

that would best address the challenges being faced by regulated entities while still protecting public health and maintaining the benefits of the Food Traceability Rule. However, we recognize Congress's desire for FDA to be transparent with stakeholders about this process, and specifically about where things stand approximately 180 days after enactment of the Continuing Appropriations Act. One goal of the discussion paper, "Identifying Additional Flexibilities for Satisfying the Food Traceability Rule's Lot-Level Tracking Requirement," is to provide that transparency.

II. Topics for Discussion at the Public Meeting

The goal of this public meeting is for FDA to hear stakeholder feedback on lot-level food traceability efforts and implementation challenges facing industry. FDA is interested in hearing about the challenges and potential solutions for satisfying the Food Traceability Rule's lot-level tracking requirements.

We are also making available a discussion paper, "Identifying Additional Flexibilities for Satisfying the Food Traceability Rule's Lot-Level Tracking Requirement," that includes potential flexibilities and questions we have around those flexibilities (Ref. 1). We intend for this discussion paper to further dialogue with regulated entities and other stakeholders, including at this public meeting, and help advance progress toward successful implementation of the Food Traceability Rule. We encourage those participating in this public meeting to consider the questions in this discussion paper as you develop your remarks for this meeting.

We want to provide all stakeholders with an opportunity to actively engage with FDA on this topic. We therefore invite and encourage all interested parties to submit feedback on the discussion paper to <https://www.regulations.gov>, Docket No. FDA-2014-N-0053. Comments do not need to cover every question that is asked in the document; you are encouraged to focus on whichever aspects of the discussion paper are of the most interest to you. To ensure that we can fully consider your feedback as we work to expeditiously identify flexibilities to implement, please submit your comments no later than July 15, 2026.

Please note that the discussion paper does not reflect an exhaustive list of options that FDA plans to consider. New ideas may emerge as a result of this public meeting and our other upcoming engagements with stakeholders. The

document is meant to capture the areas where we currently have the most questions, or where we think further dialogue would be especially helpful. Please also note that the order in which the topics are listed is not meant to represent a prioritization or a preference for any topic.

III. Participating in the Public Meeting

Registration: Please visit the following website for additional information and to register for the public meeting: https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/fda-public-meeting-challenges-and-solutions-lot-level-food-traceability-06152026?utm_medium=email&utm_source=govdelivery.

The virtual public meeting is free and open to the public, but registration is necessary to attend. General registration will remain open until June 14, 2026. Individuals who want to speak during the public comment period must register by June 5, 2026. Same-day registration is not allowed. Individuals that have already registered through the Partnership for Food Traceability website do not need to register again. Instructions for joining the virtual meeting will be provided upon registration.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during the public comment session. We will do our best to accommodate all requests to make public comments. Following the close of registration, we will determine the amount of time allotted to each presenter and will notify participants in advance. All requests to make oral presentations must be received by the close of registration on June 5, 2026. All presentations must be given orally; slides or visuals will not be able to be accommodated on the virtual platform. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

IV. References

1. Food and Drug Administration, "Discussion Paper: Identifying Additional Flexibilities for Satisfying the Food Traceability Rule's Lot-Level Tracking Requirement". 2026.

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

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-10603 Filed 5-27-26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-4390]

AI-Enabled Optimization of Early-Phase Clinical Trials Pilot Program; Request for Information; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for information; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice entitled "AI-Enabled Optimization of Early-Phase Clinical Trials Pilot Program; Request for Information" that appeared in the **Federal Register** of April 29, 2026. In the notice, FDA requested comments to solicit input on a proposed pilot program to assess how artificial intelligence (AI)-enabled technologies can improve efficiency, speed, and quality of decision-making in early phase clinical trials. The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the request for information published April 29, 2026 (91 FR 23100). Either electronic or written comments must be submitted by June 29, 2026.

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 June 29, 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-4390 for "AI-Enabled Optimization of Early-Phase Clinical Trials Pilot Program; Request for Information." 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 docket, 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:

Mallika Mundkur, Deputy Chief Medical Officer, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-8800. Please send relevant correspondence to Juliane Carvalho, Senior Advisor, Office of the Commissioner, juliane.carvalho@fda.hhs.gov with "RTCT-Response to RFI" in the subject line.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 29, 2026, FDA published a notice with a 30-day comment period to request comments on the document entitled "AI-Enabled Optimization of Early-Phase Clinical Trials Pilot Program; Request for Information." FDA issued this request for information to solicit input on a proposed pilot program to assess how AI-enabled technologies can improve efficiency, speed, and quality of decision-making in early phase clinical trials.

The Agency has received a request for a 30-day extension of the comment period for the request for information.

FDA has considered the request and is extending the comment period for the request for information for 30 days, until June 29, 2026. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Training and Career Development (K Awards).

Date: June 25, 2026.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Steven G. Britt, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435-0000, steve.britt@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neural Basis of Motivated Behavior.

Date: June 25-26, 2026.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Jennifer C. Schiltz, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496-3553, jennifer.sanders@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Research Enhancement Awards: Molecular Biology Technologies.

Date: June 25, 2026.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: David R. Filpula, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of