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.

FOR FURTHER INFORMATION CONTACT: Sam Raney, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4706, Silver Spring, MD 20993, 240–402–7967, email: *Sameersingh.Raney@fda.hhs.gov;* or Markham Luke, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4712, Silver Spring, MD 20993, 301–796–5556, email: *Markham.Luke@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The conventional approach to establish bioequivalence (BE) for most topical dermatological generic drug products relies upon clinical endpoint BE studies. The risk of failing to demonstrate BE due to the relative insensitivity of these clinical endpoint studies, combined with their burden and length, may represent a barrier to generic drug development and may adversely impact patient access to some topical dermatological generic drug products. FDA is evaluating alternative BE approaches for topical dermatological generic drug products, using methods that are more efficient, and also more sensitive and reproducible. FDA believes that these BE approaches would benefit from public discussion.

II. Topics for Discussion at the Public Workshop

This public workshop will focus on a discussion of current regulatory science initiatives intended to foster the development of topical dermatological generic drug products, examining alternative BE approaches that may be more efficient and less risky than traditional approaches. FDA is also interested in receiving public input about any barriers that may limit the use of such alternative BE approaches in the development of topical dermatological generic drug products. Public input is also sought about strategies to overcome these barriers.

III. Participating in the Public Workshop

Registration: Persons interested in attending this public workshop must register online at *https://survey.co1.qualtrics.com/jfe/form/SV_9YQDLZJRjXtYiXz.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by October 13, 2017, midnight, Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization.

If you need special accommodations due to a disability, please contact Sam Raney (see **FOR FURTHER INFORMATION CONTACT**) no later than October 13, 2017.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for a joint presentation, or to submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by October 16, 2017. All requests to make oral presentations must be received by the close of registration on October 9, 2017. If selected for presentation, any presentation materials must be emailed to *GDUFARegulatoryScience@fda.hhs.gov* no later than October 13, 2017. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming webcast of the public workshop: This public workshop will also be webcast. A live webcast of this workshop will be viewable at *https://collaboration.fda.gov/ogddermaldrug/* on the day of the workshop.

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/Drugs/NewsEvents/ucm557252.htm.*

Dated: September 28, 2017.

Anna K. Abram,

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

[FR Doc. 2017–21186 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–5670]

Abbreviated New Drug Applications Submissions—Amendments To Abbreviated New Drug Applications Under the 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 ''ANDA Submissions—Amendments to Abbreviated New Drug Applications Under GDUFA.'' This draft guidance is intended to explain to applicants how

the review goals established as part of the Generic Drug User Fee Amendments Reauthorization of 2017 (GDUFA II) apply to amendments to abbreviated new drug applications (ANDAs) and prior approval supplements (PASs) to FDA under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This draft guidance describes amendment classifications and categories and explains how amendment submissions may affect an application's review goal dates. The draft guidance also describes how FDA will review amendments submitted to ANDAs and PASs received prior to October 1, 2017, the effective date to implement the GDUFA II review goals.

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 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–2017–D–5670 for ''ANDA Submissions—Amendments to Abbreviated New Drug Applications Under GDUFA.'' 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: 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 ''ANDA Submissions—Amendments to Abbreviated New Drug Applications Under GDUFA.'' This guidance is intended to assist applicants preparing to submit amendments to ANDAs or PASs to FDA under section 505(j) of the FD&C Act (21 U.S.C. 355(j)) by explaining how the review goals established as part of GDUFA II apply to these submissions. In accordance with the ''GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018–2022'' (GDUFA II Commitment Letter, available at: *https://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM525234.pdf*), FDA agreed to certain review goals and procedures for the review of amendments pending as of or received on or after the GDUFA II effective date.

The GDUFA II Commitment Letter reflects significant changes in the classification of and review goals for amendments to ANDAs and PASs under the Generic Drug User Fee Amendments of 2012 (GDUFA I). Under GDUFA I, amendments were classified into a complex tier system based on the following factors:

- Whether the amendment was solicited (submitted in response to a complete response letter) or unsolicited (submitted on the applicant's own initiative).
- Whether the amendment was major or minor.
- The number of amendments submitted to the ANDA or PAS.
- Whether an inspection was necessary to support the information contained in the amendment.

GDUFA II simplified the amendment review goals and no longer subjects them to a tier system; however, review

goals are still dependent on several factors. In general, under GDUFA II, amendments will be designated as either standard or priority, will be classified as major or minor, and will receive a goal date based on the factors discussed in the draft guidance, including whether a preapproval inspection is needed. When finalized, this draft guidance will replace the December 2001 guidance for industry ''Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications.'' This draft guidance supersedes the July 2014 draft guidance for industry ''ANDA Submissions—Amendments and Easily Correctable Deficiencies Under GDUFA.''

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 ''ANDA Submissions—Amendments to Abbreviated New Drug Applications 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. This guidance is not subject to Executive Order 12866.

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 collections of information in 21 CFR 314.96 have been approved under OMB control number 0910–0001.

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 27, 2017.

Anna K. Abram,

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

[FR Doc. 2017–21175 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–N–5891]

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Endocrinologic and Metabolic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The public meeting will be held on October 18, 2017, from 8 a.m. to 5 p.m.

ADDRESSES: Tommy Douglas Conference Center, the Ballroom, 10000 New Hampshire Ave., Silver Spring, MD 20903. The conference center's telephone number is 240–645–4000. Answers to commonly asked questions about FDA Advisory Committee meetings may be accessed at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm*. Information about the Tommy Douglas Conference Center can be accessed at: *http://www.tommydouglascenter.com/*.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2017–N–5891. The docket will close on October 17, 2017. Submit either electronic or written comments on this public meeting by October 17, 2017. Late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 17, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of October 17, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before October 11, 2017, will be provided to the committee. Comments received after that date will be taken into consideration by the Agency. You may submit comments 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–2017–N–5891for ''Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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