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Electronic Submission Template for Investigational Device Exemption (IDE) Applications

Draft Guidance for Sponsors and Food and Drug Administration Staff

DRAFT GUIDANCE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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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 GUI00007080 and complete title of the guidance in the request.

Additional copies of this guidance are available from the Center for Biologics Evaluation and Research, Food and Drug Administration by calling 1-800-835-4709 or 240-402-8010, or email industry.biologics@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 Investigational Device Exemption (IDE) Applications

Draft Guidance for Sponsors and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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The Food and Drug Administration (FDA or Agency) is issuing this draft guidance document for sponsors of Investigational Device Exemption (IDE) applications[1] to the Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER). It introduces those sponsors to the current publicly available resources and associated content developed to support the electronic submissions of IDE applications not otherwise exempted in Section VI.A[2] (hereafter "IDE 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 This draft guidance is intended to represent one of several steps in meeting FDA's commitment to the development of electronic submission templates to serve as guided submission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 sponsors to improve submission consistency and enhance efficiency in the review process.[3] When finalized, this draft 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 exemptions from the requirements.

[1]For the purposes of this guidance, Original IDE applications (21 CFR 812.20), IDE supplemental applications (21 CFR 812.35), amendments to Original IDE applications and IDE supplemental applications, and related IDE submissions are collectively referred to as "IDE applications."

[2] For example, IDE Reports and amendments to IDE Reports are exempted.

[3] 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

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 IDE 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 electronic submission standards. 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 draft 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 draft 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 sections 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.[4]

In addition, in the Medical Device User Fee Amendments of 2017 (MDUFA IV) Commitment Letter[5] 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.[6]

In February 2020, CDRH piloted the use of the electronic Submission Template And Resource (eSTAR) electronic submission template by launching the eSTAR Pilot Program.[7] 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.[8]

During the transition time, up to the point when IDE electronic submissions will be required (*see* Section VI.B below), anyone can voluntarily use eSTAR for submission of IDE applications.[9] As

[4] *See* section 745A(b)(3)(B) of the FD&C Act.
[5] *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
[6] *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
[7] *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/estar-program
[8] *See* FDA's website on the eSTAR program at https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program
[9] For the current list of the submission types that can be submitted using eSTAR, see the "eSTAR Program webpage."

described below, eSTAR is the only electronic submission template currently available to enable IDE electronic submissions.

III. Scope

This draft guidance describes the technical standards associated with the preparation of the electronic submission template for IDE applications, that enable submission of the electronic IDE 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 elements of an IDE application required under 21 CFR Part 812. This draft guidance is not intended to specify the user-interface and detailed content of the eSTAR but instead is limited to establishing the IDE 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 sponsors. An electronic submission template walks the sponsor 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.[14]

eSTAR (electronic Submission Template And Resource): An electronic submission template[15] 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 IDEs as eSubmissions. For simplicity, the electronic submission created with this electronic submission template is often referred to as an eSTAR.

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[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 the sponsor completes 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] https://www.fda.gov/media/102699/download

[15] 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

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 IDE electronic submissions. eSTAR consists of a collection of questions, text, logic, and prompts within a template that guides a user through construction of an IDE application addressing all the elements required by 21 CFR Part 812. eSTAR is highly automated, includes integrated databases (e.g., FDA-recognized voluntary consensus standards), and includes targeted questions designed to collect specific data and information from the sponsor. eSTAR also includes applicable links to regulations, relevant guidances, and other resources for the sponsor's reference. Finally, eSTAR is structured to collect and assemble content in the IDE application as an electronic submission that closely follows the content of the Submission Memo And Review Template or "SMART" IDE review memo template, an internal review tool used by FDA reviewers.

FDA intends[16] to review and reach a decision on every IDE electronic submission within 30 days from the date of receipt[17] of the IDE application. For more information on FDA's processes regarding IDE application decisions, please see the guidance "FDA Decisions for Investigational Device Exemption Clinical Investigations."

A. Structure of the Current IDE Electronic Submission Template

Table 1 below shows a high-level overview of the structure of the current electronic submission template for IDE applications including a summary of the anticipated submission content provided by the sponsor in each section:[18,19]

[16] For IDE applications involving an exception from informed consent under 21 CFR 50.24, FDA will provide a written determination within 30 days. Clinical investigations involving such exceptions from informed consent may not proceed without prior written authorization of FDA. *See* 21 CFR 812.20(a)(4)(i).

[17] The date of receipt is indicated in the acknowledgment letter sent to the IDE application correspondent.

[18] Throughout completion of the eSTAR, sponsors can add attachments as unstructured data, including but not limited to documents, PDFs, images, and videos that the sponsors 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 based on the supplement type, device characteristics, and other eSTAR responses. For example, when the use of software is affirmatively indicated, eSTAR will automatically prompt for the attachment of software documentation. Otherwise, this documentation is not requested.

[19] Note that items in this table without a specific reference to 21 CFR Part 812 are covered under 21 CFR 812.20(b)(12).

171 **Table 1: Structure of the current eSTAR IDE Electronic Submission Template**

Information Requested	Description
Application/Submission Type	Identification of key information that may be useful to FDA in the initial processing and review of the IDE application, including content from current Form FDA 3514, Section A.[20] Identification of IDE application as an Original IDE Application, IDE Supplemental Application, Additional Information Response to an Original or Supplemental IDE Application.
Cover Letter / Letters of Reference	Attach a cover letter and any documents that refer to other submissions.
Sponsor Information	Information on the sponsor and correspondent, if applicable, consistent with content from current Form FDA 3514, Sections B and C (*see* 21 CFR 812.20(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, 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).
Consensus Standards[21]	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).

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

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

Information Requested	Description
General Clinical Information	• Information about the type of study (e.g., early feasibility, feasibility, pivotal); • Confirmation that the study is to determine safety and effectiveness and whether any part of the study will occur in the United States; • If an exception from informed consent under 21 CFR 50.24 will be requested; • Confirmation that the study is not exempt under 21 CFR 812.2(c); • Confirmation that the study is a significant risk device study; • If the study is a sponsor or sponsor-investigator led study; and • Information on whether the device is to be sold, and if so the amount to be charged and why the sale of the device does not constitute commercialization (21 CFR 812.20(b)(8)).
Product Description	Identification of listing number if listed with FDA. Descriptive information for the product, including a description of the technological characteristics of the device including materials, design, energy source, and other device features. 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 (*see* 21 CFR 812.25(d)). Information on whether the product is intended to be used with accessories. Whether the product is a device-led combination product and if a Request for Designation (RFD)/pre-RFD number exists, provide the RFD number.
Intended Use	Provide the intended use as specified under 21 CFR 812.25(a).[22]

[22] As discussed in the guidance titled "Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions," FDA's assessment of benefits and risks for an IDE application takes into account the contextual setting in which the study is being proposed, including but not limited to characterization of disease or condition being treated or diagnosed, and the availability of and risks associated with alternative treatments or diagnostics.

Information Requested	Description
Report of Prior Investigations	A complete report of prior investigations of the device under 21 CFR 812.20(b). This must include reports of all prior non-clinical and clinical testing of the device required under 21 CFR 812.27.
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").
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 (*see* FDA guidance "Content of Premarket Submissions for Device Software Functions"). Submission of information regarding the assessment of cybersecurity, if applicable (*see* FDA guidance "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 guidance "Electromagnetic Compatibility (EMC) of Medical Devices" and "Radio Frequency Wireless Technology in Medical Devices").
Investigational Plan	Submission of the complete investigational plan or an accurate summary of the sections described in 21 CFR 812.25(a) through (e) (*see* 21 CFR 812.20(b)(2)). Submission of a description of any records or reports that will be maintained on the investigation (*see* 21 CFR 812.25(j)).

Information Requested	Description
Informed Consent	Submission of all forms and informational materials to be provided to subjects as part of the informed consent process (*see* 21 CFR 812.25(g)).
Investigational Sites and Investigators	Submission of information related to investigational sites and investigators, as described in 21 CFR 812.20(b)(4) through (7).
Labeling	Submission of all proposed labeling for the device that meet the general provisions provided under 21 CFR 812.5 (21 CFR 812.20(b)(10)).
Manufacturing Information	Submission of a description of the methods, facilities, and controls used for the manufacture, processing, packing, storage, and, where appropriate, installation of the device, in sufficient detail so that a person generally familiar with good manufacturing practices can make a knowledgeable judgment about the quality control used in the manufacture of the device (21 CFR 812.20(b)(3)).
References	Inclusion of any literature references, if applicable.
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 the deficiencies or issues conveyed in a disapproval or approval with conditions IDE decision letters.[23]

VI. Electronic Submission Template Waivers, Exemptions, and Timing

Upon finalization of this draft guidance, all IDE applications, unless exempt as described in Section VI.A of this draft guidance, will be required to be submitted as electronic submissions as of the implementation date. An IDE Application that is not provided as an electronic submission as of that date and as described in Section V above, will not be considered received unless an exemption from the electronic submission requirements applies.

A. Waivers and Exemptions From Electronic Submission Requirements

As stated above, IDE electronic submissions are subject to electronic submission requirements upon finalization of this draft guidance after the implementation date. However, section

[23] 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).

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 IDE applications below.

Exemptions

In the final guidance, FDA intends to exempt the following IDE applications from the IDE electronic submission requirements:

- Interactive review responses;[24]
- Appeals/requests for supervisory review;[25, 26]
- Withdrawal requests of IDE applications currently under review by FDA; and
- IDE reports and related amendments.[27]

Please note that IDE submissions related to expanded access compassionate use requests and reports and emergency use reports,[28] and adverse event reports (all types, e.g., serious, malfunctions) are already exempt from submission solely in electronic format, as stated in the FDA guidance "Providing Regulatory Submissions for Medical Devices in Electronic Format - Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act." Although submission in electronic format will not be required for these submission types, FDA encourages submission in available electronic formats of these submissions to facilitate the review process.

Waivers

At this time, FDA has not identified any particular circumstances appropriate for a waiver of the IDE electronic submission requirements and does not intend to grant requests for waiver. Given the widespread availability of software to enable use of the current IDE eSTAR PDF (available to download on FDA's website), all sponsors should have the ability to provide an IDE eSTAR.[29]

B. When Electronic Submissions Will Be Required

[24] If the reviewer used interactive review via phone or email, the sponsor 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 draft guidance is finalized and as of the specified implementation date (*see* "Amendment/Additional Information (AI) Response" category in Table 1 above).

[25] IDE appeals remain subject to any applicable eCopy requirements. For more information, *see* the FDA guidance "eCopy Program for Medical Device Submissions."

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

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

[28] *See* FDA's website on Expanded Access for Medical Devices at https://www.fda.gov/medical-devices/investigational-device-exemption-ide/expanded-access-medical-devices#emergency

[29] 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, available at https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal.

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 IDE electronic submissions. FDA intends to provide a transition period of a minimum of one year from the final guidance issuance prior to requiring that IDE applications be provided as electronic submissions. Currently, and during the transition period, eSTARs may be used voluntarily for IDE electronic submissions. As instructed at the website for the eSTAR Program (under the heading, "How to prepare a submission using eSTAR"[30]), 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 for information 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.

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

Guidance History	Date	Description
Level 1 Draft Guidance	October 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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