



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2026-N-0131]

#### FDA Rare Disease Innovation Hub Future Programming; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the following request for comments for a future public workshop series entitled “Rare disease Innovation, Science, and Exploration (RISE) Workshop.” The purpose of the public workshops is to focus on challenges that are common to multiple diseases or a class of diseases, and for which evolving science offers innovative solutions. The workshops will primarily focus on cross-cutting or common issues and will not be focused on any specific product under review by the Agency. The Agency further welcomes comments that highlight general rare disease-related issues of potential interest for the FDA Rare Disease Innovation Hub (Hub) to inform its future activities.

**DATES:** Submit either electronic or written comments by December 31, 2026. See the SUPPLEMENTARY INFORMATION section for comment deadlines corresponding to specific workshop sessions.

**ADDRESSES:** 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 31, 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-0131 for "FDA Rare Disease Innovation Hub Future Programming; Request for 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>.

*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:** Philipa Friedman, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240-402-7911, [RDInnovationHub@fda.hhs.gov](mailto:RDInnovationHub@fda.hhs.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. Background**

The FDA is publishing this request for comments to obtain suggestions for topics for future RISE Workshops. The Hub supports the RISE Workshop series pursuant to its commitment to further advance regulatory science of rare disease therapies and the Agency's PDUFA VII commitments to enhance regulatory science and expedite drug development and rare disease product review under the Food, Drug, and Cosmetic Act.

The Hub-sponsored RISE workshop series focuses on challenges that are common to multiple diseases or a class of diseases, and for which evolving science offers innovative solutions. The workshops are open to the public and designed for interaction and discourse between the various rare disease community members and perspectives, including drug developers, patient and disease organizations, academics, FDA regulators and reviewers, and relevant staff from other federal agencies. All workshops include coordination of the relevant medical product Centers and address the Centers' approaches to the relevant issues. The workshops also include a discussion of the role of patients and patient/disease organizations in the design and implementation of innovative solutions. The workshops primarily focus on cross-cutting or common issues and will not be focused on any specific product under review by the Agency. Preference will be given to submissions that are germane to multiple disease states and/or that are submitted jointly by two or more entities.

For consideration for the summer RISE Workshop, FDA requests comments by February 28, 2026. For consideration for the fall RISE Workshop, FDA requests comments by May 31, 2026. The Agency requests that submissions include:

- A description of the proposed topic;
- Suggested speakers and/or subject matter experts;
- A description of the impact of the topic on the development and regulatory science of rare disease therapies;

- The disease state(s) affected by the challenge highlighted in the submission;
- If relevant, related FDA guidances or existing programs addressing the challenge highlighted in the submission.

Notice of this meeting series is given pursuant to 21 CFR 10.65.

**Lowell M. Zeta,**

*Acting Deputy Commissioner for Policy, Legislation, and International Affairs.*

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