approximately 3 minutes (0.05 hour) per screening test, for a total of 260 hours for screening activities. Respondents who qualify for the study will be directed to the survey. Approximately 4,500 participants (1,500 youth and 3,000 adults) will complete the survey, estimated to take 20 minutes (0.33 hour) per survey, for a total of 1,500 hours for completion of both adult and adolescent samples. The length of time to complete the screening test and survey are based on the research firm's experience that panel members answer approximately 2.5 questions per minute. This data collection will take place one time in 2019. Thus, the total estimated burden is estimated to be 1,760 hours.

Dated: February 5, 2019.

**Lowell J. Schiller,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 2019–01819 Filed 2–8–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–N–4731]**

### Enhancing the Incorporation of Patient Perspectives on Clinical Trials; Public Workshop; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Enhancing the Incorporation of Patient Perspectives on Clinical Trials'' and an opportunity for public comment. The workshop will be convened by the Clinical Trials Transformation Initiative (CTTI). The topic to be discussed is stakeholders' (including patients, caregivers, industry, academic researchers, and expert practitioners) perspectives on challenges and barriers to patients participating in clinical trials and best practices and key considerations for enhancing the incorporation of patient perspectives on clinical trial access, design, conduct, and post-trial followup. The workshop will result in a publicly available report from CTTI on proceedings and recommendations from discussions at the workshop. This workshop is intended to meet an FDA commitment included in the sixth authorization of the Prescription Drug User Fee Amendments of 2017 (PDUFA VI).

**DATES:** The public workshop will be held on March 18, 2019, from 9 a.m. to 5 p.m. Submit either electronic or written comments on this public workshop by May 20, 2019. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public workshop will be held at the Tommy Douglas Conference Center, 10000 New Hampshire Ave., Silver Spring, MD 20903.

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 May 20, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 20, 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–2018–N–4731 for ''Patient Engagement on Clinical Trials; Public Workshop; Request for Comments.'' 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 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.

**FOR FURTHER INFORMATION CONTACT:** Graham Thompson, Center for Drug

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]

**BILLING CODE 4164–01–P**

## 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