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Draft – Not for Implementation

Electronic Submission Template for Medical Device De Novo Requests

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on September 29, 2023.

You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852-1740. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

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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

Preface

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CDRH

Additional copies are available from the Internet. You may also send an email request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number GUI00021027 and complete title of the guidance in the request.

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Additional copies are available from the Center for Biologics Evaluation and Research (CBER), Office of Communication, Outreach, and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Room 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-8010, by email, ocod@fda.hhs.gov, or from the Internet at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.

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Electronic Submission Template for Medical Device De Novo Requests

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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 to introduce submitters of De Novo requests[1] to the Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) to the current resources and associated content developed and made publicly available to support De Novo electronic submissions to FDA. 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[3]) 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 guidance document "Providing Regulatory Submissions for Medical Devices in Electronic Format — Submissions Under Section 745A(b) of the Federal Food, Drug, and

[1] See section 513(f)(2) of the Federal Food, Drug, and Cosmetic (FD&C) Act and 21 CFR part 860, subpart D.
[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 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.
[3] https://www.govinfo.gov/content/pkg/PLAW-115publ52/html/PLAW-115publ52.htm.

Cosmetic Act"[4] (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 De Novo electronic submissions 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 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.

[4] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-medical-devices-electronic-format-submissions-under-section-745ab

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.[5]

In addition, in the Medical Device User Fee Amendments of 2017 (MDUFA IV) Commitment Letter[6] 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 documents 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.[7]

In February 2020, CDRH piloted the use of the electronic Submission Template And Resource (eSTAR) electronic submission template through launching the eSTAR Pilot Program.[8] The eSTAR template became available for voluntary use by all 510(k) submitters in September 2020. In January 2022, CDRH expanded the eSTAR template to include the ability to submit content for De Novo requests. Subsequently, CBER began piloting the use of eSTAR for 510(k)s in June 2022.[9]

[5] See section 745A(b)(3)(B) of the FD&C Act.
[6] 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.
[7] 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.
[8] 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.
[9] See Notice and request for comments, 87 FR 36861 (June 21, 2022), available at https://www.federalregister.gov/documents/2022/06/21/2022-13210/improving-510k-submission-preparation-and-review-center-for-biologics-evaluation-and-research.

During the transition time up to the point when De Novo electronic submissions will be required (see Section VI.B below), anyone can voluntarily use eSTAR for submission of De Novo requests. As described below, eSTAR is the only electronic submission template currently available to enable De Novo electronic submissions.

III. Scope

This guidance describes the technical standards associated with preparation of the electronic submission template for De Novo classification requests[10] that enable submission of the De Novo electronic submission solely in electronic format. The electronic submission template includes the information and guided prompts FDA believes will best facilitate the collection and assembly of the necessary elements of a 'complete' submission.[11] This guidance is not intended to specify the user-interface and detailed content of the eSTAR, but instead is limited to establishing the De Novo electronic format and standards for complying with section 745(A)(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.[12]

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.[13] 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[14] that contains the data of a 'complete'[15] submission.

[10] See section 513(f)(2) of the FD&C Act and 21 CFR part 860, subpart D.
[11] See 21 CFR 860.230 and the FDA guidance "Acceptance Review for De Novo Classification Requests" at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests.
[12] See FDA's website on the eSTAR program at https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program.
[13] See 84 FR 68334 and the FDA guidance "eCopy Program for Medical Device Submissions" at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions.
[14] See 84 FR 68334 and the FDA guidance "eCopy Program for Medical Device Submissions" at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions.
[15] See 21 CFR 860.230 and the FDA guidance "Acceptance Review for De Novo Classification Requests" at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests.

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 De Novo requests as eSubmissions. For simplicity, the electronic submission created with this electronic submission template is often referred to as an eSTAR.

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 and device to facilitate submission preparation and enhance consistency, quality, and efficiency in the premarket review process.[17]

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 De Novo 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' De Novo[18] request. eSTAR is highly automated, includes integrated databases (e.g., FDA product codes,[19] FDA-recognized voluntary consensus standards[20]), and includes targeted questions designed to collect specific data and information from the submitter. eSTAR also includes applicable links to regulations, relevant guidances, and other resources for the submitter's reference. Finally, eSTAR is structured to collect and assemble content in the De Novo request as an electronic submission that closely follows the content of the "SMART" De Novo review memo template used by FDA reviewers.

Given that an electronic submission properly prepared with an electronic submission template should represent a complete submission,[21] the acceptance review under 21 CFR 860.230 has

[16] The De Novo eSTAR can be downloaded for free on FDA's website at https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program.
[17] https://www.fda.gov/media/102699/download.
[18] See 21 CFR 860.230 and the FDA guidance "Acceptance Review for De Novo Classification Requests" at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests.
[19] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/PCDSimpleSearch.cfm.
[20] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.
[21] After a submitter completes all necessary sections in their eSTAR file correctly, the status message at the top of the PDF will indicate "eSTAR Complete" to represent a complete submission.

been largely automated within the eSTAR.[22] However, FDA intends to employ a virus scanning and technical screening process for an eSTAR as part of the acceptance review process. A technical screening process is a process for verifying that eSTAR responses are consistent with descriptions of the device(s) (e.g., 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 Software Description attachment is included in response to the Software Description question if software is applicable to the submission). The technical screening process is anticipated to occur within 15 calendar days of FDA receiving the De Novo eSTAR. FDA will only begin the technical screening for De Novo electronic submissions where the appropriate user fee has been paid. If the eSTAR is not complete when submitted, FDA will notify the submitter via email[23] and identify the incomplete information, and the De Novo will be placed on hold. If a replacement eSTAR is not received within 180 days of the date of technical screening deficiency notification, FDA will consider the De Novo to be withdrawn and the submission will be closed in the system.[24] The technical screening review time does not impact the review clock for files that pass the technical screening. For a submission that passes technical screening, the review clock starts on the day the submission was received by FDA. Once the eSTAR passes technical screening and the De Novo submission is accepted, FDA will notify the requester electronically.[25] If FDA does not complete the technical screening within the acceptance review period (i.e., within 15 calendar days of receipt), FDA will accept the De Novo request for review and will notify the requester.[26]

A. Structure of the Current De Novo Electronic Submission Template

In Table 1 below, is a high-level overview of the structure of the current electronic submission template for De Novos,[27] including a summary of the anticipated submission content provided by the submitter in each section:[28]

[22] For more information on the acceptance process, please see 21 CFR 860.230 and the FDA guidance "Acceptance Review for De Novo Classification Requests" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests.

[23] For additional information about email communications with CBER, please see the "SOPP 8119: Use of Email for Regulatory Communications," available at https://www.fda.gov/media/108992/download.

[24] See 21 CFR 860.250(a)(2).

[25] 21 CFR 860.230(a). For additional information about email communications with CBER, please see "SOPP 8119: Use of Email for Regulatory Communications," available at https://www.fda.gov/media/108992/download.

[26] 21 CFR 860.230(b).

[27] As indicated above, FDA intends to employ a technical screening process to verify that electronic submission template responses accurately describe the device.

[28] Throughout completion of the eSTAR, submitters can add attachments as unstructured data, including documents, PDFs, images, and videos that the submitter believes are pertinent to the review of their device. In addition, eSTAR will prompt for any documents that are needed. For example, when the use of clinical testing to support the submission is affirmatively indicated, eSTAR will automatically prompt for the attachment of clinical testing documents and any applicable financial certifications or disclosure statements. These attachments appear within the applicable bookmark of the eSTAR PDF when viewed by the submitter or FDA.

193 **Table 1: Structure of the current eSTAR De Novo Electronic Submission Template**

Information Requested	Description
Submission Type	Identification of key information that may be useful to FDA in the initial processing and review of the De Novo request, including content from current Form FDA 3514, Section A.[29]
Cover Letter / Letters of Reference	Attach a cover letter and any documents that refer to other submissions.
Applicant[30] Information	Information on applicant and correspondent, if applicable, consistent with content from current Form FDA 3514, Sections B and C (*see* 21 CFR 860.220(a)(2)).
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 (PMA) application, humanitarian device exemption (HDE) application, De Novo classification request, requests for information under section 513(g) of the FD&C Act, or applications for emergency use authorization (EUA) (*see* 21 CFR 860.220(a)(3)).
Consensus Standards[31]	Identification of voluntary consensus standard(s) used, if applicable. This includes both FDA-recognized and non-recognized consensus standards (*see* 21 CFR 860.220(a)(12)).

[29] https://www.fda.gov/media/72421/download.

[30] As described in the eSTAR PDF, the "Applicant" is also commonly referred to as the "Submitter" or previously "Sponsor" for 510(k)s, but is not necessarily the person who submits the 510(k). The "Applicant" is the proper term for PMAs but is referred to as the "Requester" for De Novos.

[31] https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program.

Information Requested	Description
Device Description	Identification of listing number if listed with FDA. Descriptive information for the device, in accordance with 21 CFR 860.220(a)(6). Descriptive information also includes a description of the principle of operation for achieving the intended effect and the proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient. A description of existing alternative practices or procedures used in diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended or which similarly affect the structure and function of the body. Otherwise, provide a statement if there are no known or reasonably known alternative practices or procedures (*see* 21 CFR 860.220(a)(7)). Information on whether the device is intended to be marketed with accessories. If a Request for Designation (RFD) number exists, provide the RFD number that established that the device or combination product being submitted was assigned to CDRH or CBER (*see* 21 CFR 860.220(a)(3)).
Proposed Indications for Use	Identification of the proposed indications for use of the device. The term indications for use, as defined in 21 CFR 860.220(a)(5), 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. The indications for use include all the labeled patient uses of the device, including if it is prescription or over-the-counter."

Information Requested	Description
Classification	Identification of the proposed classification (Class I or II) that seems most appropriate for the subject device (*see* 21 CFR 860.220(a)(11)). Provide classification summary information, in accordance with 21 CFR 860.220(a)(8)).
Benefits, Risks, and Mitigation Measures	A summary of the probable risks to health associated with use of the device that are known or should reasonably be known to you and the proposed mitigations, including general controls and, if applicable, special controls for each risk (*see* 21 CFR 860.220(a)(9)). If the proposed classification recommendation is class II, proposed special controls to mitigate the risks to health associated with use of the device, in accordance with 21 CFR 860.220(a)(10). A discussion demonstrating that, the data and information in the De Novo request constitute valid scientific evidence within the meaning of 21 CFR 860.7(c), and pursuant to 21 CFR 860.7, when subject to general controls or general and special controls, the probable benefits to health from use of the device outweigh any probable injury or illness from such use (*see* 21 CFR 860.220(a)(14) and "Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications").[32]
Labeling	Submission of proposed labeling in sufficient detail to satisfy the requirements of 21 CFR 860.220(a)(18). 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 "Guidance on Medical Device Patient Labeling").[33]

[32] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/factors-consider-when-making-benefit-risk-determinations-medical-device-premarket-approval-and-de.
[33] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-medical-device-patient-labeling.

Information Requested	Description
Reprocessing*	Information for assessing the reprocessing validation and labeling, if applicable (*see* "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling").[34]
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* "Shelf Life of Medical Devices").[35]
Biocompatibility*	Information on the biocompatibility assessment of patient contacting materials, if applicable (*see* "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'").[36]
Software/Firmware	Submission of applicable software documentation, if applicable (*see* 21 CFR 860.220(a)(15)(ii) and "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices").[37]
Cybersecurity/Interoperability*	Submission of applicable information regarding the assessment of cybersecurity, if applicable (*see* "Content for Premarket Submissions for Management of Cybersecurity in Medical Devices"[38] and "Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices").[39]
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* "Electromagnetic Compatibility (EMC) of Medical Devices"[40] and "Radio Frequency Wireless Technology in Medical Devices").[41]

[34] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling.
[35] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/shelf-life-medical-devices
[36] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and.
[37] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices.
[38] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0.
[39] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-and-pre-market-submission-recommendations-interoperable-medical-devices.
[40] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/information-support-claim-electromagnetic-compatibility-emc-electrically-powered-medical-devices.
[41] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/radio-frequency-wireless-technology-medical-devices-guidance-industry-and-fda-staff.

Information Requested	Description
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 De Novo to demonstrate that general controls or general and special controls are sufficient to provide a reasonable assurance of safety and effectiveness (*see* "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions").[42] For in vitro diagnostic devices: Provide analytical performance, comparison studies, reference range/expected values, and clinical study information to demonstrate that general controls or general and special controls are sufficient to provide a reasonable assurance of safety and effectiveness.
References	Inclusion of any literature references in accordance with 21 CFR 860.220(a)(16).
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 responses to Additional Information requests.[43]

* The information in eSTAR for these sections is intended to fulfill the requirements of 21 CFR 860.220(a)(13) and 21 CFR 860.220(a)(15)(i).

^ The information in eSTAR for this section is intended to fulfill the requirements of 21 CFR 860.220(a)(15)(iii).

VI. Electronic Submission Template Waivers, Exemptions, and Timing

Upon finalization of this draft guidance, all submissions for De Novo requests, including original, Supplements and Amendments (amendments include add-to-files and appeals),[44] and any other subsequent submissions to an original submission unless exempted below in Section

[42] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket.

[43] While the responses to FDA additional information requests are included in this section, submitters 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).

[44] References to supplements and amendments are generally meant to capture the various submission types that typically occur in association with a De Novo file that is undergoing review or has received a final decision.

VI.A of this guidance, are required to be submitted as electronic submissions as of the implementation date. A De Novo request that is not provided as an electronic submission as of that date and as described in Section V above, will not be received unless an exemption from the electronic submission requirements or a waiver with respect to that submission applies.

A. Waivers and Exemptions From Electronic Submission Requirements

Above, FDA identified that De Novo requests 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 De Novos below.

Exemptions

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

- Interactive review responses;[45]
- Amendments:[46]
    - Appeals/requests for supervisory review;[47]
    - Substantive summary requests;
    - Change in correspondent amendments; and
    - Amendments after final decision (i.e., add-to-files).

Waivers

At this time, FDA has not identified any particular circumstances appropriate for a waiver of the De Novo electronic submission requirements and does not intend to grant requests for waiver. Given the widespread availability of software to enable use of the current De Novo eSTAR PDF (available to download on FDA's website), all submitters should have the ability to provide a De Novo eSTAR.[48]

[45] If the reviewer used interactive review via phone or email, the submitter 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).

[46] These De Novo amendments remain subject to any applicable eCopy requirements. For more information, see the FDA guidance "eCopy Program for Medical Device Submissions" at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions.

[47] 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 De Novo appeals by electronic format, the timetable for establishment of such further standards, and any criteria for a waiver from such requirements.

[48] There are currently known technical reasons that preclude certain electronic submissions via the CDRH Portal. Those impacted submissions should be mailed to the CDRH Document Control Center (DCC). For more information on the known technical reasons, please refer to FDA's CDRH Portal webpage, available at https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal.

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 De Novo electronic submissions. By September 30, 2025, FDA intends to identify a specific date on which we will require that De Novo requests be provided as electronic submissions. We anticipate that from the time we announce a date, there will be a transition period prior to requiring that all De Novo requests be provided as electronic submissions. Currently, and during the transition period, eSTARs may be used voluntarily for submission of De Novo requests. As instructed at the website for the eSTAR Program (under the heading, "How to prepare a submission using eSTAR"[49]), the electronic submission must be submitted using FDA's electronic portal when submitted 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[50] on how to submit through the Electronic Submissions Gateway.[51] You can submit questions pertaining to the preparation of submission in electronic format to CBER at ESUBPREP@fda.hhs.gov. When a date is identified, this draft guidance will be updated and finalized to provide that specific date and set forth the electronic format(s) specified in this guidance that must be used for submission of De Novo requests.

[49] https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program.
[50] https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/regulatory-submissions-electronic-format-cber-regulated-products.
[51] https://www.fda.gov/industry/electronic-submissions-gateway.