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 meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. The Committee will discuss biologics license application 761248, for donanemab solution for intravenous infusion, submitted by Eli Lilly and Co., for the treatment of early symptomatic Alzheimer's disease.

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 *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio and video components to allow the presentation of materials for online participants 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 May 24, 2024, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Eastern Time and will take place entirely through an online meeting platform. 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, and an indication of the approximate time requested to make their presentation on or before May 16, 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. The contact person will notify interested persons regarding their request to speak by May 17, 2024.

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 CONTAC**T) 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 both in-person and using an online meeting platform. 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: May 3, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–10051 Filed 5–7–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1938]

Psychopharmacologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Midomafetamine Capsules

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 Psychopharmacologic 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 June 4, 2024, from 8:30 a.m. to 4:30 p.m. Eastern Time.

ADDRESSES: FDA and invited participants may attend the meeting at 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 have the option to participate via an online teleconferencing and/or video conferencing platform, 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–1938. The docket will close on June 3, 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 June 3, 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 May 23, 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–1938 for ''Psychopharmacologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; 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.'' 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: Joyce Frimpong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–7973, email: *PDAC@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 meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. The Committee will discuss new drug application 215455, for midomafetamine (MDMA) capsules, submitted by Lykos Therapeutics, for the proposed indication of treatment of post-traumatic stress disorder. The Committee will be asked to discuss the overall benefit-risk profile of MDMA, including the potential public health impact.

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 *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio and video components to allow the presentation of materials for online participants 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 May 23, 2024, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 2 p.m. and 3 p.m. Eastern Time and will take place entirely through an online meeting platform. 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, and an indication of the approximate time requested to make their presentation on or before May 17, 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. The contact person will notify interested persons regarding their request to speak by May 20, 2024.

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 Joyce

Frimpong (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 both in-person and using an online meeting platform. 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: May 3, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–10053 Filed 5–7–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice for Public Comments on Potential Viral Hepatitis Quality Measures in Medicaid

AGENCY: Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice for public comment.

SUMMARY: The Department of Health and Human Services' (HHS) Office of Infectious Disease and HIV/AIDS Policy (OIDP) in the Office of the Assistant Secretary for Health (OASH) invites public comment on potential viral hepatitis quality measures for implementation at the state and territory level. In March 2024, OIDP hosted a technical consultation meeting (*https://youtu.be/YCVC8GwFE7E*) to initiate the process of understanding the needs and developing national consensus on clinically meaningful and feasible viral hepatitis quality measures for proposal to the Medicaid Adult Core Set.

DATES: All comments must be received by 5 p.m. ET on June 7, 2024 to be considered.

ADDRESSES: All comments must be submitted electronically to *OIDPViralHepatitis@hhs.gov* to be considered.

FOR FURTHER INFORMATION CONTACT: Jessica Deerin, Ph.D., MPH, OIDP, Viral Hepatitis Policy Advisor at *Jessica.Deerin@hhs.gov* or 202–795–7625.

SUPPLEMENTARY INFORMATION: CDC released updated hepatitis C and hepatitis B screening recommendations to screen all adults aged 18 years and older at least once in a lifetime and all pregnant women during each pregnancy in April 2020 and March 2023, respectively. Screening is an important first step in the viral hepatitis continuum of care and a necessary tool to reach viral hepatitis elimination by 2030.

Additionally, hepatitis C has a life-saving treatment resulting in a cure in >95% of patients. Yet, many patients are not linked to care and complete treatment. Less than 1 in 3 people with health insurance initiated DAA treatment within a year of hepatitis C diagnosis and people with Medicaid were less likely to initiate treatment than those with private insurance. Hepatitis B treatment can reduce hepatitis B viral load, lowering the risk of liver cancer and mortality.

Quality measures are tools to monitor and improve the quality of health care. Scaling up viral hepatitis screening, linkage to care, and access to treatment will ultimately reduce transmission, incidence of new infections, prevent liver cancer and mortality, and allow the U.S. to make strides in reaching viral hepatitis elimination by 2030.

There are currently no viral hepatitis quality measures in the Medicaid Adult Core Set. The Medicaid Adult Core Set is a core set of health care quality measures related to physical and behavioral health for adult Medicaid enrollees. The Adult Core Set encourages standardized reporting by States on a uniform set of measures to drive quality improvement. Since Medicaid provides coverage for a disproportionate number of people with hepatitis B and hepatitis C, OIDP is leading an initiative to develop consensus around clinically meaningful and feasible state level viral hepatitis quality measures to propose to the Medicaid Adult Core Set.

OIDP hosted a Viral Hepatitis Quality Measures Technical Consultation Meeting on March 7, 2024. State panelists from Medicaid and public health departments shared their experience in selection, testing, and implementation of current state viral hepatitis quality measures, as well as recommendations for measures to propose to the Medicaid Adult Core Set. State panelists reached consensus to prioritize the development, use, and adoption of a hepatitis C screening and treatment initiation measure based on the following rationale:

- Clinical and public health insights are high, leading to an understanding of the cascade of care for infected people who access treatment and cure;
- The measure drives screening and linkage to care by translating recently updated CDC recommendations into routine practice in the health care delivery system;
- Data for a screening and treatment initiation measure is available to state Medicaid programs through administrative claims and encounter data, and is consistent and comparable across states; and
- The method of using administrative data sources to represent hepatitis C treatment through pharmacy claims was explained as an acceptable proxy for receipt of treatment.

HHS hereby requests public comment on the clinical significance, usability, feasibility, and likely uptake of hepatitis C screening and hepatitis C treatment initiation quality measures, as well as recommendations with adequate justifications on other feasible viral hepatitis measures to consider.

Information Needs

HHS is seeking responses with adequate justification to the questions listed below.

1. Are you in support of adopting a hepatitis C screening and treatment initiation measure within state Medicaid programs?

a. If you represent a state Medicaid program, what is the likely uptake of this measure?

2. What other measures should HHS consider for testing and proposal to the Medicaid Adult Core Set (*i.e.,* hepatitis B screening, hepatitis B linkage to care, hepatitis C sustained virological response (SVR))? Please provide support for how that measure is clinically meaningful, feasible, and actionable for state Medicaid programs. What data source or data element can be utilized to calculate the measure?

3. Would it be feasible and clinically meaningful to implement a hepatitis B screening, hepatitis C screening and hepatitis C treatment initiation quality measure within state Medicaid programs? If you represent a state Medicaid program, what is the likely uptake of this measure?