4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-3769]

Providing Regulatory Submissions for Medical Devices in Electronic Format--Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled "Providing Regulatory Submissions for Medical Devices in Electronic Format--Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act." Amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act) by the FDA Reauthorization Act of 2017 (FDARA) require that certain pre-submissions and submissions for devices be submitted in electronic format specified by FDA beginning on such date as specified in final guidance. It also mandates that FDA issue draft guidance not later than October 1, 2019, and a final guidance not later than 1 year after the close of the public comment period, providing for further standards for the submission by electronic format, a timetable for establishment of these further standards, and criteria for waivers of and exemptions from the requirements. In addition, in the Medical Device User Fee Amendments of 2017 (MDUFA IV) Commitment Letter from the Secretary of Health and Human Services to Congress, FDA committed to developing electronic submission templates, and issuing a draft guidance on the topic. No later than 12 months after the close of the public comment period, the Agency will

issue a final guidance. This guidance is intended to satisfy the final guidance documents referenced in the FDA&C Act and the MDUFA IV Commitment Letter.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidance documents at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket No. FDA-2019-D-3769 for "Providing Regulatory Submissions for Medical Devices in Electronic Format--Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act." Received comments 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, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as

"confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see §10.115 (21 CFR 10.115(g)(5))).

An electronic copy of the guidance document is available for download from the internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Providing Regulatory Submissions for Medical Devices in Electronic Format--Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act" to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Jacqueline Gertz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1655, Silver Spring, MD 20993-0002, 240-402-9677 or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

Section 745A(b) of the FD&C Act (21 U.S.C. 379k-1(b)), amended by section 207 of FDARA (Pub. L. 115-52), requires that pre-submissions and submissions for devices under section 510(k), 513(f)(2)(A), 515(c), 515(d), 515(f), 520(g), 520(m), or 564 of the FD&C Act (21 U.S.C. 360(k), 360c(f)(2)(A), 360e(c), 360e(d), 360e(f), 360j(g), 360j(m), or 360bbb-3) or section 351 of the Public Health Service Act (42 U.S.C. 262) and any supplements to such pre-submissions or submissions, including appeals of those submissions, be submitted in electronic format specified by FDA beginning on such date as specified by FDA in final guidance. It also mandates that FDA issue a draft guidance not later than October 1, 2019, providing for further standards for the submission by electronic format, a timetable for establishment of these further standards, and criteria for waivers of and exemptions from the requirements. In addition, in the MDUFA IV Commitment Letter[1] from the Secretary of Health and Human Services to Congress, FDA committed to developing "electronic submission templates that will serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process" and "by FY [fiscal year] 2020, the Agency will issue a draft guidance document on the use of the electronic submission templates." No later than 12 months

[1] https://www.fda.gov/media/102699/download.

after the close of the public comment period, the Agency will issue a final guidance. This guidance is intended to satisfy the final guidance documents referenced in section 745A(b)(3) of the FD&C Act and the MDUFA IV Commitment Letter.

The Agency has concluded that it is not feasible to describe and implement the electronic format(s) that would apply to all the submissions covered by section 745A(b) of the FD&C Act in one guidance document. Accordingly, this guidance describes how FDA interprets and plans to implement the requirements of section 745A(b)(3) of the FD&C Act, while individual guidances will be developed to specify the formats for specific submissions and corresponding timetables for implementation. Specifically, this guidance discusses: (1) the submission types that must be submitted electronically, (2) criteria for waivers of and exemptions from the submissions in electronic format requirements, and (3) the timetable and process for implementing the requirements.

A notice of availability for the draft guidance appeared in the *Federal Register* of November 25, 2019 (84 FR 50850). FDA considered the comments received and revised the guidance as appropriate in response to the comments, including an update to add real-time review Premarket approval application (PMA) supplements and a clarification that we intend to consider the time period necessary to transition to use of the electronic format when identifying the date on which electronic format will be required.

In section 745A(b) of the FD&C Act, Congress granted explicit statutory authorization to FDA to specify in guidance the statutory requirement for electronic submissions solely in electronic format by providing standards, a timetable, and criteria for waivers and exemptions. To the extent that this document provides such requirements under section 745A(b)(3) of the FD&C Act (i.e., standards, timetable, criteria for waivers of and exemptions), indicated by the

use of the mandatory words, such as must or required, this document is not subject to the usual restrictions in FDA's good guidance practice regulations, such as the requirement that guidances not establish legally enforceable responsibilities. (See § 10.115(d).)

However, this document also contains guidance on additional submission types for which submission in electronic format is not required. To the extent that this guidance describes recommendations that are not standards, timetable, criteria for waivers of, or exemptions under section 745A(b)(3), it is being issued in accordance with FDA's good guidance practices regulation (§ 10.115). This guidance represents the Agency's current thinking on this topic, and do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used for these recommendations if such an approach satisfies the requirements of the applicable statutes and regulations. This final guidance contains both binding and nonbinding provisions.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products. This guidance is also available at https://www.regulations.gov or https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances. Persons unable to download an electronic copy of "Providing Regulatory Submissions for Medical Devices in Electronic Format--Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act" may

send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 19031 to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The collections of information in the following FDA regulations and guidances have been approved by OMB as listed in the following table:

21 CFR Part or Guidance	Topic	OMB Control No.
807, subpart E	Premarket Notification Submission	0910-0120
814, subparts A through E	Premarket Approval Application	0910-0231
814, subpart H	Humanitarian Use Device Exemption	0910-0332
812	Investigational Device Exemption	0910-0078
"De Novo Classification Process (Evaluation of Automatic Class III Designation)"	De Novo Classification Process	0910-0844
"FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act"	513(g) Request for Information	0910-0705
"Requests for Feedback on Medical Device Submissions: The Q-Submission Program and Meetings with Food and Drug Administration Staff"	Pre-Submissions	0910-0756
800, 801, and 809	Medical Device Labeling Regulations	0910-0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910-0073
"Humanitarian Device Exemption Regulation: Q&As"	Humanitarian Device Exemption Applications and Annual Distribution Number Reporting Requirements	0910-0661
"Emergency Use Authorization of Medical Products"	Emergency Use Authorization	0910-0595
601	Biologics License Applications	0910-0338

"Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices"	CLIA Waiver Applications	0910-0598
"Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization"	Administrative Procedures for CLIA Categorizations	0910-0607

Dated: July 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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