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Electronic Submission Template for Premarket Approval Applications (PMAs)

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

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Preface

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Electronic Submission Template for Premarket Approval Applications (PMAs)

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA or Agency) is issuing this draft guidance document for applicants intending to submit Premarket Approval applications (PMAs) and certain PMA supplements to the Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER). It introduces those applicants to the current publicly available resources and associated content developed to support these submissions to FDA; specifically, Original PMAs, Panel-Track Supplements, 180-day Supplements, Real Time Supplements, and 30-Day Notices/135-Day Supplements (hereafter "Designated Application Types").[1] This draft guidance is intended to represent one of several steps in meeting FDA's commitment to the development of electronic submission templates to serve as guided submission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.[2] 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), 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

[1] For the current list of the submission types that can be submitted using eSTAR, see the "eSTAR Program webpage."

[2] *See* 163 CONG. REC. S4729-S4736 (daily ed. August 2, 2017) (Food and Drug Administration User Fee Reauthorization), also available at https://www.fda.gov/media/102699/download and 168 CONG. REC. S5194-S5203 (daily ed. September 28, 2022) (Food and Drug Administration User Fee Reauthorization), also available at https://www.fda.gov/media/158308/download

exemptions from the requirements.

FDA's guidance document "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 the Designated Application Types solely in electronic format.

In section 745A(b)(3) of the FD&C Act, Congress granted explicit statutory authorization to FDA to specify in guidance the electronic submissions requirement by providing standards, criteria for waivers and exemptions, and a timetable for such submissions. Accordingly, to the extent that this document provides such requirements under section 745A(b)(3) of the FD&C Act, indicated by the use of mandatory words, such as must or required, this guidance is not subject to the usual restrictions in section 701(h) of the FD&C Act and FDA's good guidance practices (GGPs) regulations, such as the requirement that guidances not establish legally enforceable responsibilities. *See* 21 CFR 10.115(d).

This document provides draft guidance on FDA's interpretation of the statutory requirement for electronic submissions solely in electronic format. Therefore, to the extent that this draft guidance describes recommendations that are not "standards," "timetable," or "criteria for waivers" and "exemptions" under section 745A(b)(3) of the FD&C Act, this document does not create or confer any rights for or on any person and does not operate to bind FDA or the public, but does represent the Agency's current thinking on this topic, once final. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff listed on the title page of this draft guidance.

To comply with the GGP regulations and make sure that regulated entities and the public understand that guidance documents are nonbinding, FDA guidances ordinarily contain standard language explaining that guidances should be viewed only as recommendations unless specific regulatory or statutory requirements are cited. This draft guidance, when finalized, will contain both binding and nonbinding provisions. Insofar as this draft guidance provides "standards," "timetable," or "criteria for waivers" and "exemptions" pursuant to section 745A(b) of the FD&C Act, it will have a binding effect when final.

For those provisions not identified as binding, the contents of this document are not intended to have the force and effect of law. This document, other than the binding provisions when finalized, is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the

word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

Section 745A(b) of the FD&C Act, amended by section 207 of FDARA, 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 or section 351 of the Public Health Service Act, 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 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.[3]

In addition, in the Medical Device User Fee Amendments of 2017 (MDUFA IV) Commitment Letter[4] 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." In addition, the MDUFA IV Commitment Letter states that "[n]o later than 12 months after the close of the public comment period, the Agency will issue a final guidance." The 745A(b) device parent guidance was intended to satisfy the final guidance document referenced in section 745A(b)(3) of the FD&C Act and the MDUFA IV Commitment Letter. The Medical Device User Fee Amendments of 2022 (MDUFA V) Commitment Letter affirmed FDA's commitment to the continued development of electronic submission templates for a variety of premarket submission types.[5]

In February 2020, CDRH piloted the use of the electronic Submission Template And Resource (eSTAR) electronic submission template by launching the eSTAR Pilot Program.[6] Since that time, the development and availability of eSTAR templates, and new versions of those templates, has expanded and currently available templates and versions can be found on FDA's website.[7]

During the transition time, up to the point when electronic submissions will be required for

[3] *See* section 745A(b)(3)(B) of the FD&C Act.
[4] *See* 163 CONG. REC. S4729-S4736 (daily ed. August 2, 2017) (Food and Drug Administration User Fee Reauthorization), also available at https://www.fda.gov/media/102699/download
[5] *See* 168 CONG. REC. S5194-S5203 (daily ed. September 28, 2022) (Food and Drug Administration User Fee Reauthorization), also available at https://www.fda.gov/media/158308/download
[6] *See* Notice and request for comments, 85 FR 11371 (Feb. 27, 2020), available at https://www.federalregister.gov/d/2020-03945. The FDA eSTAR website is available at https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program
[7] *See* FDA's website on the eSTAR program at https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program

Designated Application Types, anyone can voluntarily use eSTAR for those submissions.[8] As described below, eSTAR is the only electronic submission template currently available to enable electronic submissions for the Designated Application Types.

III. Scope

This guidance describes the technical standards associated with preparation of the electronic submission template for PMAs/PMA supplements that enable submission of the Designated Application Types solely in electronic format. This does not include PMA Modules and Modular Shells. This guidance discusses the information and guided prompts in the electronic submission template that FDA believes will best facilitate the collection and assembly of the necessary elements of a 'complete' submission.[9] This guidance does not address the information needed for the filing review. This guidance document will be updated accordingly as other PMA submission types are implemented within the eSTAR program. This guidance is not intended to specify the user-interface and detailed content of the eSTAR, but instead is limited to establishing the PMA electronic format and standards for complying with section 745A(b)(3) of the FD&C Act. FDA intends to implement new versions of eSTAR as relevant policies change. FDA also has an ongoing process to collect and consider public comments and stakeholder feedback, which is described on FDA's website.[10]

IV. Significant Terminology

For the purpose of this document, the following significant terminology is described:

eCopy: An electronic copy is a duplicate device submission in electronic format of the previously required paper copy submission sent to FDA.[11] An electronic copy is not considered to be an electronic submission, as defined below.

Electronic Submission (eSubmission): The submission package produced by an electronic submission template[12] that contains the data of a 'complete'[13] submission.

Electronic submission template: A guided submission preparation tool for industry. An electronic submission template walks industry through the relevant contents and components for the respective premarket submission type[14] and device to facilitate submission preparation and

[8] For the current list of the submission types that can be submitted using eSTAR, see the "eSTAR Program webpage."
[9] For Original PMAs and Panel-Track Supplements, a "complete" submission is one that is "administratively complete." *See* the FDA guidance "Acceptance and Filing Reviews for Premarket Approval Applications (PMAs)."
[10] *See* FDA's website on the eSTAR program at https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program
[11] *See* 84 FR 68334 and the FDA guidance "eCopy Program for Medical Device Submissions."
[12] *See* 84 FR 68334 and the FDA guidance "eCopy Program for Medical Device Submissions."
[13] After applicants complete all necessary sections in the eSTAR file, the status message at the top of the PDF will indicate "eSTAR Complete" to represent a complete eSTAR submission.
[14] Certain PMA submission types are further described on the FDA webpage "PMA Supplements and Amendments."

enhance consistency, quality, and efficiency in the premarket review process.[15]

eSTAR (electronic Submission Template And Resource): An electronic submission template[16] built within a structured dynamic PDF that guides a user through construction of an eSubmission. eSTAR is the only type of electronic submission template that is currently available to facilitate the preparation of PMAs/PMA supplements as eSubmissions. For simplicity, the electronic submission created with this electronic submission template is often referred to as an eSTAR.

Structured data: Data and content that are captured in the fields, dropdown boxes, checkboxes, etc., within the electronic submission template.

Unstructured data: Data and content that are submitted as attachments to the electronic submission template.

V. Current Electronic Submission Template Structure, Format, and Use

The electronic submission template, eSTAR, is the only currently available electronic submission template at this time to facilitate the preparation of PMA/PMA supplement electronic submissions. eSTAR consists of a collection of questions, text, logic, and prompts within a template that guides a user through construction of a 'complete' submission.[17] eSTAR is highly automated, includes integrated databases (e.g., FDA product codes, FDA-recognized voluntary consensus standards), and includes targeted questions designed to collect specific data and information from the applicant. eSTAR also includes applicable links to regulations, relevant guidances, and other resources for the applicant's reference. Finally, eSTAR is structured to collect and assemble content in the PMA/PMA supplement as an electronic submission that closely follows the content of the Submission Memo And Review Template ("SMART"), a review template and internal review tool used by FDA reviewers for certain PMA submission types.

Given that an electronic submission properly prepared with an electronic submission template should represent an administratively complete submission,[18] submissions currently subject to the refuse to accept (RTA) process (i.e., Original PMAs and Panel-Track Supplements) are not anticipated to undergo the RTA process described in the guidance "Acceptance and Filing Reviews for Premarket Approval Applications (PMAs)." However, FDA intends to employ a virus scanning and technical screening process for eSTAR submissions. A technical screening process is a process for verifying that eSTAR responses accurately describe the device(s) (e.g.,

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

[16] The eSTAR PDF can be downloaded for free on FDA's website at https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program.

[17] For Original PMAs and Panel-Track Supplements, a "complete" submission is one that is "administratively complete." *See* the FDA guidance "Acceptance and Filing Reviews for Premarket Approval Applications (PMAs)."

[18] After applicants complete all necessary sections in the eSTAR file, the status message at the top of the PDF will indicate "eSTAR Complete" to represent a complete eSTAR submission.

there are, in fact, no tissue contacting components if indicated as such) and that there is at least one relevant attachment per each applicable attachment-type question (e.g., a Product Description attachment is included in response to the Product Description question).[19] For PMAs/PMA supplements, the technical screening process is anticipated to occur within 15 calendar days of FDA receiving the PMA eSTAR. FDA intends to begin the technical screening for PMA electronic submissions only where the appropriate user fee has been paid. If the PMA eSTAR does not pass technical screening, FDA will notify the applicant via email and identify the incomplete information, and the PMA/PMA supplement will be placed and remain on hold until additional information is submitted to FDA. If a response (i.e., an updated eSTAR with additional information in the applicable sections) is received within the 360-day timeframe, this will be logged in as an amendment. If a response is not received within 360 days of the date of technical screening deficiency notification, FDA will consider the PMA/PMA supplement to be withdrawn and the submission will be closed in the system. Upon receipt of the newly submitted information, the review clock will restart at day 0, and FDA staff will conduct the technical screening again, following the same procedure, within the first 15 days of the restarted review clock, to assess whether the new information makes the submission complete. When a submission passes technical screening (whether it is the first technical screening or multiple have occurred), the review clock continues for the rest of the review process. At this time, FDA will notify the applicant electronically and the submission proceeds to substantive review.

Note that all Original PMAs and Panel-Track Supplements that pass technical screening then undergo filing review,[20] which occurs within 45 calendar days after FDA receives the submission.[21]

A. Structure of the Current PMA Electronic Submission Template

Table 1 below shows a high-level overview of the structure of the current electronic submission template for PMAs/PMA supplements,[22] including a summary of the anticipated submission content provided by the applicant in each section:[23]

[19] For Original and Panel-Track PMAs, given that an eSubmission properly prepared with an eSTAR should represent an administratively complete submission as described in the PMA Acceptance Checklist in the FDA guidance "Acceptance and Filing Reviews for Premarket Approval Applications (PMAs)," the technical screening process ensures that the content within the PMA Acceptance Checklist has been submitted.

[20] For more information on filing review, see the FDA guidance "Acceptance and Filing Reviews for Premarket Approval Applications (PMAs)."

[21] *See* 21 CFR 814.42

[22] As indicated above, FDA intends to employ a technical screening process for all PMA submissions previously subject to the RTA process to verify that electronic submission template responses accurately describe the device.

[23] Throughout completion of the eSTAR, applicants can add attachments as unstructured data, including but not limited to documents, PDFs, images, and videos that the applicants believe are pertinent to the review of their device. In addition, eSTAR will prompt for any documents that are needed or may be optionally provided.

210 **Table 1: Structure of the current eSTAR PMA Electronic Submission Template**
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Information Requested	Description
Submission Type	Identification of key information that may be useful to FDA in the initial processing and review of the PMA/PMA supplement, including content from current Form FDA 3514, Section A.[24]
Cover Letter / Letters of Reference	Attach a cover letter and any documents that refer to other submissions.
Applicant Information	Information on applicant and correspondent, if applicable, consistent with content from current Form FDA 3514, Sections B and C (*see* 21 CFR 814.20(b)(1)).
Pre-Submission Correspondence & Previous Regulator Interaction	Information on prior or ongoing submissions for the same device included in the current submission, such as submission numbers for a prior not substantially equivalent (NSE) determination, prior deleted or withdrawn 510(k), Q-Submission, Investigational Device Exemption (IDE) application, premarket approval application (PMA), humanitarian device exemption (HDE) application, De Novo classification request, requests for information under section 513(g) of the FD&C Act, or requests for emergency use authorization (EUA) (*see* FDA Guidance "Acceptance and Filing Reviews for Premarket Approval Applications (PMAs)")
Consensus Standards[25]	Identification of voluntary consensus standard(s) used, if applicable. This includes both FDA-recognized and non-recognized consensus standards (*see* section 514(c) of the FD&C Act and 21 CFR 814.20(b)(5)).
Device Description	Identification of listing number if listed with FDA. A complete description of the device (*see* 21 CFR 814.20(b)(4)).
Proposed Indications for Use	Identification of the proposed indications for use of the device. The term indications for use, as defined in 21 CFR 814.20(b)(3)(i), is "a general description of the disease or condition the device is intended to diagnose, treat, prevent, cure or mitigate, or affect the structure or function of the body, including a description of the patient population for which the device is intended."

[24] https://www.fda.gov/media/72421/download
[25] https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program

Information Requested	Description
Market History	A brief description of the foreign and U.S. marketing history, if any, of the device, including a list of all countries in which the device has been marketed and a list of all countries in which the device has been withdrawn from marketing for any reason related to the safety or effectiveness of the device. The description shall include the history of the marketing of the device by the applicant and, if known, the history of the marketing of the device by any other person (21 CFR 814.20(b)(3)(iv)).
Benefits, Risks, and Mitigation Measures	A discussion demonstrating that the probable benefits to health from use of the device outweigh any probable injury or illness from such use (*see* 21 CFR 814.20(b)(3)(vi) and 860.7). Data and information in the PMA supporting this should constitute valid scientific evidence within the meaning of 21 CFR 860.7(c) (*see also* FDA guidance "Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications"). A description of existing alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended (21 CFR 814.20(b)(3)(iii)).
Labeling	Submission of proposed labeling in sufficient detail to satisfy the requirements of 21 CFR 814.20(b)(10). Generally, if the device is an *in vitro* diagnostic device, the labeling must also satisfy the requirements of 21 CFR 809.10. Additionally, the term "labeling" generally includes the device label, instructions for use, and any patient labeling (*see* sections 201(k) and (m) of the FD&C Act and FDA guidance "Guidance on Medical Device Patient Labeling").
Reprocessing*	Information for assessing the reprocessing validation and labeling, if applicable (*see* FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling").
Sterility*	Information on sterility and validation methods, if applicable.
Shelf Life*	Summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality), if applicable (*see* FDA guidance "Shelf Life of Medical Devices").

Information Requested	Description
Biocompatibility*	Information on the biocompatibility assessment of patient contacting materials, if applicable (*see* FDA guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'").
Software/Firmware, Cybersecurity, and Interoperability*	Submission of applicable software documentation, if applicable (*see* FDA guidance "Content of Premarket Submissions for Device Software Functions"). Submission of information regarding the assessment of cybersecurity, if applicable (*see* FDA guidances "Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions" and "Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices").
Electromagnetic Compatibility (EMC), Electrical, Mechanical, Wireless and Thermal Safety*	Submission of the EMC, Electrical, Mechanical, Wireless and Thermal Safety testing for your device or summarize why testing is not needed (*see* FDA guidances "Electromagnetic Compatibility (EMC) of Medical Devices" and "Radio Frequency Wireless Technology in Medical Devices").
Performance Testing*^	For non-in vitro diagnostic devices: Provide information on the non-clinical and clinical test reports submitted, referenced, or relied on in the PMA to provide a reasonable assurance of safety and effectiveness (*see* FDA guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions"). For in vitro diagnostic devices: Provide analytical performance, comparison studies, reference range/expected values, and clinical study information to demonstrate to provide a reasonable assurance of safety and effectiveness.

Information Requested	Description
Quality Management System Regulation (QMSR) Information	Provide information related to the methods used in, and the facilities and controls used for, designing, manufacturing, packaging, labeling, storing, installing, and servicing of the subject device (*see* 21 CFR 814.20(b)(4)(v) and 21 CFR Part 820).
Post-Market Study Plans[26] (when applicable)	The term "Post-Market Study" refers to post-market clinical or nonclinical studies that may be required as a condition of approval (also referred to as "post-approval studies" (PAS)) and does not include FDA 522 studies. Provide the number of Post-Market Studies agreed upon as part of the PMA approval and information related to each study. The information requested may include study protocols, statistical analysis, milestones, and design.
References	Inclusion of any literature references in accordance with 21 CFR 814.20(b)(8).
Administrative Documentation	Inclusion of additional administrative forms applicable to the submission, including but not limited to a general summary of submission/executive summary (recommended).
Amendment/Additional Information (AI) response	Inclusion of amendments with additional information and/or responses to deficiency letters.[27]

* The information in eSTAR for these sections is intended to fulfill the requirements of 21 CFR 814.20(b)(3)(v) and 21 CFR 814.20(b)(6)(i)
^ The information in eSTAR for this section is intended to fulfill the requirements of 21 CFR 814.20(b)(6)(ii)

VI. Electronic Submission Template Waivers, Exemptions, and Timing

Upon finalization of this draft guidance, all Designated Application Types, unless exempted below in section VI.A of this guidance, will be required to be submitted as electronic submissions as of the implementation date. A PMA/PMA supplement for a Designated Application Type that is not provided as an electronic submission as of that date and as described

[26] For more information on studies required as part of a PMA approval, see the FDA guidance "Procedures for Handling Post-Approval Studies Imposed by PMA Order"

[27] While the responses to FDA additional information requests are included in this section, applicants should include the actual changes to the information to be reviewed by FDA in the respective section of eSTAR (e.g., updated draft labeling should be included in the Labeling section).

above, will not be considered received unless an exemption from the electronic submission requirements applies.

A. Waivers and Exemptions From Electronic Submission Requirements

Above, FDA identified that Designated Application Types are subject to electronic submission requirements upon finalization of this draft guidance after the implementation date. However, section 745A(b)(2) of the FD&C Act allows for FDA to set forth criteria for exemptions and waivers from electronic submission requirements. FDA has identified such criteria for PMAs below.

Exemptions

Upon finalization of this draft guidance, FDA intends to implement exemptions for the following information from the PMA electronic submission requirements:

- Interactive review responses;[28]
- Certain amendments, such as:[29]
  - Appeals/requests for supervisory review;[30]
  - Substantive summary requests;
  - Change in correspondent/change of legal entity/change in applicant address;
  - Amendments after decision (e.g., final labeling amendments);
- Withdrawal requests;[31]
- Reports, including but not limited to:[32]
  - Annual/Periodic reports under 21 CFR 814.84(b)
  - Post Approval study reports

Waivers

At this time, FDA has not identified any particular circumstances appropriate for a waiver of the PMA electronic submission requirements for the Designated Application Types and does not

[28] If the reviewer used interactive review via phone or email, the applicant should reply to the reviewer via email with the requested attachments and additional information. Other responses to requests for additional information must be submitted in eSTAR once this guidance is finalized and specifies an implementation date (*see* "Amendment/Additional Information (AI) Response" category in Table 1 above).

[29] These PMA amendments remain subject to any applicable eCopy requirements. For more information, see the FDA website eCopy Medical Device Submissions and FDA guidance "eCopy Program for Medical Device Submissions."

[30] Section 745A(b)(3) of the FD&C Act authorizes FDA to also require that appeals be submitted solely in such electronic format as specified by the Agency in guidance. Once FDA develops such a format, FDA intends to update this guidance to specify any further standards for the submission of PMA appeals by electronic format, the timetable for establishment of such further standards, and any criteria for a waiver from such requirements.

[31] Submission withdrawal requests remain subject to any applicable eCopy requirements. For more information, see the FDA guidance "eCopy Program for Medical Device Submissions." FDA recommends that withdrawal requests be submitted electronically via email or to the CDRH Portal.

[32] These PMA reports remain subject to any applicable eCopy requirements. For more information, see the FDA guidance "eCopy Program for Medical Device Submissions."

intend to grant requests for waiver. Given the widespread availability of software to enable use of the current PMA eSTAR PDF (available to download on FDA's website), all applicants should have the ability to provide a PMA eSTAR.[33]

B. When Electronic Submissions Will Be Required

As described in the 745A(b) device parent guidance, this draft guidance, once finalized, will be used to specify the corresponding timetable(s) for implementation of PMA electronic submissions. FDA intends to provide a transition period of a minimum of one year from the final guidance issuance prior to requiring that the Designated Application Types be provided as electronic submissions. Currently, and during the transition period, eSTARs may be used voluntarily for PMAs/PMA supplements. As instructed at the website for the eSTAR Program (under the heading, "How to prepare a submission using eSTAR"[34]), the electronic submission must be submitted using FDA's electronic portal when submitting to CDRH. You can submit questions pertaining to the preparation of submission in electronic format to CDRH at OPEQSubmissionSupport@fda.hhs.gov. For electronic submissions to CBER, please refer to Regulatory Submissions in Electronic Format for CBER-Regulated Products on how to submit through the Electronic Submissions Gateway. You can submit questions pertaining to the preparation of submission in electronic format to CBER at ESUBPREP@fda.hhs.gov.

[33] There are currently known technical reasons that preclude electronic submission via the CDRH Portal. Those impacted submissions should be mailed to the CDRH Document Control Center (DCC). For a list of the known technical reasons, please refer to FDA's CDRH Portal webpage.

[34] https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program#prepare

Guidance History*	Date	Description
Level 1 Draft Guidance	September 2026	See Notice of Availability for more information.**

**The Notice of Availability is accessible via the Search for FDA Guidance Documents webpage.

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