



BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-D-9429]

Electronic Submission Template for Medical Device Premarket Approval

Applications (PMAs); Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “Electronic Submission Template for Medical Device Premarket Approval Applications (PMAs).” FDA is issuing this draft guidance for submitters of certain PMAs to the Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER). It introduces those submitters to the current publicly available resources and associated content developed to support electronic submissions of certain PMAs and PMA supplements to FDA. This draft guidance, when finalized, is intended to represent one of several steps in meeting FDA's commitment to the development of electronic submission templates to serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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-2026-D-9429 for “Electronic Submission Template for Medical Device Premarket Approval Applications (PMAs).” 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 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 draft guidance document entitled “Electronic Submission Template for Medical Device Premarket Approval Applications (PMAs)” to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave.,

Bldg. 66, Rm. 5441, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 301-796-6353; or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this draft guidance document to introduce submitters of certain PMAs to CDRH and CBER to the current resources and associated content developed and made publicly available to support electronic submissions of certain PMAs/PMA supplements to FDA. These include Original PMAs, Panel-Track Supplements, 180-day Supplements, Real Time Supplements, and 30-Day Notices/135-Day Supplements. This draft guidance is intended to represent one of several steps in meeting FDA's commitment to the development of electronic submission templates to serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process. When finalized, this guidance will also facilitate the implementation of the FDA's mandate under section 745A(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379k-1(b)), amended by section 207 of the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115-52), to provide 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.

FDA's final guidance document published on July 15, 2020 (85 FR 42864):
“Providing Regulatory Submissions for Medical Devices in Electronic Format--
Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act”
(hereafter referred to as the “745A(b) device parent guidance”) provides a process for the
development of templates to facilitate the preparation, submission, and review of
regulatory submissions for medical devices solely in electronic format. As described in
the 745A(b) device parent guidance, FDA plans to implement the requirements of section
745A(b)(3) of the FD&C Act with individual guidances specifying the formats for
specific submissions and corresponding timetables for implementation. When finalized,
this guidance will provide such information for electronic submissions of certain
PMAs/PMA supplements solely in electronic format.

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 draft guidance 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)). To the extent that this draft
guidance describes recommendations that are not standards, timetable, criteria for
waivers of, or exemptions under section 745A(b)(3) of the FD&C Act, it is being issued
consistent with FDA’s good guidance practices regulation (§ 10.115).

The draft guidance, when finalized, will represent the current thinking of FDA on Electronic Submission Template for PMAs/PMA supplements. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Electronic Access

Persons interested in obtaining a copy of the draft 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 document is also available at <https://www.regulations.gov>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics>. Persons unable to download an electronic copy of “Electronic Submission Template for Medical Device Premarket Approval Applications (PMAs)” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number GUI00007079 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved

collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521). The collections of information in the following table have been approved by OMB:

21 CFR Part	Topic	OMB Control No.
814, subparts A through E	Premarket approval	0910-0231
800, 801, 809, and 830	Medical Device Labeling Regulations; Unique Device Identification	0910-0485
820	Current Good Manufacturing Practice (CGMP); Quality Management System Regulation (QMSR)	0910-0073

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-19181 Filed: 9/17/2026 8:45 am; Publication Date: 9/18/2026]