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.

DATES: The meeting will be held on September 13, 2024, from 8:30 a.m. to 5 p.m. Eastern Time.

ADDRESSES: The public may attend the meeting at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. The public will also have the option to participate, and the advisory committee meeting will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform.

Answers to commonly asked questions about FDA advisory committee meetings, including information regarding special accommodations due to a disability, visitor parking, and transportation, may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2024–N–3569. The docket will close on September 12, 2024. 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 September 12, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before August 29, 2024, will be provided to the Committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

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

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–3569 for ''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.'' 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.'' FDA 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 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 the 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: Jessica Seo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–7699, email: *GIDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The Committee will discuss supplemental new drug application (sNDA) 207999 S–011, for OCALIVA (obeticholic acid) 5 mg titrated to 10 mg oral tablets, administered once a day, submitted by Intercept Pharmaceuticals, Inc., to fulfill the accelerated approval postmarketing requirements specified in the OCALIVA approval letter dated May 27, 2016. The sNDA included data proposed to describe and verify clinical benefit for the indication for the treatment of adult patients with primary biliary cholangitis without cirrhosis or with compensated cirrhosis who do not have evidence of portal hypertension, either in combination with ursodeoxycholic acid (UDCA) with an inadequate response to UDCA or as

monotherapy in patients unable to tolerate UDCA.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference and/or video conference meeting will be available at the location of the advisory committee meeting and at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link. The meeting presentations will also be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. The online presentation of materials will include slide presentations with audio and video components in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before August 29, 2024, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 1:30 p.m. to 2:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, whether they would like to present online or in-person, and an indication of the approximate time requested to make their presentation on or before August 21, 2024. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. Similarly, room for interested persons to participate in-person may be limited. If the number of registrants requesting to speak in-person during the open public hearing is greater than can be reasonably accommodated in the venue for the in-person portion of the advisory committee meeting, FDA may conduct a lottery to determine the speakers who will be invited to participate in-person. The contact person will notify interested persons regarding their request to speak by August 22, 2024. Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Jessica Seo (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform in conjunction with the physical meeting room (see location). This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: August 7, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17926 Filed 8–9–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; COVID–19 Provider Relief Programs Single and Commercial Audits and Delinquent Audit Reporting Submission Activities—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than September 11, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: COVID–19 Provider Relief Programs Single and Commercial Audits and Delinquent Audit Reporting Submission Activities, OMB No. 0906–0083—Revision

Abstract: The Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136); the Paycheck Protection Program and Health Care Enhancement Act (Pub. L. 116–139); the Coronavirus Response and Relief Supplemental Appropriations Act (Pub. L. 116–260); the Families First Coronavirus Response