[FR Doc. 2018–24673 Filed 11–9–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2017–N–0558; FDA–2017–N–1315; FDA–2011–N–0776; FDA–2018–N–3038; FDA–2018–N–0405; FDA–2014–N–1048; FDA–2011–N–0908; FDA–2011–N–0920; and FDA–2018–N–1857]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *http://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Disclosures in Professional and Consumer Prescription Drug Promotion	0910–0860	9/30/2020
Experimental Study of Risk Information Amount and Location in Direct-to-Consumer Print Ads	0910–0861	9/30/2020
Reclassification Petitions for Medical Devices	0910–0138	9/30/2021
Request for Samples and Protocols	0910–0206	9/30/2021
Medical Device Recall Authority	0910–0432	9/30/2021
Food Safety, Health, and Diet Survey	0910–0345	10/31/2020
Medical Device Labeling Regulations	0910–0485	10/30/2021
GFI: Clinical Trial Sponsors on the Establishment and Operation of Clinical Trial Data Monitoring Committees	0910–0581	10/31/2021
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food	0910–0751	10/31/2021
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals	0910–0789	10/31/2021

Dated: November 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24609 Filed 11–9–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4100]

Drug Development Tool Process Under the 21st Century Cures Act and Prescription Drug User Fee Act VI; 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 (FDA or the Agency) is announcing a public meeting entitled ''Drug Development Tool Process under the 21st Century Cures Act and PDUFA VI.'' This public meeting is intended to fulfill commitments made by FDA under the sixth authorization of the Prescription Drug User Fee Act (PDUFA VI) and the 21st Century Cures Act (Cures Act) by soliciting comments on Drug Development Tool Qualification at FDA related to the qualification process under section 507 of the Federal Food, Drug, and Cosmetic Act (FD&C Act); discussing taxonomy for biomarkers and related concepts used in drug development; and planning activities to define a framework with appropriate standards and scientific approaches to support qualification for a specified context of use.

DATES: The public meeting will be held on December 11, 2018, from 9 a.m. to 5 p.m. Submit either electronic or written comments on this public meeting by January 31, 2019. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503A (the Great Room), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, 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 may not be considered. For timely consideration we request that electronic comments be submitted on or before January 31, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time on January 31, 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