Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993–0002, 301–796–5003, Fax: 301–847–8443, *Graham.Thompson@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

This public workshop is intended to meet one of the performance goals included in PDUFA VI. This PDUFA reauthorization is part of the FDA Reauthorization Act of 2017 signed by the President on August 18, 2017. The complete set of performance goals and procedures documented in the PDUFA Reauthorization Performance Goals And Procedures Fiscal Years 2018 Through 2022 (Goals Letter) is available at *https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf.* These goals were developed in consultation with patient and consumer advocates, health care professionals, and other public stakeholders, as part of negotiations with regulated industry. Section I.J.1 of the Goals Letter, ''Enhancing the Incorporation of the Patient's Voice in Drug Development and Decision-Making,'' outlines the requirement for FDA to conduct a public workshop.

II. Topics for Discussion at the Public Workshop

This workshop will provide FDA the opportunity to better understand patients' perspectives on current barriers to participating in clinical trials and will discuss best practices and key considerations for enhancing the incorporation of patient perspectives into clinical trial development. At the workshop, patients (including patients with experience in participating in clinical trials and patients who have not participated in clinical trials but who are interested in doing so), caregivers, and other patient representatives will provide perspectives on several key topics related to clinical trials. These topics will include challenges and barriers patients face with access to trials, trial design, trial conduct, and trial followup. The meeting will also gather input from patients, caregivers, industry experts, academic researchers, and other external stakeholders on approaches and best practices to address these challenges and barriers. For more information on meeting topics and discussion questions, visit *http://events.r20.constantcontact.com/register/event?llr=w8jl4kkab&oeidk=a07efuk61xm39d90653.* FDA will also post the agenda and other workshop materials to this site approximately 5 business days before the workshop.

The format of the meeting will consist of a series of presentations, panel discussions, and audience Q&A. In addition to input generated through this public workshop, FDA is interested in receiving input through written comments, which can be submitted to the public docket (see **ADDRESSES**).

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website *https://events.r20.constantcontact.com/register/eventReg?oeidk=a07efuk61xm39d90653&oseq=&c=&ch.* Please register by March 11, 2019. Persons without access to the internet can call 919–668–5938 to register. If you are unable to attend the workshop in person, you can register to view a live webcast of the workshop. You will be asked to indicate in your registration if you plan to attend in person or via the webcast. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by March 11, 2019, 11:59 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation once they have been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Graham Thompson (see **FOR FURTHER INFORMATION CONTACT**) no later than March 11, 2019, 11:59 p.m. Eastern Time.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. Please register for the webcast by visiting *https://events.r20.constantcontact.com/register/eventReg?oeidk=a07efuk61xm39d90653&oseq=&c=&ch=.*

FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.*

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It also may be viewed at the Dockets Management Staff (see **ADDRESSES**).

Dated: January 24, 2019.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2019–01826 Filed 2–8–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2012–N–0438; FDA–2018–D–1592; FDA–2014–D–2138; FDA–2018–N–0180; FDA–2014–N–1960; FDA–2015–N–1837; and FDA–2016–D–4308]

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 *https://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
Recommendations for Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use	0910–0583	10/31/2021
Guidance for Industry on Controlled Correspondence Related to Generic Drug Development	0910–0797	10/31/2021
Guidance for Industry on Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act	0910–0800	10/31/2021
Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications	0910–0810	10/31/2021
MedWatch: Adverse Event and Product Experience Reporting System (Paper-Based)	0910–0291	11/30/2021
Electronic User Fee Payment Form Requests	0910–0805	11/30/2021
Labeling of Red Blood Cell Units with Historical Antigen Typing Results	0910–0862	11/30/2021
Postmarketing Adverse Drug Experience Reporting	0910–0230	12/31/2021

Dated: February 5, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–01812 Filed 2–8–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0429]

Agency Information Collection Activities; Proposed Collection; Comment Request; Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on certain labeling statements for nonprescription human drug products marketed without an approved application.

DATES: Submit either electronic or written comments on the collection of information by April 12, 2019.

ADDRESSES: 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 April 12, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 12, 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 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–2007–D–0429 for ''Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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