''Qualified Health Plan (QHP)'' with the QHP issuer's name on the cover page. CMS is also proposing to update the QHP Enrollee Survey sampling protocol to allow oversampling at any level. CMS is also seeking to add a third email reminder on Day 40 of the fielding timeline and to extend the telephone dialing period by one week to begin on Day 48 of the fielding timeline. Finally, CMS is proposing revisions to the survey instrument, prenotification letter, reminder letter, survey cover letter, and notification/reminder emails for plain language to reduce repetition and improve readability. *Form Number:* CMS–10488 (OMB control number: 0938–1221); *Frequency:* Annually; *Affected Public Sector:* (Individuals and Households), Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 72,008 respondents; *Total Annual Responses:* 72,008; *Total Annual Hours:* 12,013. (For policy questions regarding this collection contact Preeti Hans 301–492–5114).

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2026–14087 Filed 7–13–26; 8:45 am]

BILLING CODE 4169–69–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7542]

Considerations for Potential Future Therapeutic Use of Psychedelic Drugs; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public hearing on the potential future therapeutic use of psychedelic drugs. In collaboration with federal partners, FDA is holding this public hearing to obtain feedback and perspectives on issues associated with the potential future therapeutic use of drug products containing a psychedelic drug substance in supervised and supportive settings.

DATES: The public hearing will be held with an in-person and virtual option (*i.e.,* hybrid) on September 14, 2026, from 12:30 p.m. to 4:30 p.m. Eastern Time. Registration, including requests to present at the public hearing, must be completed through the meeting registration page at *www.fda.gov/news-events/fda-meetings-conferences-and-workshops/considerations-potential-future-therapeutic-use-psychedelic-drugs-public-hearing-09142026* by 11:59 p.m. Eastern Time on August 21, 2026. Questions about registration and participation should be sent to *PsychedelicsHearing@fda.hhs.gov* and should include the title of this notice. See the **SUPPLEMENTARY INFORMATION** section for attendance and registration information.

Comments may be submitted at any time until October 5, 2026. Comments received after that date will not be considered. See the **ADDRESSES** section for how to submit comments.

ADDRESSES:

Location: The public hearing will be held at the White Oak Great Room, 10903 New Hampshire Ave., Silver Spring, MD 20993. The entrance for public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For security and parking information, please refer to *https://www.fda.gov/about-fda/visitor-information/public-meeting-information* and *https://www.fda.gov/about-fda/visitor-information/visitor-parking-and-campus-map.*

Additional details, including any changes to the time of the public hearing and registration information, will be posted at *www.fda.gov/news-events/fda-meetings-conferences-and-workshops/considerations-potential-future-therapeutic-use-psychedelic-drugs-public-hearing-09142026.* The online web conference meeting link can be accessed at *www.fda.gov/news-events/fda-meetings-conferences-and-workshops/considerations-potential-future-therapeutic-use-psychedelic-drugs-public-hearing-09142026* on the day of the meeting.

You may submit comments as follows. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time on October 5, 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 must include the Docket No. FDA–2026–N–7542 for ''Considerations for Potential Future Therapeutic Use of Psychedelic Drugs; Public Hearing; Request for Comments.'' Timely comments (see **DATES**) 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 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: Caroline Huang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6117, Silver Spring, MD 20993–0002, 855–543–3784, *PsychedelicsHearing@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is responsible under the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 301 *et seq.*) and the Public Health Service Act for protecting and promoting the public health through the regulation of human drugs, biological products, medical devices, foods, and other products. FDA's oversight of drug products, including potential psychedelic drug products, spans preclinical investigation through the full lifecycle of an approved product. FDA remains committed to advancing innovation while upholding its public health mission to ensure that drugs are safe, effective, and of high quality. With respect to psychedelic drug development, FDA has made significant advances.

In April 2026, FDA issued national priority vouchers to companies studying psilocybin for treatment-resistant depression (TRD), psilocybin for major depressive disorder (MDD), and methylone for post-traumatic stress disorder (PTSD) (U.S. Food and Drug Administration, 2026). Through enhanced regulatory engagement and streamlined review procedures, national priority vouchers are designed to significantly reduce review times for qualifying drug applications for products that align with critical U.S. national health priorities, while maintaining FDA's rigorous scientific and regulatory standards.

FDA has also granted Breakthrough Therapy designation to specific psychedelic drug development programs, including MDMA for the treatment of PTSD (Multidisciplinary Association for Psychedelic Studies, 2017) and psilocybin for TRD (COMPASS Pathways, 2018) and MDD (Khan, 2019). Breakthrough Therapy designation facilitates and expedites the development and review of drugs intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available treatments on a clinically significant endpoint (U.S. Food and Drug Administration, 2018). Neither national priority voucher issuance nor Breakthrough Therapy designation constitutes an FDA determination of safety or effectiveness, and neither is a substitute for marketing approval.

This hearing also supports implementation of Executive Order 14401 of April 18, 2026, ''Accelerating Medical Treatments for Serious Mental Illness'' (91 FR 21709, April 22, 2026), which establishes a policy of accelerating innovative research models and appropriate drug approvals to help increase access to psychedelic drugs for serious mental illness, and which directs HHS and FDA to collaborate with other federal departments and agencies, as appropriate and consistent with applicable law, to increase clinical trial participation, data sharing, and real-world evidence generation regarding psychedelic drugs.

Given this background, and as part of that coordinated federal effort, FDA and federal partners seek input on considerations for the potential future therapeutic use of psychedelic drugs in supervised and supportive settings.

II. Notice of Hearing Under Part 15

FDA will hold a public hearing consistent with 21 CFR part 15 (part 15) to provide the opportunity for the public to present information and views on the potential future therapeutic use of psychedelic drugs in supervised and supportive settings. The hearing will be conducted by a presiding officer, who will be accompanied by FDA panelists, including subject matter experts from the Center for Drug Evaluation and Research, as well as federal partner panelists. As provided in § 15.30(f) (21 CFR 15.30(f)), the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may pose questions; they may question any person during or at the conclusion of each presentation.

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR part 10, subpart C). Under 21 CFR 10.205, representatives of the media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as provided in § 15.30(b) (see also TRANSCRIPTS). To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

III. Topics for Discussion at the Public Hearing

FDA and our federal partners are interested in public input on the potential future therapeutic use of psychedelic drugs in supervised and supportive settings, including the following topics: (1) provider training and credentialing, (2) promotion of patient safety, (3) considerations for access, and (4) best practices for data collection and standardization.

Certain topics identified below implicate the authorities of other federal agencies or of states; FDA seeks this input to inform coordinated consideration and does not intend this notice to suggest FDA regulatory action outside our statutory authority. Input on operational, workforce, and access considerations may also inform understanding of how any measures to promote safe use could affect patient access to, and healthcare system capacity to deliver, these therapies.

Provider Training and Credentialing

- The evidence base for training and educational curricula, and the expert body(ies), if any, that would be expected to develop, review, or endorse them.
- Personnel and training needs by phase of care (screening and preparation, administration and monitoring, and follow-up), including minimum staffing during administration and monitoring and the roles and qualifications of non-prescriber personnel such as licensed counselors and peer support specialists.

○ Training for care coordination across primary care, behavioral health, and specialty providers.

○ Credentialing and licensure considerations, ranging from background education and experiential qualifications to supervision and practice hour requirements.

• *Promotion of Patient Safety*

○ Best practices to promote patient safety, including patient education and counseling, assessment of side effects, and considerations of set and setting (*i.e.,* mindset and environment).

○ Topics that should be explicitly addressed in informed consent procedures, *e.g.,* the potential for an amplified power imbalance between patient and provider, the use of therapeutic touch, and the risk of psychological distress or a challenging psychedelic experience.

○ Recommended practices to screen patients before treatment for medical and psychiatric conditions associated with greater risk of adverse outcomes (*e.g.,* cardiovascular disease, psychosis, or suicidality).

○ Strategies to mitigate potential diversion and non-medical use of psychedelic drugs, once approved by FDA.

○ Mechanisms to prevent, detect, and report ethical violations by practitioners to appropriate authorities.

○ Criteria for determining appropriate monitoring during and after drug administration, as well as coordination of post-administration follow-up, including with emergency and crisis response services where needed.

• *Considerations for Access*

○ Evidence needs for coverage, benefit design, reimbursement, and payment models, including healthcare economic impact analyses.

○ Preparation and coordination between providers and payors to enable appropriate access to services.

○ Considerations for implementation of access to services, including workforce, space, scheduling, storage, security, and clinic capacity.

○ Telehealth screening, follow-up, and care coordination.

• *Best Practices for Data Collection and Standardization*

○ Creation of data repositories (*e.g.,* Coordinated Registry Networks) that may inform real-world assessment of safety.

○ Data sources and coordination across data sources—including electronic health records, insurance claims, registries, pharmacy data, adverse event reports, patient- and clinician-reported outcomes, national surveillance systems, federally funded surveys, and state programs for psychedelic use—to characterize both medical and non-medical use.

○ Establishment of common data elements across data sources for drug, dosage, indication, setting, and patient characteristics (*e.g.,* comorbidities).

○ Approaches to defining, identifying, and reporting adverse events in the context of the acute and long-term effects of psychedelic drugs.

○ Considerations for interoperability and linkages across healthcare delivery systems and settings, data quality, privacy-protection, and longitudinal follow-up.

FDA is not seeking comment on the following topics: (1) the safety or effectiveness of any particular drug product, or the merits of any pending or anticipated application before the Agency; (2) the scheduling status of any substance under the Controlled Substances Act, which is addressed through separate statutory processes; (3) the legalization or decriminalization of psychedelic substances, or the merits of state or local programs authorizing their use, although FDA welcomes input on data collection from such programs as described above; (4) religious, ceremonial, or personal (non-medical) use of psychedelic substances; or (5) individual disputes, enforcement matters, or complaints regarding specific practitioners or entities. Comments and presentations addressing these topics may not be considered.

IV. Participating in Public Hearing

Registration: To register to attend the free public hearing, please visit the following website: *www.fda.gov/news-events/fda-meetings-conferences-and-workshops/considerations-potential-future-therapeutic-use-psychedelic-drugs-public-hearing-09142026.* Registration will open on July 13, 2026. Live closed captioning will be provided during the public hearing. Additional information on requests for special accommodations due to a disability will be provided during registration.

Requests to Present: During online registration, you may request to present information and views at the hearing. Each request to present must include: (1) the presenter's name, title, affiliation, and contact information; (2) the organizations or interests, if any, on whose behalf the presenter would appear, including disclosure of any financial relationships with entities developing, manufacturing, or expecting to provide products or services related to psychedelic drugs; and (3) the topic area(s) identified in section III that the presentation will address. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and to designate a single presenter.

FDA anticipates that requests to present will exceed the time available. If so, FDA will select presenters and allot presentation time with the goal of having a broad representation of ideas and issues presented at the meeting. Following the close of registration, FDA will determine the time allotted to each presenter and the approximate start time of each presentation and will notify participants ahead of the hearing. All written requests for participation must be received by August 21, 2026, 11:59 p.m. Eastern Time. No commercial or promotional material will be permitted to be presented or distributed at the public hearing.

Selection to present at the meeting is not a prerequisite for having your views considered. Persons not selected to present, or who prefer not to present, may submit the same information as written or electronic comments to the docket (see **ADDRESSES**), and FDA will consider timely written comments equally with oral presentations.

Transcripts: A transcript of the public hearing will be available at *https://www.regulations.gov* as soon as possible after the hearing and may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available at *www.fda.gov/news-events/fda-meetings-conferences-and-workshops/considerations-potential-future-therapeutic-use-psychedelic-drugs-public-hearing-09142026.*

V. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* FDA has verified the website addresses as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

* COMPASS Pathways. (2018). COMPASS Pathways receives FDA Breakthrough Therapy designation for psilocybin therapy for treatment-resistant depression. Retrieved from *https://ir.compasspathways.com/News--Events-/news/news-details/2018/COMPASS-Pathways-receives-FDA-Breakthrough-Therapy-designation-for-psilocybin-therapy-for-treatment-resistant-depression/default.aspx*

* Khan, T. (2019). Usona Institute's psilocybin receives the US FDA Breakthrough Therapy designation for major

depressive disorder. Retrieved from *https://www.usonainstitute.org/updates/fda-grants-breakthrough-therapy-designation-to-usona-institutes-psilocybin-program-for-major-depressive-disorder*

* Multidisciplinary Association for Psychedelic Studies. (2017). FDA grants Breakthrough Therapy designation for MDMA-assisted therapy for PTSD, agrees on Special Protocol Assessment for phase 3 trials. Retrieved from *https://www.maps.org/news/media/6786-press-release-fda-grants-breakthrough-therapy-designation-for-mdma-assisted-psychotherapy-for-ptsd,-agrees-on-special-protocol-assessment-for-phase-3-trials*

* U.S. Food and Drug Administration. (2018). Breakthrough Therapy. Retrieved from *https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy*

* U.S. Food and Drug Administration. (2026). FDA accelerates action on treatments for serious mental illness following Executive Order. Retrieved from *https://www.fda.gov/news-events/press-announcements/fda-accelerates-action-treatments-serious-mental-illness-following-executive-order*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–14155 Filed 7–13–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0080]

Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry titled ''Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs.'' This guidance provides recommendations to industry on formal meetings between FDA and sponsors or requestors of over-the-counter (OTC) monograph drugs or organizations nominated by sponsors or requestors to represent their interests in a proceeding and discusses the procedures and principles for these formal meetings. This guidance finalizes the draft guidance of the same title issued on February 7, 2022. FDA is required to issue this guidance under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: The announcement of the guidance is published in the **Federal Register** on July 14, 2026.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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–2022–D–0080 for ''Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs.'' Received comments 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 dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Phong Pham, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD