section 505G: (1) Section 505G(l)(1), which requires FDA to issue guidance that specifies the procedures and principles for formal meetings between FDA and sponsors or requestors for drugs subject to section 505G; (2) section 505G(h), which requires FDA to establish procedures under which meeting requestors can meet with appropriate FDA officials to obtain advice on the studies and other information necessary to support submissions under section 505G, other matters relevant to the regulation of nonprescription drugs, and the development of new nonprescription drugs under section 505G; and (3) section 505G(i), which requires FDA to, among other things, establish procedures to facilitate efficient participation in joint meetings by multiple meeting requesters and/or organizations nominated by them to represent their interests. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required for these collections of information.

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information subject to review by the Office of Management and Budget (OMB) under the PRA. The collections of information in 21 CFR 312 for investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR 201 subpart C for Labeling requirements for Over-the-Counter drugs and submission of OTC monograph fees have been approved under OMB control number 0910–0340. The information collections for OTC meetings and OTC information not exempted from PRA under section 505G of the FD&C Act have been approved under OMB control number 0910–0340.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,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. 2026–14120 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–2170]

Topical Dermatologic Corticosteroids: In Vivo Bioequivalence; 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 ''Topical Dermatologic Corticosteroids: In Vivo Bioequivalence.'' This guidance provides recommendations to applicants who submit abbreviated new drug applications (ANDAs) for topical dermatologic corticosteroids of all potency groups (referred to in this notice as topical corticosteroids). The guidance describes recommendations for an in vivo pharmacodynamic approach to demonstrate the bioequivalence (BE) of topical corticosteroids. This guidance provides clarity for potential ANDA applicants on the appropriate pilot dose duration vasoconstrictor response and pivotal vasoconstrictor BE studies and other recommendations for pharmacodynamic approaches to assess the BE of topical corticosteroids. This guidance finalizes the draft guidance of the same title ''Topical Dermatologic Corticosteroids: In Vivo Bioequivalence'' issued on October 24, 2022, and replaces the guidance for industry of the same title issued on June 2, 1995.

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–2170 for ''Topical Dermatologic Corticosteroids: In Vivo Bioequivalence.'' 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 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