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.

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: Susan Levine, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1674, Silver Spring, MD 20993–0002, 240–402–7936, *Susan.Levine@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry titled ''Topical Dermatologic Corticosteroids: In Vivo Bioequivalence.'' This guidance provides recommendations to applicants who submit ANDAs for topical corticosteroids. This guidance describes recommendations for an in vivo pharmacodynamic approach to demonstrate the BE of topical corticosteroids.

This guidance finalizes the draft guidance titled ''Topical Dermatologic Corticosteroids: In Vivo Bioequivalence'' issued on October 24, 2022 (87 FR 64229), and replaces the final guidance of the same title issued June 2, 1995. FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include clarifications noting that study subjects used for chromameter and operator qualification could differ from those enrolled in the pilot dose duration vasoconstrictor response and pivotal vasoconstrictor BE studies, and the addition of history of hypopigmentation as a subject exclusion criterion. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Topical Dermatologic Corticosteroids: In Vivo Bioequivalence.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR 314 have been approved under OMB control number 0910–0001. The collections of information pertaining to controlled correspondence related to generic drug development have been approved under OMB control number 0910–0727.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–14119 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–2023–D–1987

Psychedelic Drugs: Considerations for Clinical Investigations; Guidance for Industry; Availability

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 ''Psychedelic Drugs: Considerations for Clinical Investigations.'' Because interest in the therapeutic potential of psychedelic drugs has been increasing and designing clinical trials to evaluate these compounds presents unique challenges, FDA developed the draft guidance to present foundational aspects for sponsors to consider. This final guidance provides general considerations for sponsors developing psychedelic drugs for the treatment of medical conditions (*e.g.,* psychiatric disorders, substance use disorders) and discusses recommendations for clinical investigations psychedelic drugs. This guidance finalizes the draft guidance of the same title issued on June 26, 2023.

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–2023–D–1987 for ''Psychedelic Drugs: Considerations for Clinical Investigations.'' 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.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.

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

Submit written requests for single copies of the final 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 final guidance document.

FOR FURTHER INFORMATION CONTACT: Kofi Ansah, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4334, Silver Spring, MD 20993–0002, 301–796–4158.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry titled ''Psychedelic Drugs: Considerations for Clinical Investigations.'' This final guidance outlines general considerations for drug development programs considering the therapeutic potential of psychedelic drugs for the treatment of medical conditions (*e.g.,* psychiatric disorders, substance use disorders). This final guidance applies to clinical trials on investigational products and addresses recommendations for study design, including considerations for data collection, data generation, and patient monitoring.

This guidance finalizes the draft guidance of the same title issued on June 26, 2023 (88 FR 41407). FDA considered docket comments received in response to the draft guidance as part of this revision. To enhance clarity, a few revisions were made in this revised version.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Psychedelic Drugs: Considerations for Clinical Investigations.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

FDA considered the applicability of Executive Order 14192, per OMB guidance in M–25–20, and finds this action to be neither regulatory nor deregulatory.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information relating to the protection of human subjects and institutional review boards in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130. The collections of information in 21 CFR parts 210 and 211 relating to current good manufacturing practice requirements for drugs and biologics have been approved under OMB control number 0910–0139. The collections of information in 21 CFR part 312 relating to the investigational new drug applications pathway, which includes clinical trials and clinical trial design, the submission of chemistry, manufacturing and controls information, study protocols, and pharmacological and toxicology information under 21 CFR 312.23, and IND safety reports under 21 CFR 312.32, as well as related meetings between sponsors or applicants and FDA or other communication with appropriate FDA officials to obtain advice on the studies and other information necessary to support submissions, have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 relating to the submission of new drug applications, including the submission of data from a clinical study or studies under 21 CFR 314.50(d)(5) and risk evaluation and mitigation strategies, as well as related meetings between sponsors or applicants and FDA or other communication with appropriate FDA officials to obtain advice on the studies and other information necessary to support submissions, have been approved under OMB control number 0910–0001. In addition, the guidance recommends the use of questionnaires to assess clinical trial subjects' expectations about potential drug effects and at the end of treatment to improve data interpretability. The collection of information from ''individuals under treatment or clinical examination in connection with research or prophylaxis to prevent a clinical disorder, [or] direct treatment of that disorder . . .'' is not subject to review by OMB under 5 CFR 1320.3(h)(5).

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://*

www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or *https://www.regulations.gov.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–14158 Filed 7–13–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources & Services Administration

Request for Information, Training and Care Delivery Models for Safe Administration of Potential FDA-Approved Psychedelic Therapies in Ambulatory Clinical Settings

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

ACTION: Notice, request for information.

SUMMARY: On April 18, 2026, President Trump issued Executive Order (E.O.) 14401, ''Accelerating Medical Treatments for Serious Mental Illness'', acknowledging that individuals suffering from serious mental illness may not always respond to existing therapies. This request for information (RFI) solicits stakeholder feedback on training and care delivery models that could be used to ensure safe and effective delivery of potential future Food and Drug Administration (FDA)-approved psychedelic drugs, including drugs administered in ambulatory clinic settings, such as health centers and rural health clinics.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by August 13, 2026.

FOR FURTHER INFORMATION CONTACT: To request more information on this RFI, please contact Ashley Stultz and Ann Sheehy at *informationRFI@hrsa.gov.* When submitting comments or requesting information, please include the RFI title for reference.

ADDRESSES: In commenting, refer to the RFI title. Comments, including mass comment submissions, must be submitted in one of the following two ways (please choose only one of the ways listed):

1. *Electronically.* Starting July 14, 2026, you may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address: Health Resources and Services Administration, Department of Health and Human Services, 5600 Fishers Lane, Room 13N194, Rockville, MD 20857.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. All comments received before the close of the comment period will be posted on the following website as soon as possible after they have been received: *http://www.regulations.gov.* HRSA will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. HRSA continues to encourage individuals not to submit duplicative comments. HRSA will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments. HRSA encourages commenters to include supporting facts, research, and evidence in their comments. When doing so, commenters are encouraged to provide citations to the materials referenced, including active hyperlinks. Likewise, commenters who reference materials that have not been published are encouraged to upload relevant data collection instruments, data sets, and detailed findings as a part of their comment. Providing such citations and documentation will assist HRSA in analyzing the comments.

I. Background

On April 18, 2026, President Trump issued Executive Order (E.O.) 14401, ''Accelerating Medical Treatments for Serious Mental Illness'', acknowledging that individuals suffering from serious mental illness may not always respond to existing therapies, and emphasizing the importance of exploring psychedelic therapies as new treatment options. This RFI solicits stakeholder feedback on recommended training and care delivery models that could be used to ensure safe and effective delivery of any potential future FDA-approved psychedelic drugs. In particular, HRSA has interest in ensuring that patients in medically underserved communities have access to these therapies, if approved, and request stakeholder feedback on how psychedelics might be delivered in these settings, including ambulatory clinics such as health centers. HRSA also requests input on workforce training in psychedelic care delivery.

II. Solicitation of Public Comments

While HRSA accepts all relevant input, we are specifically inviting responses on the following topics, noting this RFI does not necessarily solicit comments on the full scope of topics related to psychedelic therapy. When responding, please provide clear explanations along with detailed responses, including protocols, publications, data and any other relevant materials that may assist HRSA in this RFI.

Workforce Training

HRSA recognizes that clinical delivery of psychedelic therapies in health care delivery sites must start with counseling and identification of appropriate patients for such therapies prior to administration of the drug. There also must be appropriate follow up in place following the administration of a psychedelic drug. Although these phases may not be mutually exclusive or entirely distinct, for the purposes of the RFI we are asking questions about training requirements in each of these three phases:

- *Pre-administration patient eligibility, screening and counseling:* What training should be required of providers counseling, screening, and identifying patients eligible for psychedelic therapy? Should a broad screening process and a more detailed diagnostic assessment be conducted as two separate activities (and if so, provided by different individuals) or combined into a single screening session? What competencies do providers need to achieve to serve patients in this phase of care? Should providers be required to have a professional degree (social work, psychologist, other)? Should providers be required to have a medical degree (physician, nurse practitioner, physician assistant, nurse, other), or not (peers or other trained non-professionals)? Is telehealth an appropriate means of screening and identifying patients for these therapies, and counseling patients on what to expect during psychedelic administration? How do multiple providers (*e.g.,* primary care and behavioral health providers) communicate plans for psychedelic therapies and/or collaborate to provide psychedelic therapies?
- *In-clinic day of drug administration:* What training should be