of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

II. *Electronic Access.* Persons interested in seeing the completed Staff Manual Guide can find it on FDA's Webs site at: *http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm.*

(Authority: 44 U.S.C. § 3101.)

Dated: June 28, 2018.

Alex M. Azar II,

Secretary.

[FR Doc. 2018–14375 Filed 7–3–18; 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 Application Submissions—Amendments to Abbreviated New Drug Applications Under the Generic Drug User Fee Act; 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 entitled ''ANDA Submissions—Amendments to Abbreviated New Drug Applications Under GDUFA.'' This guidance finalizes the October 2017 draft guidance for industry ''ANDA Submissions—Amendments to Abbreviated New Drug Applications Under GDUFA.'' This 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 either abbreviated new drug applications (ANDAs) or prior approval supplements (PASs) submitted to FDA under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This guidance describes amendment classifications and categories and explains how amendment submissions may affect an application's review goal dates. The 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: The announcement of the guidance is published in the **Federal Register** on July 5, 2018.

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–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: *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 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: 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 guidance for industry entitled ''ANDA Submissions—Amendments to Abbreviated New Drug Applications Under GDUFA.'' This guidance finalizes the October 2017 draft guidance for industry ''ANDA Submissions—Amendments to Abbreviated New Drug Applications Under GDUFA.'' This guidance is intended to assist applicants preparing to submit amendments to ANDAs or to 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: *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: (1) Whether the amendment was solicited (submitted in response to a complete response letter) or unsolicited (submitted on the applicant's own initiative); (2) whether the amendment was major or minor; the number of amendments submitted to the ANDA or PAS; and (3) 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. This guidance supersedes the December 2001 guidance for industry ''Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications'' and the July 2014 draft guidance for industry ''ANDA Submissions—Amendments and Easily Correctable Deficiencies Under GDUFA,'' both of which will be withdrawn. This guidance finalizes the October 2017 draft guidance for industry ''ANDA Submissions—Amendments to Abbreviated New Drug Applications Under GDUFA.'' The final guidance contains clarifications to the draft guidance of the same title that published in October 2017.

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 ''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 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 guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: June 29, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–14429 Filed 7–3–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Council on Alzheimer's Research, Care, and Services; Meeting

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council on Alzheimer's Research, Care, and Services provides advice on how to prevent or reduce the burden of Alzheimer's disease and related dementias on people with the disease and their caregivers. The Advisory Council will spend the majority of the July meeting considering recommendations made by each of the three subcommittees to present to the Secretary of HHS and Congress. Additional presentations in the afternoon will include a presentation on a recent study by RAND on the health care infrastructure, the CDC/Alzheimer's Association's joint Healthy Brain Initiative Roadmap, federal workgroup updates, and updates on work by the non-federal members.

DATES: The meeting will be held on July 30, 2018 from 9:00 a.m. to 5:00 p.m. EDT.

ADDRESSES: The meeting will be held in Room 800 in the Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201.

Comments: Time is allocated in the afternoon on the agenda to hear public comments. The time for oral comments will be limited to two (2) minutes per individual. In lieu of oral comments, formal written comments may be submitted for the record to Rohini Khillan, OASPE, 200 Independence Avenue SW, Room 424E, Washington, DC 20201. Comments may also be sent to *napa@hhs.gov.* Those submitting written comments should identify themselves and any relevant organizational affiliations. Those intending to make public comments at the meeting must submit their comments either by mail or email ahead of time for the record. Comments are due no later than Monday, July 23, 2018.

FOR FURTHER INFORMATION CONTACT: Rohini Khillan (202) 690–5932, *rohini.khillan@hhs.gov.* Note: Seating may be limited. Those wishing to attend the meeting must send an email to *napa@hhs.gov* and put ''July 30 Meeting Attendance'' in the Subject line by Friday, July 20, so that their names may be put on a list of expected attendees and forwarded to the security officers at the Department of Health and Human Services. Any interested member of the public who is a non-U.S. citizen should include this information at the time of registration to ensure that the appropriate security procedure to gain entry to the building is carried out. Although the meeting is open to the public, procedures governing security and the entrance to Federal buildings may change without notice. If you wish to make a public comment, you must note that within your email.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the