The Directors of CBER and CDER (Directors) will lead the Hub, co-chairing the Rare Disease Innovation Hub Steering Committee, which will include senior leaders from CBER's Office of Therapeutic Products, CDER's Office of New Drugs, and across FDA, such as the Center for Devices and Radiological Health, Oncology Center of Excellence, Office of Orphan Products Development, and Office of Combination Products. The Rare Disease Innovation Hub will leverage the activities of the CDER Accelerating Rare disease Cures program and CBER Rare Disease Program and enhance existing cross-center collaborations. In addition, the Hub will be anchored by the new Director for Strategic Coalitions for the Hub (Associate Director for Rare Disease Strategy), who will serve as a single point of connection and engagement with stakeholders on behalf of the Hub, including patient and caregiver groups, trade organizations, and scientific/academic organizations, on cross-cutting rare disease-related issues. The Directors will develop approaches to ensure appropriate FDA staff involvement or appropriate settings for further external engagement and will seek input from the community to inform the priorities of the Hub.

The Reagan-Udall Foundation for the FDA will facilitate the public meeting. The Reagan-Udall Foundation for the FDA is an independent 501(c)(3) not-for-profit organization created by Congress to advance the mission of FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development; accelerate innovation; and enhance product safety. With the ultimate goal of improving public health, the Foundation provides a unique opportunity for different sectors (FDA, patient groups, academia, other government entities, and industry) to work together in a transparent way to create exciting new research and engagement projects to advance regulatory science.

## II. Topics for Discussion at the Public Meeting

This public meeting is being convened for FDA to provide information on the Rare Disease Innovation Hub, including its proposed priorities and initiatives, and to serve as an opportunity for those in the rare disease community, including patients and caregiver groups, industry organizations, and scientific/academic organizations, to provide input on the priorities of the Rare Disease Innovation Hub and how the Hub can best engage with members of the rare disease community. In particular, FDA is interested in receiving comments on the following:

1. What specific rare disease-related scientific, regulatory, or policy issues should be prioritized for consideration by the Rare Disease Innovation Hub?
2. To the extent the issues identified in response to Question 1 are related to specific types of rare diseases or conditions, please explain.
3. What specific types of rare disease-related activities do you believe would benefit from enhanced collaboration, focused attention, or increased transparency (to the extent legally permissible) under the Rare Disease Innovation Hub? Please identify in your comments rare disease-related activities or initiatives currently being undertaken by CDER or CBER that you believe would benefit from being undertaken by the Rare Disease Innovation Hub as a joint endeavor.
4. Please comment on approaches that the Rare Disease Innovation Hub should follow for engagement with patients and caregiver groups, industry organizations, and scientific/academic organizations (including different approaches for different types of engagement, as appropriate).

Comments will be accepted until 11:59 p.m. Eastern Time on October 31, 2024.

## III. Participating in the Public Meeting

*Registration:* To register for the public meeting, please visit the following website to register: *https://reaganudall.org/news-and-events/events/advancing-rare-disease-therapies-through-an-fda-rare-disease-innovation-hub.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register online by October 15, 2024, at 5 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization.

If you need special accommodations due to a disability, please contact Lea Ann Browning-McNee, Director of Communication and Stakeholder Engagement, Reagan-Udall Foundation for FDA, 202–849–2075, *Lmcnee@reaganudall.org,* no later than October 9, 2024, at 5 p.m. Eastern Time.

*Requests for Oral Presentations:* During online registration you may indicate if you wish to present during a public comment session and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. We will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin and will select and notify participants by October 4, 2024. All requests to make oral presentations must be received by 11:59 p.m. on September 25, 2024. If selected for a presentation, you will be contacted by Lea Ann Browning-McNee, Director of Communication and Stakeholder Engagement, Reagan-Udall Foundation for FDA regarding submission of a single slide in PowerPoint format. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

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

Dated: August 7, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–17924 Filed 8–9–24; 8:45 am]

**BILLING CODE 4164–01–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2024–N–3609]**

### Development of an Enhanced Systematic Process for the Food and Drug Administration's Post-Market Assessment of Chemicals in Food; Public Meeting; Request for Comments

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

**ACTION:** Notice of public meeting; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the following public meeting entitled ''Development of an Enhanced Systematic Process for FDA's Post-Market Assessment of Chemicals in Food.'' This public meeting will assist in developing the post-market chemicals assessment program we will establish under the new FDA Human Foods Program. The purpose of the public meeting is to hear from interested parties about approaches to systematic post-market assessment of chemicals in food.

**DATES:** The public meeting will be held on September 25, 2024, from 12:30 p.m. to 4:30 p.m. Eastern Time. FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2024–N–3609. The docket will close on December 6, 2024. Submit electronic or written comments on this public meeting by December 6, 2024. See ''Participating in the Public Meeting'' in the **SUPPLEMENTARY INFORMATION** section of this document for registration and other information regarding meeting participation.

**ADDRESSES:** The public meeting will be held virtually and with limited in-person attendance on the FDA White Oak campus. For more information on the public meeting, see *https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/public-meeting-development-enhanced-systematic-process-fdas-post-market-assessment-chemicals-food.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 6, 2024. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 6, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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–2024–N–3609 for ''Development of an Enhanced Systematic Process for FDA's Post-Market Assessment of Chemicals in Food.'' 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.'' We will review this copy, including the claimed confidential information, in our 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:** *For general questions about the public meeting or for special accommodations due to disability:* Jessica Rowden, 240–461–0669, *CFSAN-Comms@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA endeavors to become more efficient, nimble, and prepared for the ever-changing and complex industries we regulate. In May 2024, FDA announced that we received approval for our reorganization proposal to create a unified Human Foods Program. These changes will allow us to more effectively realize the vision laid out in the FDA Food Safety Modernization Act, elevate the importance of nutrition, strengthen local, state, and international partnerships, and position FDA to regulate innovative food and agricultural products more effectively as we oversee the safety of the nation's food supply. One important goal of this reorganization is to have a modernized FDA that optimizes resources to help us meet our public health mission. FDA is planning to implement the reorganization on October 1, 2024.

As part of this reorganization, we are developing a systematic process for conducting post-market assessments of chemicals in food. Such an assessment includes ingredients considered generally recognized as safe, food additives, color additives, food contact substances, and contaminants. We are holding a public meeting to discuss this systematic process with interested parties to hear ideas and perspectives to inform our thinking and help us further develop a systematic process. The systematic process is intended to guide our post-market assessment work in the new Human Foods Program and will include a transparent process to help ensure post-market assessments are conducted consistently across chemicals and are prioritized based on the greatest public health needs, support confidence in the food supply, and ensure that our food safety efforts continue to reflect the most current and best available science.

## II. Topics for Discussion at the Public Meeting

The public meeting will address a variety of topics related to development of an enhanced systematic process for FDA's post-market assessment of chemicals in food, including:

- Principles for the post-market assessment process,
- Steps in the post-market assessment process,
- Prioritizing chemicals for post-market assessment, and
- Engaging stakeholders throughout the post-market assessment process.

## III. Participating in the Public Meeting

*Registration:* This public meeting is a hybrid meeting offering both online and in-person attendance. Registration is free and open for virtual attendance. In-person attendance is free, but seating is limited. Please note that in-person registration will be accepted in the order of registration. We encourage organizations to consider attendance numbers to help accommodate as many groups as possible for in-person attendance. To register to attend the public meeting on the ''Development of an Enhanced Systematic Process for FDA's Post-Market Assessment of Chemicals in Food,'' please register at *https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/public-meeting-development-enhanced-systematic-process-fdas-post-market-assessment-chemicals-food* for in-person attendance by September 20, 2024, and for webcast attendance by September 24, 2024, at 11:59 p.m. Eastern Time. Registrants will receive confirmation when they have been accepted and will be provided the webcast link for those who plan to attend virtually.

*Request to Provide Open Public Comment:* During online registration, you may indicate if you wish to make open public comments during the public meeting and which topic(s) you would like to address. All requests to make public comments must be received by September 3, 2024, at 11:59 p.m. Eastern Time. We will do our best to accommodate requests to make public comments. We are seeking to have a broad representation of ideas and issues presented at the meeting. Individuals and organizations with common interests are urged to consolidate or coordinate their comments. We will determine the amount of time for each public comment and will notify all registrants who requested an opportunity to make an open public comment.

*Streaming Webcast of the Public Meeting:* This public meeting will be broadcast via Zoom.

*Transcripts:* Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the meeting website page at *https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/public-meeting-development-enhanced-systematic-process-fdas-post-market-assessment-chemicals-food.*

For more meeting specifics, please see *https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/public-meeting-development-enhanced-systematic-process-fdas-post-market-assessment-chemicals-food.* FDA will post an agenda and other meeting materials on this web page in advance of the meeting.

Dated: August 6, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–17791 Filed 8–9–24; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2024–N–1532]**

### Agency Information Collection Activities; Proposed Collection; Risk/Safety Considerations and Motivations for Purchase and Use of Kratom and Psychedelics Alone and in Combination With Other Substances; Withdrawal of Notice

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

**ACTION:** Notice; withdrawal.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal of a notice that was published in the **Federal Register** of August 2, 2024.

**DATES:** The notice is withdrawn on August 12, 2024.

**FOR FURTHER INFORMATION CONTACT:** Darren Eicken, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6206, Silver Spring, MD 20993–0002, 240–402–0978.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of August 2, 2024 (89 FR 63202), ''Agency Information Collection Activities; Proposed Collection; Comment Request: Risk/Safety Considerations and Motivations for Purchase and Use of Kratom and Psychedelics Alone and in Combination With Other Substances,'' FDA requested comment on the information collection associated with the proposed study entitled ''Risk/Safety Considerations and Motivations for Purchase and Use of Kratom and Psychedelics Alone and in Combination With Other Substances.''

Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice.

In the August 2, 2024, **Federal Register** notice, FDA proposed a new collection of information. However, FDA no longer intends to proceed with the proposed study as described because circumstances occurred necessitating changes to the scope of the study. Therefore, we are withdrawing the August 2, 2024, notice.

Dated: August 6, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–17793 Filed 8–9–24; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2024–N–3569]**

### Gastrointestinal Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Supplemental New Drug Application 207999 S–011 for OCALIVA (obeticholic acid) Oral Tablets

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

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Gastrointestinal Drugs Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.