appropriate advice, information, and recommendations to the Commissioner.

II. Nomination Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting representative of the interests of the tobacco manufacturing industry. Nominations must include a current résumé or curriculum vitae for each nominee, including current business address and/or home address, telephone number, and email address, if available. Nominations must specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. The nomination should be sent to the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.)

III. Selection Procedure

The Agency is also seeking names of organizations to participate in the selection of the nonvoting representative of the interests of the tobacco manufacturing industry. Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest in participating in the selection group, attaching a complete list of all organizations participating in selection; and a list of all non-voting nominees along with their current résumés. The letter will also state that it is the responsibility of the interested organizations on the selection group to confer with one another and to select a candidate and an alternative as backup, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the TPSAC. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: October 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–22683 Filed 10–16–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0108]

Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products; 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 ''Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products.'' This guidance provides recommendations to applicants planning to request a waiver or reduction in user fees. This guidance finalizes the draft guidance for industry of the same title issued in June 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on October 17, 2019.

ADDRESSES: You may submit 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–2011–D–0108 for ''Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products.'' 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 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; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Keith Verrett, Division of User Fee Management and Budget Formulation, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., Rm. 2179, Silver Spring, MD 20993, 301–796–7900, *CDERCollections@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products.'' This guidance provides recommendations to applicants regarding requests for waivers, reductions, or refunds of user fees assessed under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379g and 379h). This guidance describes the types of waivers, reductions, and refunds permitted under the user fee provisions of the FD&C Act and the procedures for submitting requests for waivers, reductions, refunds, as well as requests for reconsiderations or appeals. The guidance also provides additional clarification on certain issues such as user fee exemptions for orphan drugs and FDA's current thinking on considerations relevant to eligibility for user fee waivers, reductions, and refunds under the applicable statutory provisions.

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 ''Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products.'' 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 collection of information of this guidance has been approved under OMB control number 0910–0693. The collection of information associated with Form FDA 3397 has been approved under OMB control number 0910–0297. The collections of information associated with new drug applications or biologics license applications have been approved under OMB control numbers 0910–0001 and 0910–0338, respectively. See section X of the guidance document.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,* or *https://www.regulations.gov.*

Dated: October 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–22690 Filed 10–16–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Council on Graduate Medical Education

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Council on Graduate Medical Education (COGME or Council) will hold public meetings for the 2020 calendar year (CY). Information about COGME, agendas, and materials for these meetings can be found on the COGME website at *https://www.hrsa.gov/advisory-committees/graduate-medical-edu/index.html.*

DATES: April 28–29, 2020, 8:30 a.m.–5:00 p.m. Eastern Time (ET) and 8:30 a.m.–2:00 p.m. ET; July 17, 2020, 10:00 a.m.–5:00 p.m. ET; December 8–9, 2020, 8:30 a.m.–5:00 p.m. ET and 8:30 a.m.–2:00 p.m.

ADDRESSES: The meetings scheduled on April 28–29, 2020, and December 8–9, 2020, will be held in-person at 5600 Fishers Lane, Room 5E29, Rockville, Maryland 20857. The meeting scheduled on July 17, 2020, will be held by teleconference/Adobe Connect webinar. Instructions for joining the meetings either in person or remotely will be posted on the COGME website 30 business days before the date of the meeting. For meeting information updates, go to the COGME website meeting page at *https://www.hrsa.gov/advisory-committees/graduate-medical-edu/meetings/index.html.*

FOR FURTHER INFORMATION CONTACT: Kennita Carter, MD, Senior Advisor and Designated Federal Official (DFO), Division of Medicine and Dentistry, Bureau of Health Workforce (BHW), HRSA, 5600 Fishers Lane, 15N116, Rockville, Maryland 20857; 301–945–9505; or *BHWCOGME@hrsa.gov.*

SUPPLEMENTARY INFORMATION: COGME makes recommendations to the Secretary of HHS (Secretary) and Congress on policy, program development, and other matters of significance as specified by section 762 of Title VII of the Public Health Service (PHS) Act. Issues addressed by COGME include the supply and distribution of the physician workforce in the United States, including any projected shortages or excesses; foreign medical school graduates; the nature and financing of undergraduate and graduate