

## 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.*

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## 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.*

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## 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.