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* 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 This guidance finalizes the draft guidance of the same title issued on February 7, 2022.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

20993–0002, 301–837–7656, *Phong.Pham@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA 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 nonprescription drugs without approved new drug applications that are governed by section 505G of the FD&C Act (21 U.S.C. 355h) (hereafter referred to as OTC monograph drugs) or organizations nominated by sponsors or requestors to represent their interests in a proceeding. For the purposes of this guidance, a *formal meeting* includes any meeting that is requested by a sponsor or requestor of OTC monograph drugs (hereafter referred to collectively as meeting requester(s)) to obtain advice on the studies and other information necessary to support OTC monograph order submissions, to obtain advice on other matters relevant to OTC monograph drug regulation, or to obtain advice on OTC monograph drug development and includes meetings conducted in any format (*i.e.,* hybrid in person face-to-face, virtual face-to-face video conference, teleconference, and written response only).

Section 505G of the FD&C Act was added by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116–136, 134 Stat. 281, 457, which was enacted on March 27, 2020. As required by section 505G(l) of the FD&C Act (21 U.S.C. 355l), this guidance discusses the procedures and principles for formal meetings between FDA and meeting requesters. In doing so, and as required by section 505G(h) of the FD&C Act, this guidance describes procedures under which meeting requesters can meet with appropriate FDA officials to obtain advice on the studies and other information necessary to support submissions under section 505G of the FD&C Act, to obtain advice on other matters relevant to the regulation of nonprescription drugs, and to obtain advice on the development of new OTC monograph drugs. This guidance also applies to meetings with FDA to obtain advice on clinical investigations that may be conducted under an investigational new drug application (IND) where the purpose of the IND is to conduct a clinical investigation to support a determination of whether an OTC monograph condition is generally recognized as safe and effective under section 505G(b) of the FD&C Act. As required by section 505G(i) of the FD&C Act, this guidance also describes procedures to facilitate efficient participation in joint meetings by multiple meeting requesters and/or organizations nominated by them to represent their interests.

This guidance does not apply to formal meetings for the development of nonprescription drug products intended for submission in new drug applications or abbreviated new drug applications under section 505 of the FD&C Act.

In support of the CARES Act, FDA agreed to specific performance goals and procedures described in the document ''Over-the-Counter Monograph User Fee Program Performance Goals and Procedures—Fiscal Years 2018–2022,'' commonly referred to as the OMUFA Commitment Letter (the document can be accessed at *https://www.fda.gov/media/106407/download* and the document with updated goal dates for fiscal years 2021–2025 can be accessed at *https://www.fda.gov/media/146283/download*). In the OMUFA Commitment Letter, FDA committed to issuing this guidance under specific timelines. Under the reauthorization of the Over-the-Counter Monograph User Fee Amendments (OMUFA) (Pub. L. 119–37, 139 Stat. 637), which was enacted on November 12, 2025, FDA continued to agree to specific performance goals and procedures as described in the document ''Over-the-Counter Monograph Drug User Fee Program Performance Goals and Procedures—Fiscal Years 2026–2030 document (OMUFA II commitment letter) and to apply them to formal meetings between FDA staff and meeting requesters (the document can be accessed at *https://www.fda.gov/media/182750/download*). The OMUFA II commitment letter includes updated meeting management goals for formal meetings that occur between FDA and meeting requesters, which are incorporated into this guidance.

This guidance finalizes the draft guidance titled ''Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs'' issued on February 7, 2022 (87 FR 6877). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft guidance to the final guidance are primarily intended to improve clarity and to address comments. On our own initiative, we revised the guidance to apply to meetings with FDA to obtain advice on clinical investigations that may be conducted under an IND, where the purpose of the IND is to conduct a clinical investigation to support a determination of whether there are conditions under which a nonprescription drug is generally recognized as safe and effective. To conform to the OMUFA II commitment letter, FDA also made clarifying revisions to specify the requirements in order to qualify for specific meeting performance goals. For consistency and clarity, FDA clarified the meeting formats. To address commenters' concerns that FDA was limiting the number of Type Y meetings, which could affect OTC monograph order development, we explain that there are three different categories of Type Y meetings and that generally FDA will grant one Type Y meeting per category during the course of the meeting requester's OTC monograph order development program. On our own initiative, we revised the meetings formats (*i.e.,* in person face-to-face, virtual face-to-face, teleconference, and written response only (WRO)) to better accommodate virtual and hybrid meetings. To address apparent commenter confusion, we removed the use of the term ''OTC monograph industry working group'' and replaced it with the term ''joint meeting requester'' to avoid confusion. To address commenter concerns about confidentiality, we clarified when information submitted to FDA in connection with formal meetings is considered confidential and when FDA would post information in connection with a formal meeting. To address commenter questions, we explained the process for meeting requesters to submit clarifying questions on information in the meeting minutes or WRO to FDA following their receipt.

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

Under section 505G(o) of the FD&C Act, the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) does not apply to collections of information made under section 505G of the FD&C Act. The information collections made in this guidance implement the provisions of three subsections of

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.

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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