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

FOR FURTHER INFORMATION CONTACT: Jonathan Resnick, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3160, Silver Spring, MD 20993–0002, 301–796–7997, Jonathan.Resnick@fda.hhs.gov; or Chris McCormick, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7266, Silver Spring, MD 20993–0002, 301–651–7158, Chris.McCormick@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is issuing this **Federal Register** notice to announce that eCTD v3.2.2 validations 2024 and 2025 and the eCTD v4.0 validations eCTD4–084, eCTD4–085, US-eCTD4–561, US-eCTD4–562, US-eCTD4–563, and US-eCTD4–564 (described in Specifications for eCTD Validation Criteria and Specifications for eCTD v4.0 Validation Criteria, respectively) will become effective. Beginning January 16, 2027, FDA will reject electronic submissions that fail these validations.

According to the guidance for industry titled “Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications” (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications>), submissions subject to section 745A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379k–1(a)) must be submitted in eCTD format using the version of eCTD currently supported by FDA unless such submission is exempt from the electronic submission requirements or if FDA has granted a waiver. The version of eCTD currently supported by FDA is specified in the FDA Data Standards Catalog (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog>). FDA plans to update the Specifications for eCTD Validation Criteria and the Specifications for eCTD v4.0 Validation Criteria to add the effective dates for the above-referenced high-severity validations after publication of this notice. Specifications and validation criteria for eCTD are available on FDA’s eCTD web page (available at <https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ectd>).

Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.
 [FR Doc. 2026–21195 Filed 10–15–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–12214]

Fit-for-Purpose Rare Disease Framework Initiative; Public Meeting; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for information and comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public meeting entitled “Fit-for-Purpose Rare Disease Framework Initiative”. Convened by the Reagan-Udall Foundation for, and in collaboration with FDA, the meeting will focus on developing a fit-for-purpose framework for the development and regulatory review of rare disease therapies. There will be an opportunity to request to provide public comments at the meeting. In addition, FDA is establishing a public docket to collect feedback on and input related to its Rare Disease Framework Initiative.

DATES: The hybrid public meeting will be held on October 28, 2026, from 1 to 5 p.m. Eastern Time, and will take place in-person and virtually. Either electronic or written comments must be submitted by December 11, 2026. See the **SUPPLEMENTARY INFORMATION** section for registration information.

ADDRESSES: The hybrid public meeting will be held in-person at the FDA White Oak Campus, 10903 New Hampshire Ave., White Oak Conference Center, Bldg. 2, Rm. 2047, Silver Spring, MD 20993–0002, and virtually using the Zoom platform. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For security and parking information, please refer to <https://www.fda.gov/about-fda/visitor-information> and <https://www.fda.gov/about-fda/visitor-information/visitor-parking-and-campus-map>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 11, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2026-N-12214 for “Fit-For-Purpose Rare Disease Framework; Public Meeting; Request for Information and Comments.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

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FOR FURTHER INFORMATION CONTACT:

Philipa Friedman, Rare Disease Innovation Hub, 202-940-6508, rdinnovationhub@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the launch of its Rare Disease Framework Initiative (Framework Initiative) to develop a regulatory framework purpose-built for rare disease therapies. Roughly 1 in 10 Americans lives with a rare disease, and only approximately 5 percent of rare conditions have an FDA-approved treatment. Developing therapies for rare diseases can present scientific and practical challenges, including small patient populations, limited understanding of certain diseases, and disease heterogeneity. FDA’s Framework Initiative will respond to these challenges via a holistic approach that approaches regulatory review according to the particularities of each product based on specific disease state, product type, patient population, and attainable evidence.

The Framework Initiative—spearheaded by the Rare Disease Innovation Hub, the Office of the Commissioner, the Center for Biologics Evaluation and Research (CBER), and the Center for Drug Evaluation and Research (CDER)—will result in a rare disease drug development and review process that:

1. *Provides greater clarity, consistency, and predictability for drug developers, patients, disease advocates, and researchers regarding rare disease regulatory decision-making through tailored guidance and transparent communication based on the latest science.*
2. *Embeds the patient voice both early and at clearly defined milestones in the development and review process for rare disease therapies* such that both sponsors and reviewers can benefit from patient perspectives on disease burden, benefit-risk priorities, and meaningful measures of progress.

3. *Further leverages external expertise to support a tailored approach in regulatory review*, especially for rare conditions with very small patient populations and limited understanding of natural history, as a structural feature to direct FDA reviewers in customizing

their decision-making to each specific development program, product, and disease state.

4. *Builds shared resources, robust training, and institutional knowledge on rare disease drug development and review* to ensure consistency in drug development and review.

5. *Applies risk-based approaches, particularly to chemistry, manufacturing, and controls review and pre-approval inspections*, to support earlier patient access without compromising rigorous quality, safety, and effectiveness standards.

6. *Champions the use of cutting-edge science, novel methods and clinical trial designs, and innovative statistical approaches in the development of rare disease therapies* via guidance, transparent communication, and programming that reflects FDA’s commitment to partnering with rare disease innovators to accelerate patient access to rare disease therapies.

II. Issues for Consideration and Request for Information

FDA is seeking feedback from the public—including rare disease drug developers, patients living with rare diseases and their caregivers, disease advocates, and researchers—on persistent challenges for the development of rare disease therapies, as well as input on how a tailored approach to regulatory review might mitigate these challenges. Feedback will inform development of the framework and potential implementation actions, which may include new or revised guidance documents related to rare disease drug development and regulatory review, revisions to FDA’s regulations, training for FDA review staff, and organizational enhancements.

This Request for Information and Comments is being published in conjunction with a public meeting on October 28, 2026, to solicit feedback on the Rare Disease Framework Initiative. Interested parties may provide feedback on FDA’s Rare Disease Framework Initiative by requesting to provide public comments at the public meeting, providing comments in the public docket that will be open from October 28 through December 11, 2026, or both. Registration information for the October 28, 2026, free public meeting, including information about how to request to provide public comments, can be found at the following web address: <https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/fda-rare-disease-framework-initiative-public-meeting-10282026>. In-person attendance is based on space availability, with priority given to early registrants. Early

registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If you need special accommodations due to a disability, please email rdinnovationhub@fda.hhs.gov no later than October 26, 2026, 11:59 p.m. Eastern Time.

FDA welcomes suggestions, ideas, and comments regarding CDER and CBER's roles in rare disease drug development and review. Below are four broad focus areas outlined in the Framework Initiative. We seek suggestions and comments within these topic areas and ask that you be as specific as possible in your feedback or recommendation. To help FDA review comments efficiently, please identify the topic area to which you are responding by its associated number. If you are responding to more than one topic area, please identify each topic area to which you are responding:

1. Fit-for-purpose review of rare disease therapies based on attainable evidence, particular disease state, and population.
2. Consistency and predictability of FDA's rare disease drug development and review regulatory requirements.
3. FDA engagements with external parties—including patients, disease experts, and researchers—to inform review decision-making for rare disease therapies.
4. Considerations for chemistry, manufacturing, and controls (CMC) specific to rare disease therapies.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–21142 Filed 10–14–26; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1216]

Electronic Common Technical Document (eCTD); Data Standards; Supporting Forward Compatibility for eCTD 4.0

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research are announcing support for

Forward Compatibility for Electronic Common Technical Document (eCTD) Version 4.0 (v4.0)-based electronic submissions.

DATES: FDA support for Forward Compatibility for eCTD v4.0 electronic submissions begins October 16, 2026. Submit either electronic or written comments at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

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- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instruction."

Instructions: All submissions received must include the Docket No. FDA–2018–D–1216 for "Electronic Common Technical Document; Data Standards; Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research Supporting Electronic Common Technical Document Version 4.0." Received comments will be placed

in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

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FOR FURTHER INFORMATION CONTACT:

Jonathan Resnick, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3160, Silver Spring, MD 20993–0002, 301–796–7997, Jonathan.Resnick@fda.hhs.gov; or Chris McCormick, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7266, Silver Spring, MD 20993–0002, 301–651–7158, Chris.McCormick@fda.hhs.gov.