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Submit written requests for single copies of the revised draft guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002. Send two self-addressed adhesive labels to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Katherine Collins or Deirdre Jurand, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1373, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a revised guidance for industry entitled ''Listing of Ingredients in Tobacco Products.'' The revised guidance document is intended to assist persons making tobacco product ingredient submissions to FDA as required by the Tobacco Control Act.

We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate given the requirement that ingredient listing submissions be submitted by May 8, 2018 (§ 10.115(g)(2)). We made this determination because FDA needs to timely communicate that the guidance presents a less burdensome policy that is consistent with the public health and clarifies ways in which tobacco product manufacturers and importers can submit ingredient listing submissions as required by section 904(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387d(a)(1)). Although this guidance document is immediately effective, it remains subject to comment in accordance with FDA's GGP regulation.

The Tobacco Control Act, enacted on June 22, 2009, amends the FD&C Act and provides FDA with the authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health (Pub. L. 111–31, 123 Stat. 1776). Among its many provisions, the Tobacco Control Act added section 904 to the FD&C Act, establishing requirements for tobacco product ingredient submissions.

II. Significance of Guidance

This revised 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 listing of ingredients in tobacco 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.

III. Paperwork Reduction Act of 1995

This revised guidance refers to previously approved collections of information found in FDA regulations. The revised draft guidance includes information and recommendations for how to provide ingredient listing submissions for tobacco products. 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 section 904(a)(1) of the FD&C Act have been approved under OMB control number 0910–0650.

IV. Electronic Access

Persons with access to the internet may obtain an electronic version of the revised guidance at either *https://www.regulations.gov* or *https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: April 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–07973 Filed 4–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0001]

Advisory Committees; Filing of Closed Meeting Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that, as required by the Federal Advisory Committee Act, the Agency has filed with the Library of Congress the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2017.

ADDRESSES: Copies are available at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500. You also may access the docket at *https://www.regulations.gov* for the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2017. Insert the docket number found in brackets in the heading of this document at *https://www.regulations.gov* into the ''Search'' box, clear filter under Document Type (left side of screen), and check ''Supporting and Related Material,'' then Sort By Best Match (from the drop-down menu; top right side of screen), ''ID Number (Z–A)'' or Sort By Best Match (from the drop-down menu) ''Title (A–Z),'' also found in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Russell Fortney, Director, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1068.

SUPPLEMENTARY INFORMATION: Under section 10(d) of the Federal Advisory Committee Act (5 U.S.C. app.) and 21 CFR 14.60(d), FDA has filed with the Library of Congress the annual reports for the following FDA advisory committees that held closed meetings during the period October 1, 2016, through September 30, 2017:

Center for Biologics Evaluation and Research:

Allergenic Products Advisory

Committee
Blood Products Advisory Committee
National Center for Toxicological Research:
Science Board to the National Center for Toxicological Research
Center for Drug Evaluation and Research:
Joint Meetings of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee
Drug Safety and Risk Management Advisory Committee

Annual Reports are available for public inspections between 9 a.m. and 4 p.m., Monday through Friday, at:

(1) The Library of Congress, Madison Building, Newspaper and Current Periodical Reading Room, 101 Independence Ave. SE, Rm. 133, Washington, DC 20540; and

(2) Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: April 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–07981 Filed 4–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1203]

Pilot Meetings Program for Model-Informed Drug Development Approaches

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The sixth iteration of the Prescription Drug User Fee Act (PDUFA VI), incorporated as part of the FDA Reauthorization Act of 2017 (FDARA), highlights the goal of advancing model-informed drug development (MIDD). The Food and Drug Administration (FDA or Agency) is announcing a pilot program that affords sponsors or applicants who are selected for participation the opportunity to meet with Agency staff to discuss MIDD approaches in medical product development. Meetings under the pilot program will be conducted by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) during fiscal years 2018 to 2022. This pilot program is being conducted to fulfill FDA's performance commitment under PDUFA VI. For this pilot program, MIDD is defined as the application of exposure-based, biological, and/or statistical models derived from preclinical and clinical data sources to address drug development and/or regulatory issues (see Supplementary Information, I. Background, and II. Eligibility and Selection for Participation of this notice). For each approved proposal, the pilot program consists of two meetings between sponsors or applicants and the relevant center and will provide an opportunity for drug developers and FDA to discuss the application of MIDD approaches to the development and regulatory evaluation of medical products in development.

DATES: FDA will accept requests to participate in the program on a continuous basis beginning on April 17, 2018 through June 15, 2022. See section III of this notice for instructions about how to request participation in the pilot program. Meeting-granted and -denied decisions will be made the last 2 weeks of each quarter of the fiscal year based on submissions received to date. Requesters will receive a meeting-granted or -denied notification the first week of the new quarter.

The pilot program meetings will begin in Q4 of FY 2018 (July 1–September 30, 2018), and run through Q4 of FY 2022 (September 30, 2022). Proposals not selected for a given quarter will be so notified by the Agency. Sponsors who are not chosen to participate in the pilot program may seek Agency interaction through existing channels (*e.g.,* Type C meeting requests, critical path innovation meetings).

ADDRESSES: Comments about this pilot program can be submitted until May 17, 2018. You may submit comments about the MIDD pilot meetings program 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–2018–N–1203 for ''Pilot Meetings Program for Model-Informed Drug Development Approaches.'' 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