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been increasing and designing clinical trials to evaluate these compounds presents unique challenges, FDA developed the draft guidance to present foundational aspects for sponsors to consider.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 This guidance finalizes the draft guidance of the same title issued on June 26, 2023.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 [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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.

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