

legal status of the drug product covered by ANDA 083483.

An ANDA holder who decides to seek a hearing must file the following: (1) a written notice of participation and request for a hearing (see **DATES** and **ADDRESSES**) and (2) the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing (see **DATES** and **ADDRESSES**). Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation and request for a hearing, the information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 and in 21 CFR part 12.

The failure of an ANDA holder to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that ANDA holder not to avail itself of the opportunity for a hearing concerning CDER's proposal to withdraw approval of the ANDA and constitutes a waiver of any contentions concerning the legal status of the drug product. FDA will then withdraw approval of the ANDA, and the drug product may not thereafter be lawfully introduced or delivered for introduction into interstate commerce. Any new drug product introduced or delivered for introduction into interstate commerce without an approved ANDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing (§ 314.200(g)). If a request for a hearing is not complete or is not supported, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing (§ 314.200(g)(1)).

All submissions under this notice of opportunity for a hearing must be filed in two copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <https://www.regulations.gov>.

This notice is issued under section 505(e) of the FD&C Act and under authority delegated to the Director of CDER by the Commissioner of Food and Drugs.

Dated: October 14, 2022.

**Patrizia Cavazzoni,**

*Acting Director, Center for Drug Evaluation and Research.*

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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; Draft 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 draft guidance for industry entitled "Topical Dermatologic Corticosteroids: In Vivo Bioequivalence." This draft guidance is intended to assist applicants who submit abbreviated new drug applications (ANDAs) for topical dermatologic corticosteroid products of all potency groups (referred to in this notice as topical corticosteroids). The draft guidance describes recommendations for an in vivo pharmacodynamic approach to demonstrate the bioequivalence of topical corticosteroids. When finalized, this guidance will replace FDA's 1995 guidance for industry of the same name. Revising this guidance will provide clarity for potential ANDA applicants on the appropriate pilot and pivotal studies and other recommendations for pharmacodynamic approach to assess the bioequivalence of topical dermatologic corticosteroids. These recommendations have evolved since the original guidance was issued in 1995.

**DATES:** Submit either electronic or written comments on the draft guidance by December 23, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance 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://](https://www.regulations.gov)

[www.regulations.gov](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 the draft 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 draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Susan Levine, Office of Generic Drugs, 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](mailto:Susan.Levine@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “Topical Dermatologic Corticosteroids: In Vivo Bioequivalence.” This draft guidance is intended to assist applicants who submit ANDAs for topical corticosteroids. This draft guidance describes recommendations for an in vivo pharmacodynamic approach to demonstrate the bioequivalence of topical corticosteroids. When finalized, this guidance will replace FDA’s 1995 guidance for industry of the same name.

This draft guidance provides recommendations for the study design, method qualification, data analysis, and data reporting for the pilot dose-duration vasoconstrictor response study and pivotal vasoconstrictor bioequivalence study used for topical corticosteroids. The draft guidance also discusses considerations and approaches for estimating key study parameters and sample size for the pivotal vasoconstrictor bioequivalence study.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR 314 have been approved under OMB control number 0910-0001. The collections of information related to current good manufacturing practices have been approved under OMB control number 0910-0139. The collections of information pertaining to controlled correspondence related to generic drug development have been approved under OMB control number 0910-0797.

##### **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>.

Dated: October 18, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2022-D-1864]

#### **Physicochemical and Structural (Q3) Characterization of Topical Drug Products Submitted in Abbreviated New Drug Applications; Draft 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 draft guidance for industry entitled “Physicochemical and Structural (Q3) Characterization of Topical Drug Products Submitted in ANDAs.” This draft guidance is intended to assist applicants who submit abbreviated new drug applications (ANDAs) for liquid-based and/or other semisolid products applied to the skin, including integumentary and mucosal (*e.g.*, vaginal) membranes (referred to as “topical products”). This draft guidance document provides recommendations for physicochemical and structural (collectively, “Q3”) characterizations that can be used to identify the dosage form of a proposed generic (test) topical product, and to describe properties of the drug product that may be critical to its performance (to support a demonstration of bioequivalence (BE)).

**DATES:** Submit either electronic or written comments on the draft guidance by December 23, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance 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