the ''Discontinued Drug Product List'' section of the Orange Book.

Lachman Consultant Services, Inc. submitted a citizen petition dated April 21, 2017 (Docket No. FDA–2017–P–2530), under 21 CFR 10.30, requesting that the Agency determine whether SPECTAZOLE (econazole nitrate) topical cream, 1%, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that SPECTAZOLE (econazole nitrate) topical cream, 1%, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that SPECTAZOLE (econazole nitrate) topical cream, 1%, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of SPECTAZOLE (econazole nitrate) topical cream, 1%, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list SPECTAZOLE (econazole nitrate) topical cream, 1%, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: September 27, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–21174 Filed 10–2–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5739]

Formal Meetings Between the Food and Drug Administration and Abbreviated New Drug Application Applicants of Complex Products Under Generic Drug User Fee Act; Draft Guidance for Industry; Availability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 ''Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA.'' This draft guidance describes an enhanced pathway for discussions between FDA and a prospective applicant preparing to submit (or an applicant that has submitted) to FDA an abbreviated new drug application (ANDA) for a complex product. Specifically, this draft guidance provides information on requesting and conducting product development meetings, pre-submission meetings, and mid-review-cycle meetings with FDA. This draft guidance will assist applicants in generating and submitting a meeting request and the associated meeting package to FDA for complex products to be submitted under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and as contemplated in the commitments made by FDA in connection with the reauthorization of the Generic Drug User Fee Amendments for Fiscal Years (FYs) 2018–2022 (GDUFA II).

DATES: Submit either electronic or written comments on the draft guidance by December 4, 2017 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 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 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–2017–D–5739 for ''Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA; Draft Guidance for Industry; Availability.'' 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.

- 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.

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: Elizabeth Giaquinto Friedman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1670, Silver Spring, MD 20993–0002, 240–402–7930, *elizabeth.giaquinto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA.'' This draft guidance describes an enhanced pathway for discussions between FDA and an applicant (or prospective applicant) preparing to submit an ANDA for a complex product to FDA. Specifically, this draft guidance provides information on requesting and conducting product development meetings, pre-submission meetings, and mid-review-cycle meetings with FDA.

This draft guidance reflects a unified approach to all formal meetings between FDA and ANDA applicants or prospective ANDA applicants for complex products. This draft guidance is intended to assist ANDA applicants and prospective ANDA applicants in generating and submitting to FDA a meeting request and the associated meeting package for these complex products, as defined in this guidance, to be submitted under section 505(j) of the FD&C Act (21 U.S.C 355(j)) and as contemplated in GDUFA II.

As part of the commitments FDA made in connection with GDUFA II, FDA agreed to develop a program to assist ANDA applicants and prospective ANDA applicants of complex products before the submission of an ANDA to FDA. As stated in the ''GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018–2022'' (GDUFA II Goals or Commitment Letter), this pre-ANDA program is intended to:

> . . . clarify regulatory expectations for prospective applicants early in product development, assist applicants to develop more complete submissions, promote a more efficient and effective ANDA review process, and reduce the number of review cycles required to obtain ANDA approval, particularly for [complex products](GDUFA II Commitment Letter at 14).

To facilitate development of complex products that may be submitted in an ANDA, FDA and industry agreed to a series of meetings between ANDA applicants and prospective ANDA applicants and FDA to discuss the proposed complex product and support submission of a high-quality, approvable ANDA.

In addition to developing a robust pre-ANDA program, FDA agreed to respond to requests for and conduct meetings related to the development of complex products submitted on or after October 1, 2017, within specific timeframes.

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 ''Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA.'' 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

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information has been approved under OMB control number 0910–0797.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: September 28, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–21190 Filed 10–2–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5846]

Abbreviated New Drug Applications Submissions—Refuse-To-Receive Standards: Questions and Answers; 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 ''ANDA Submissions—Refuse-to-Receive Standards: Questions and Answers.'' This draft guidance is intended to assist applicants preparing to submit abbreviated new drug applications (ANDAs) and certain prior approval supplements (PASs) to ANDAs. This guidance provides answers to questions we have received from applicants regarding the guidance for industry, ''ANDA Submissions—Refuse-to-Receive Standards'' (RTR Standards guidance). The questions and answers address general issues about the organization of an ANDA, filing decisions made by FDA, the review of and deficiencies related to Drug Master Files (DMFs), product quality, and bioequivalence (BE) and clinical reviews, and are intended to clarify the deficiencies that may cause FDA to refuse to receive (RTR) an ANDA.

DATES: Submit either electronic or written comments on the draft guidance by December 4, 2017 to ensure that the