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 Allowed in Electronic Format

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is proposing 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. If finalized, 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. This action is part of FDA's implementation of Executive Orders (EOs) 13771 and 13777. Under these EOs, FDA is comprehensively reviewing existing regulations to identify opportunities for repeal, replacement, or modification that will result in meaningful burden reduction while allowing the Agency to achieve our public health mission and fulfill statutory obligations.

DATES: Submit either electronic or written comments on this proposed rule by [INSERT DATE 90 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 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 90 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-2018-N-0628 for "Medical Device Submissions: Amending Premarket Regulations that Require Multiple Copies and Specify Paper Copies to be Allowed in Electronic Format." 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.gpo.gov/fdsys/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: Diane Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5424, Silver Spring, MD 20993, 301-796-6559, email: Diane.Garcia@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

This proposed rule would 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 premarket submission program for medical devices and to create a more efficient submission program. Because a medical device premarket submission in electronic format is easily reproducible, and 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.

II. Background

On February 24, 2017, EO 13777, "Enforcing the Regulatory Reform Agenda" (https://www.gpo.gov/fdsys/pkg/FR-2017-03-01/pdf/2017-04107.pdf, 82 FR 12285 (March 1, 2017)) was issued. One of the provisions in the EO 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 proposed rule.

FDA's current medical device regulations that require multiple copies and paper submissions predate the authority provided to FDA in the Federal Food, Drug, and Cosmetic Act (FD&C Act) to require electronic submissions (see 21 CFR parts 807, 812, and 814 and section 745A of the FD&C Act (21 U.S.C. 379k-1)).

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 will 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), or 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 does 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) of the FD&C Act and section 207 of FDARA). The amended provisions in the FD&C Act require presubmissions and submissions, 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).

III. Legal Authority

FDA is issuing this proposed 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, 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 and section 207 of FDARA provide 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.

IV. Description of the Proposed Rule

We are proposing to revise FDA's regulations for devices to remove the requirements for multiple copies of submissions and to instead require one electronic version. The affected submissions include premarket notification submissions (510(k) submissions) (21 CFR 807.90),

including confidentiality of information certification (21 CFR 807.95); investigational device exemption applications (21 CFR 812.20); premarket approval applications (PMA) (21 CFR 814.20), including PMA supplements (21 CFR 814.39); and humanitarian device exemption applications (21 CFR 814.104). This proposed rule also affects submissions for Center for Biologics Evaluation and Research (CBER) regulated devices.

Another amendment that the proposed rule will make, if finalized, is to the sections of the regulations that identify FDA's mailing addresses for submissions. Current regulations include specific mailing addresses for submissions. If a mailing address needs to be updated, this necessitates an amendment to the regulations to update that address. A simpler and more efficient means of providing current mailing addresses is to create a website that can list current mailing addresses. Any changes to mailing addresses can be added to the website without the need for an amendment to the regulations. This proposed rule will amend the regulations to remove the mailing addresses for submissions and replace those addresses with a website address for the Center for Devices and Radiological Health (CDRH) and CBER.

The submission of an eCopy is separate and distinct from FDA's electronic submission programs (eSubmitter), which include the Electronic Submission Gateway (ESG) and CDRH's 510(k) eSubmissions Pilot Program (79 FR 24732, May 1, 2014). Nevertheless, FDA considers both 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 ESG for the receipt and processing of many types of

electronic regulatory submissions (Ref. 2). FDA considers eCopies, submissions copied to a CD, DVD, or flash drive and mailed to FDA, and eSubmissions, to be submissions in electronic format.

These changes are intended 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.

FDA is proposing to amend current medical device regulations that require multiple copies and paper submissions (21 CFR parts 807, 812, and 814). FDA is taking this action because the requirement for multiple copies (whether in electronic format or paper form) listed in the regulation is no longer necessary, and it is beneficial to the public to limit any burden and expense to submitters caused by requiring additional copies.

V. Proposed Effective Date

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

VI. Economic Analysis of Impacts

We have examined the impacts of the proposed rule under EO 12866, EO 13563, EO 13771, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). EOs 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). EO 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 EO 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 proposed rule amends the existing premarket regulations requiring multiple copies and paper submissions to electronic format submissions without imposing any new requirements, 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 $150 million, using the most current (2017) 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.

The purpose of this proposed rule is to amend device regulations requiring that firms submit a specific number of copies with a premarket presubmission or submission to a single submission in electronic form. The proposed rule also amends all device regulations containing references to submission media (i.e., paper copies) to a submission in electronic form. The amendment will produce cost savings for firms without imposing any additional regulatory

burdens for 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 Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full analysis of economic impacts is available in the docket for this proposed rule (Ref. 3) and at https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.

Summary of Costs and Benefits

The proposed rule, if finalized, would amend device regulations requiring the number of copies firms must submit with a premarket presubmission or submission. The proposed rule would also amend all device regulations containing a reference to the specific form of a submission to require an electronic submission. The amendment would produce cost savings for firms without imposing any additional regulatory burdens for submissions or affecting the Agency's ability to review submissions. Firms would 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.

Table 1 summarizes the benefits, costs, and distributional effects of the proposed rule. We find that the proposed rule would result in annualized net benefits in the form of cost savings of around $2.80 million with a 3 percent discount rate and $2.71 million with a 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	$3.37	$1.31	$5.47	2016	7%	10 years	Benefits are cost savings
		$3.37	$1.31	$5.47	2016	3%	10 years	Benefits are cost savings
	Annualized Quantified					7%		
						3%		
	Qualitative							
Costs	Annualized Monetized $millions/year	$0.67	$0.67	$0.67	2016	7%	10 years	
		$0.57	$0.57	$0.57	2016	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year					7%		
						3%		
	From/ To	From:			To:			
	Other Annualized Monetized $millions/year					7%		
						3%		
	From/To	From:			To:			

Table 2 summarizes the EO 13771 impacts of the proposed rule. Over an infinite time horizon, the present value of the total net costs would range from $40.01 million to $182.94 million at a 3 percent discount rate and from $15.04 million to $78.67 million at a 7 percent discount rate. Over an infinite time horizon, the total annualized net costs would range from $1.17 million to $5.33 million at a 3 percent discount rate, and range from $0.98 million to $5.15 million at a 7 percent discount rate. This proposed rule, if finalized, is considered an Executive Order 13771 deregulatory action.

Table 2.--Summary of the Executive Order 13771 Impacts of the Proposed Rule over an Infinite Time Horizon (2016 $ millions)

	Primary Estimate (3%)	Lower Bound (3%)	Upper Bound (3%)	Primary Estimate (7%)	Lower Bound (7%)	Upper Bound (7%)
Present Value of Costs	$5.01	$5.01	$5.01	$5.01	$5.01	$5.01
Present Value of Cost Savings	$115.79	$45.02	$187.95	$51.55	$20.04	$83.68
Present Value of Net Costs	($110.78)	($40.01)	($182.94)	($46.54)	($15.04)	($78.67)
Annualized Costs	$0.15	$0.15	$0.15	$0.33	$0.33	$0.33
Annualized Cost Savings	$3.37	$1.31	$5.47	$3.37	$1.31	$5.47
Annualized Net Costs	($3.23)	($1.17)	($5.33)	($3.04)	($0.98)	($5.15)

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

VII. 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.

VIII. Paperwork Reduction Act of 1995

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

IX. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in EO 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 rule does not contain policies that have

federalism implications as defined in the EO and, consequently, a federalism summary impact statement is not required.

X. Consultation and Coordination with Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in EO 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. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XI. 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/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf.

2. Electronic Submission Gateway procedure for electronic regulatory submission is available at: https://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm.

3. Preliminary economic impacts analysis for this proposed rule available at: https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.

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 proposed to be 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, 371, 374, 379k-1, 381, 393; 42 U.S.C. 264, 271.

2. In § 807.90, revise paragraph (a), remove and reserve paragraph (b), and revise paragraph (c).

The revisions 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 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, 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.

* * * * *

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, 360bbb-8b, 360c-360j, 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. Revising paragraph (c);

d. Revising paragraph (e) introductory text; and

e. 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 http://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.

* * * * *

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: September 7, 2018.

Scott Gottlieb,

Commissioner of Food and Drugs.

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