TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB—Continued

Title of collection	OMB control No.	Date approval expires
Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act	0910–0732	8/31/2022
Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco	0910–0749	8/31/2022
Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007	0910–0775	8/31/2022
Medicated Feed Mill License Application	0910–0337	9/30/2022
Guidance on Informed Consent for In Vitro Diagnostic Studies Using Leftover Human Specimens That Are Not Individually Identifiable	0910–0582	9/30/2022
Manufactured Food Regulatory Program Standards	0910–0601	9/30/2022
Information to Accompany Humanitarian Device Exemption Applications and Annual Distribution Number Reporting Requirements	0910–0661	9/30/2022
Generic Clearance for Quick Turnaround Testing of Communication Effectiveness	0910–0876	9/30/2022

Dated: October 17, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23251 Filed 10–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4560]

Pediatric Stakeholder Meeting; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration's (FDA or the Agency) Office of Pediatric Therapeutics (OPT), the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) are announcing a public meeting seeking input from patient/parent groups, consumer groups, regulated industry, academia, and other interested parties to obtain any recommendations or information relevant to the report to Congress that FDA is required to submit concerning pediatrics, as outlined in section 508 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (see the **SUPPLEMENTARY INFORMATION** section for additional background information).

DATES: The public meeting will be held on November 21, 2019, from 9 a.m. to 3 p.m. Registration to attend the meeting should be received by November 15, 2019. Onsite registration on the day of the meeting will be based on space availability. Submit either electronic or written comments on the public meeting by December 19, 2019. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (1503–A), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For information on parking and security procedures, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 19, 2019. 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.

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 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–2019–N–4560 for ''Pediatric Stakeholder Meeting.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docker 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 CR 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: Terrie Crescenzi, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, *terrie.crescenzi@fda.hhs.gov* or Elizabeth Sanford, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, *elizabeth.sanford@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub L. 112–144). Section 508 of FDASIA directs the Secretary of HHS to submit a report to Congress on the implementation of the Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act (PREA). The first report was required to be submitted to Congress by July 9, 2016, and subsequent reports are required every 5 years thereafter. FDASIA also requires FDA to obtain, at least 180 days prior to submission of the report, stakeholder input from patient groups, consumer groups, regulated industry, academia, and any other interested parties to obtain any recommendations or information relevant to the report including suggestions for modifications that would improve pediatric drug research and pediatric labeling of drugs and biological products. In addition, on August 18, 2017, the Food and Drug Administration Reauthorization Act (FDARA) (Pub L. 115–52) was signed into law, which outlined additional requirements to be included in the report.

Some of the issues to be discussed at the meeting will include, but not be limited to:

- Hearing from patients/parents and patient/parent groups, industry, academia and other stakeholders about the public health impact that pediatric legislation may have had on them or their communities;
- Understanding the effects of the requirement of pediatric studies under PREA or the incentives under BPCA on drug/biologic development plans; and
- Understanding if there are any barriers or resource issues preventing undertaking or completing studies under PREA and BPCA.

II. Meeting Attendance and Participation

If you wish to attend this meeting, visit *https://www.eventbrite.com/e/stakeholder-input-on-pediatric-legislation-registration-74306461627.* Please register by November 15, 2019. Those who are unable to attend the meeting in person can register to view a live webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the webcast. Your registration will also contain your complete contact information, including name, title, affiliation, address, email address, and phone number. Seating will be limited so early registration is recommended. Registration is free and will be on a first-come, first-served basis. Onsite registration on the day of the meeting will be based on space availability. To view the webcast, visit: *https://collaboration.fda.gov/pediatriclegislation/.* If you need special accommodations due to a disability, please contact Elizabeth Sanford (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance. Persons attending the meeting are advised that FDA is not responsible for providing access to electrical outlets.

Persons interested in presenting comments at the meeting will be asked to indicate this in their registration. If you intend to use a PowerPoint presentation, please email the presentation to *opt@fda.hhs.gov* by November 15, 2019. FDA will try to accommodate all participant requests to speak, however the duration of comments may be limited by time constraints.

Comments: Regardless of attendance at the public meeting, you can submit electronic or written comments to the public docket (see **ADDRESSES**) by December 19, 2019. Received comments may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: October 21, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23264 Filed 10–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0283]

Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic 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 ''Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act.'' This draft guidance revises the guidance for industry of the same name issued April 1, 2011. The draft guidance is being revised to describe the multiple factors that FDA considers, before requiring a postmarketing study or clinical trial for the purposes described in the Federal Food, Drug, and Cosmetic Act (FD&C Act), when determining the sufficiency of the reports under the FD&C Act and the active postmarket risk identification and analysis (ARIA) system available under the FD&C Act to meet these purposes. The draft guidance is also being revised to reflect certain provisions enacted under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act as they relate to postmarketing studies and clinical trials.