and eSubmissions, submission package produced by an electronic submission template, to be submissions in electronic format. While eCopy provides for submissions to be in electronic format, the eCopy submissions must still be mailed to FDA. By contrast, eSubmitter allows for electronic submissions to be transmitted over the internet. FDA has been moving toward transforming all regulatory submissions from mailed copies to electronic means via the internet. Since January 1999, FDA has accepted voluntary electronic submissions through eSubmitter. FDA presently utilizes the Electronic Submission Gateway for the receipt and processing of many types of electronic regulatory submissions (Ref. 2).

IV. Legal Authority

FDA is issuing this final rule from the same authority under which FDA initially issued these regulations: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360h–360j, 360c–360j, 360bbb–8b, 371, 372, 373, 374, 375, 379, 379e, 381, 382, 393; 42 U.S.C. 216, 241, 262, 263b–263n, 264, 271. In addition, section 745A of the FD&C Act provides FDA authority with respect to electronic format for submissions and any appeals, and section 701(a) of the FD&C Act grants FDA general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act.

V. Comments on the Proposed Rule and FDA Response

A. Introduction

In response to the proposed rule announcing FDA's intent to amend requirements for medical device premarket submissions to remove paper and multiple copies and replace them with requirements for a single submission in electronic format, FDA received 14 comments—from industry organizations, individuals, and anonymous.

We describe and respond to the comments in section V.B. We have numbered each comment to help distinguish between different comments. We have grouped similar comments under the same number for purposes of our responses. 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. Description of Comments and FDA Response

Several commenters made general remarks supporting the proposed rule without focusing on a particular proposed provision. In the following paragraphs, we discuss and respond to such general comments as well as more specific comments.

(Comment 1) Several commenters were supportive of the implementation of the proposed amendments to regulations on medical device submissions to remove requirements for paper and multiple copies and replace them with requirements for a single submission in electronic format. The commenters suggested that single copy submissions in electronic format will be easier, improve efficiency of the review process, reduce paper, costs, errors, and support innovation. The commenters also suggested that submissions in electronic format will provide easy storage and access to records and reduce the time for creating the submissions. Most of the commenters did not suggest any further edits to the proposed rule. A commenter suggested assigning IDs or reference numbers to each product to

advance post market surveillance of medical devices.

(Response 1) FDA agrees with the commenters that submission in electronic format will improve the efficiency with lower costs and easier storage and access to records. Regarding the comment related to the ID/reference numbers, FDA did not modify the final rule based on this comment as it is outside the scope of the requirement for a single submission in electronic format. Accordingly, in response to this comment, FDA did not make any changes in the final rule.

(Comment 2) A commenter supported the implementation of the rule but also suggested that electronic submissions be made via the internet, in an Extensible Markup Language (XML) format. The commenter suggested that FDA should be developing specifications for industry submission authoring software that would integrate directly into FDA's review platform; the commenter explained that this type of submission authoring software could create elements of structured data within a submission.

(Response 2) In response, FDA acknowledges the advantages of electronic submissions. FDA notes that the rule is written broadly enough to permit electronic submissions and allow for structured data when such platforms are available. Accordingly, we have made no change in the final rule.

(Comment 3) A commenter suggested applying a logical and least burdensome approach in all FDA guidances, regulatory decisions, and administrative processes. The commenter further indicated that they supported removing paper and multiple copies and replacing them with a single submission in electronic format.

(Response 3) FDA acknowledges this comment and agrees that the least burdensome principles should be considered in all FDA guidances, regulatory decisions and administrative processes (Ref. 3). FDA believes this final rule limits any burdens and expenses to submitters caused by requiring multiple copies of a submission. Accordingly, in response to this comment, FDA did not make any changes in the final rule.

(Comment 4) A commenter acknowledged the benefits of the rule and supported implementation with a recommendation to amend the rule and include additional regulations within the scope and description of the rule. Specifically, the commenter proposed revising FDA's regulation for devices to remove the requirement for multiple copies of submissions and to instead require one electronic version for those regulations noted in the proposed rule in addition to the following: Content and format of a 510(k) summary (§ 807.92); content and format of a 510(k) statement (§ 807.93); format of a class III certification (§ 807.94); supplemental applications (§ 812.35); reports (§ 812.150); reports (§ 814.84); PMA amendments and submitted PMAs (§ 814.37); and post approval requirements and reports (§ 814.126).

(Response 4) FDA agrees with the commenter that this rule should apply to all premarket regulatory submissions that are specified in section 745A(b) of the FD&C Act. The requirement for a single submission in electronic format applies to all submission types that fall within the provisions listed in section 745A(b) of the FD&C Act; under this final rule, FDA is only amending those regulations that specifically mention paper and/or multiple copies of such regulatory submissions and are not consistent with this final rule. Any regulations that are currently silent on the method for submitting such regulatory submissions to the FDA will not be modified as they remain consistent with the final rule. Accordingly, in response to this comment, FDA did not make any changes in the final rule.

VI. Effective Date

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

VII. Economic Analysis of Impacts

We have examined the impacts of the final rule under E.O. 12866, E.O. 13563, E.O. 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). E.O.s 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). E.O. 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 final rule is not a significant regulatory action as defined by E.O. 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final rule amends the existing premarket regulations requiring multiple copies and paper submissions to instead require submissions in electronic format without imposing any new requirements, we certify that the final 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 final rule will not result in an expenditure in any year that meets or exceeds this amount.

This final rule will amend the device regulations describing the number of copies firms must submit with a premarket presubmission or submission. The final rule will also amend all device regulations containing a reference to the specific form of a submission media (*i.e.,* paper copies) to require a submission in electronic format. The final rule will produce cost-savings for firms without imposing any additional regulatory burdens for submissions or affecting the Agency's ability to review submissions. Firms will incur minimal administrative costs to read and understand the rule. We expect the economic impact of this regulation to be a total net costs savings yielding positive net benefits.

We have developed a comprehensive final 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. 4) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

Summary of Costs and Benefits

Table 1 summarizes the benefits, costs, and distributional effects of the final rule. We estimate that the final rule will result in annualized net benefits of $1.76 million with a 3 percent discount rate and $1.76 million with a 7 percent discount rate, over 10 years. We also estimate that the final rule will result in annualized costs of $0.75 million at a 3 percent discount rate and $0.87 million at a 7 percent discount rate, over 10 years.

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	$1.76	$0.63	$3.73	2017	7	10	Benefits are cost savings.
	1.76	0.63	3.73	2017	3	10	Benefits are cost savings.
Annualized Quantified	.....	.....	.....	.....	7	.....	
	.....	.....	.....	.....	3	.....	
Qualitative							
Costs:							
Annualized Monetized $millions/year	0.87	0.87	0.87	2017	7	10	
	0.75	0.75	0.75	2017	3	10	
Annualized Quantified	.....	.....	.....	.....	7	.....	
	.....	.....	.....	.....	3	.....	
Qualitative							
Transfers:							
Federal Annualized Monetized $millions/year	.....	.....	.....	.....	7	.....	
	.....	.....	.....	.....	3	.....	
	From:			To:			
Other Annualized Monetized $millions/year	.....	.....	.....	.....	7	.....	
	.....	.....	.....	.....	3	.....	
	From:			To:			

In line with E.O. 13771, in Table 2 we present annualized values of costs and cost savings over an infinite time horizon. With a 7 percent discount rate, the estimated annualized net cost-savings equal $1.31 million in 2016 dollars over an infinite horizon. Based on these cost savings, this final rule, is considered a deregulatory action under E.O. 13771.

TABLE 2—SUMMARY OF THE EXECUTIVE ORDER 13771 IMPACTS OF THE FINAL RULE OVER AN INFINITE TIME HORIZON

[2016 $ millions]

	Primary estimate (7%)	Primary estimate (3%)
Present Value of Costs	$6.43	$6.43
Present Value of Cost Savings	26.45	59.40
Present Value of Net Costs	(20.01)	(52.97)
Annualized Costs	0.42	0.19
Annualized Cost Savings	1.73	1.73
Annualized Net Costs	(1.31)	(1.54)

Note: Values in parentheses denote net negative costs (*i.e.,* cost-savings).

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) and 25.34(a) 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.

IX. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no collection of information subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995. Rather, the final rule removes requirements to submit multiple paper copies of certain medical device presubmissions and submissions and replaces them with one copy in an electronic format.

X. Federalism

We have analyzed this final rule in accordance with the principles set forth in E.O. 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 E.O. and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this final rule in accordance with the principles set forth in E.O. 13175. We have 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. 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.

XII. References

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

1. ''eCopy Program for Medical Device Submissions; Guidance for Industry and Food and Drug Administration Staff'' available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions.*

2. Electronic Submission Gateway procedure for electronic regulatory submission is available at: *https://www.fda.gov/industry/electronic-submissions-gateway/about-esg.*

3. ''The Least Burdensome Provisions: Concept and Principles; Guidance for Industry and Food and Drug Administration Staff'' available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles.*

4. Economic impacts analysis for this final rule available at: *https://www.fda.gov/about-fda/economic-impact-analyses-fda-regulations/medical-device-submissions-amending-premarket-regulations-require-multiple-copies-and-specify-paper.*

List of Subjects

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

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 the authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 807, 812, and 814 are amended as follows:

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

■ 1. The authority citation for part 807 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360, 360c, 360e, 360i, 360j, 360bbb–8b, 371, 374, 379k–1, 381, 393; 42 U.S.C. 264, 271.

■ 2. Amend § 807.90 by revising paragraph (a), removing and reserving paragraph (b), and revising paragraph (c) to read as follows:

§ 807.90 Format of a premarket notification submission.

* * * * *

(a)(1) For devices regulated by the Center for Devices and Radiological Health, be addressed to the current address displayed on the website *https://www.fda.gov/cdrhsubmissionaddress.*

(2) For devices regulated by the Center for Biologics Evaluation and Research, be addressed to the current address displayed on the website *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm385240.htm;* or for devices regulated by the Center for Drug Evaluation and Research, be addressed to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B Ammendale Rd., Beltsville, MD 20705–1266. Information about devices regulated by the Center for Biologics Evaluation and Research is available at *https://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/default.htm.*

(3) All inquiries regarding a premarket notification submission should be sent to the address in this section or one of the current addresses displayed on the Food and Drug Administration's website.

* * * * *

(c) Be submitted as a single version in electronic format.

* * * * *

■ 3. Amend § 807.95 by revising paragraph (b)(1) introductory text to read as follows:

§ 807.95 Confidentiality of information.

* * * * *

(b) * * *

(1) The person submitting the premarket notification submission requests in the submission that the Food and Drug Administration hold as confidential commercial information the intent to market the device and submits a certification to the Commissioner:

* * * * *

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

■ 4. The authority citation for part 812 is revised to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 360bbb–8b, 371, 372, 374, 379e, 379k–1, 381, 382, 383; 42 U.S.C. 216, 241, 262, 263b–263n.

■ 5. Amend § 812.19 by revising paragraphs (a)(1) and (2) to read as follows:

§ 812.19 Addresses for IDE correspondence.

(a) * * *

(1) For devices regulated by the Center for Devices and Radiological Health, send it to the current address displayed on the website *https://www.fda.gov/cdrhsubmissionaddress.*

(2) For devices regulated by the Center for Biologics Evaluation and Research, send it to the current address displayed on the website *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm385240.htm.*

* * * * *

■ 6. Amend § 812.20 by revising paragraph (a)(3) to read as follows:

§ 812.20 Application.

(a) * * *

(3) A sponsor shall submit a signed ''Application for an Investigational Device Exemption'' (IDE application), together with accompanying materials in electronic format, to one of the addresses in § 812.19, and if eCopy by registered mail or by hand. Subsequent correspondence concerning an application or a supplemental application shall be submitted in electronic format and if eCopy by registered mail or by hand.

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PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

■ 7. The authority citation for part 814 is revised 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.

■ 8. Amend § 814.20 by:

■ a. Revising paragraph (b) introductory text and paragraph (b)(2);

■ b. Removing the phrase ''of the act'' and adding in its place ''of the Federal Food, Drug, and Cosmetic Act'' in paragraphs (b)(5) introductory text, (b)(5)(i), and (b)(10);

■ c. Removing the comma at the end of paragraph (b)(5)(i) and adding a semicolon in its place;
■ d. Revising paragraphs (c) and (e) introductory text;
■ e. Removing the commas at the ends of paragraphs (e)(1) and (2) and adding semicolons in their place; and
■ f. Revising paragraphs (f) and (h)(1) and (2).

The revisions read as follows:

§ 814.20 Application.

* * * * *

(b) Unless the applicant justifies an omission in accordance with paragraph (d) of this section, a PMA shall include in electronic format:

* * * * *

(2) A table of contents that specifies the volume and page number for each item referred to in the table. A PMA shall include separate sections on nonclinical laboratory studies and on clinical investigations involving human subjects. A PMA shall be submitted as a single version. The applicant shall include information that it believes to be trade secret or confidential commercial or financial information in the PMA and identify the information that it believes to be trade secret or confidential commercial or financial information.

* * * * *

(c) Pertinent information in FDA files specifically referred to by an applicant may be incorporated into a PMA by reference. Information in a master file or other information submitted to FDA by a person other than the applicant will not be considered part of a PMA unless such reference is authorized in a record submitted to FDA by the person who submitted the information or the master file. If a master file is not referenced within 5 years after the date that it is submitted to FDA, FDA will return the master file to the person who submitted it.

* * * * *

(e) The applicant shall periodically update its pending application with new safety and effectiveness information learned about the device from ongoing or completed studies that may reasonably affect an evaluation of the safety or effectiveness of the device or that may reasonably affect the statement of contraindications, warnings, precautions, and adverse reactions in the draft labeling. The update report shall be consistent with the data reporting provisions of the protocol. The applicant shall submit any update report in electronic format and shall include in the report the number assigned by FDA to the PMA. These updates are considered to be amendments to the PMA. The time frame for review of a PMA will not be extended due to the submission of an update report unless the update is a major amendment under § 814.37(c)(1). The applicant shall submit these reports—

* * * * *

(f) If a color additive subject to section 721 of the Federal Food, Drug, and Cosmetic Act is used in or on the device and has not previously been listed for such use, then, in lieu of submitting a color additive petition under part 71 of this chapter, at the option of the applicant, the information required to be submitted under part 71 may be submitted as part of the PMA. When submitted as part of the PMA, the information shall be submitted in electronic format. A PMA for a device that contains a color additive that is subject to section 721 of the Federal Food, Drug, and Cosmetic Act will not be approved until the color additive is listed for use in or on the device.

* * * * *

(h) * * *

(1) For devices regulated by the Center for Devices and Radiological Health, send it to the current address displayed on the website *https://www.fda.gov/cdrhsubmissionaddress.*

(2) For devices regulated by the Center for Biologics Evaluation and Research, send it to the current address displayed on the website *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm385240.htm.*

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■ 9. Amend § 814.39 by revising paragraph (c)(1) to read as follows:

§ 814.39 PMA supplements.

* * * * *

(c)(1) All procedures and actions that apply to an application under § 814.20 also apply to PMA supplements except that the information required in a supplement is limited to that needed to support the change. A summary under § 814.20(b)(3) is required for only a supplement submitted for new indications for use of the device, significant changes in the performance or design specifications, circuits, components, ingredients, principles of operation, or physical layout of the device, or when otherwise required by FDA. The applicant shall submit a PMA supplement in electronic format and shall include information relevant to the proposed changes in the device. A PMA supplement shall include a separate section that identifies each change for which approval is being requested and explains the reason for each such change. The applicant shall submit additional information, if requested by FDA, in electronic format. The time frames for review of, and FDA action on, a PMA supplement are the same as those provided in § 814.40 for a PMA.

* * * * *

■ 10. Amend § 814.104 by revising paragraphs (d) introductory text and (d)(1) and (2) to read as follows:

§ 814.104 Original applications.

* * * * *

(d) *Address for submissions and correspondence.* All original HDEs, amendments and supplements, as well as any correspondence relating to an HDE, must be provided in electronic format. These materials must be sent or delivered to one of the following:

(1) For devices regulated by the Center for Devices and Radiological Health, send it to the current address found on the website *https://www.fda.gov/cdrhsubmissionaddress.*

(2) For devices regulated by the Center for Biologics Evaluation and Research, send it to the current address displayed on the website *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm385240.htm.*

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Dated: December 9, 2019.

Brett P. Giroir,

Acting Commissioner of Food and Drugs.

[FR Doc. 2019–27047 Filed 12–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[Docket No. DEA–511]

Technical Correction to Regulation Regarding Registration

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule; technical correction.

SUMMARY: This final rule corrects an erroneous cross-reference in a Drug Enforcement Administration regulation involving registration and ocean vessels, aircraft, and other entities. This change will provide clarity.

DATES: This rule is effective December 16, 2019.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701