Hours: 120. For policy questions regarding this collection contact Christopher Lofts at 410–786–4076.

Dated: November 8, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–24755 Filed 11–13–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4900]

Patient-Focused Drug Development Guidance: Incorporating Clinical Outcome Assessments Into Endpoints for Regulatory Decision Making; 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 a public workshop to convene a discussion on incorporating clinical outcome assessments (COAs) into endpoints for regulatory decision making. This workshop will inform development of patient-focused drug development guidance as required by the 21st Century Cures Act (Cures Act) and as part of commitments made by FDA under the sixth authorization of the Prescription Drug User Fee Amendments (PDUFA VI). The Agency will publish a discussion document approximately 1 month before the workshop date. FDA is interested in seeking information and comments on the approaches proposed in the discussion document, as well as input on examples that could be illustrated in the forthcoming draft guidance, where approaches proposed in the discussion document have been successfully applied.

DATES: The public workshop will be held on December 6, 2019, from 9 a.m. to 5 p.m. Submit either electronic or written comments on this public workshop by February 4, 2020. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop 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 will not be considered. Electronic comments must be submitted on or before February 4, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 4, 2020. 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–2019–N–4900 for ''Patient-Focused Drug Development Guidance: Incorporating Clinical Outcome Assessments into Endpoints for Regulatory Decision Making; 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: Meghana Chalasani, Center for Drug Evaluation and Research, Food and

Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6304, Silver Spring, MD 20993–0002, 240–402–6525, Fax: 301–847–8443, *meghana.chalasani@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This public workshop is intended to support FDA implementation of requirements for guidance development under section 3002 of the Cures Act (Pub. L. 114–255) and to meet a performance goal included in PDUFA VI. Section 3002 of Title III, Subtitle A of the Cures Act directs FDA to develop patient-focused drug development guidance to address a number of areas, including methodologies, standards, and technologies to collect and analyze COA data for purposes of regulatory decision-making.

In addition, FDA committed to meet certain performance goals under PDUFA VI. This reauthorization, part of the FDA Reauthorization Act of 2017 (Pub. L. 115–52), signed by President Trump on August 18, 2017, includes a number of performance goals and procedures that are documented in the PDUFA VI Commitment Letter, which is available at *https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf.*

These goal commitments were developed in consultation with patient and consumer advocates, healthcare professionals, and other public stakeholders, as part of negotiations with regulated industry. Section J.1 of the commitment letter, ''Enhancing the Incorporation of the Patient's Voice in Drug Development and Decision-Making,'' (*https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf*) outlines work, including the development of a series of guidance documents and associated public workshops to facilitate the advancement and use of systematic approaches to collect and utilize robust and meaningful patient and caregiver input that can more consistently inform drug development, and, as appropriate, regulatory decision making.

Prior to the issuance of each guidance, as part of the development, FDA will conduct a public workshop to gather input from the wider community of patients, patient advocates, academic researchers, expert practitioners, drug developers, and other stakeholders.

II. Topics for Discussion at the Public Workshop

During the public workshop, speakers and participants will address a range of issues and considerations related to incorporating COAs into endpoints for regulatory decision-making. The range of issues and considerations includes: (1) Endpoint development; (2) estimands and analysis models; (3) addressing heterogeneity in disease symptoms and functional status between patients and within the same patient over time; and (4) data collection, storage, transmission, and analysis.

III. Participating in the Public Workshop

Registration: Interested parties are encouraged to register early. To register electronically, please visit *https://patientfocuseddrugdevelopment.eventbrite.com.* Registration for in-person attendance will close on December 3, 2019. Registration for the webcast will remain open until the day of the workshop. Persons without access to the internet can call 301–796–0621 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. Seating will be limited, so early registration is recommended.

Registration is free. FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the workshop will be based on space availability.

If you need special accommodations due to a disability, please contact Meghana Chalasani (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the workshop.

Requests for Oral Presentations: There will be time allotted during the workshop for open public comment. Sign-up for this session will be on a first-come, first-served basis on the day of the workshop. Individuals and organizations with common interests are urged to consolidate or coordinate, and request time for a joint presentation. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast at *https://collaboration.fda.gov/pfddg123119/.* 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.* 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.

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 may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/drugs/news-events-human-drugs/patient-focused-drug-development-guidance-collection-and-analysis-clinical-outcome-assessment-data.*

Dated: November 8, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24726 Filed 11–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2310]

Process To Request a Review of Food and Drug Administration's Decision Not To Issue Certain Export Certificates for Devices; Guidance for Industry and Food and Drug Administration Staff; 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 final guidance entitled ''Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices.'' FDA is issuing this guidance to comply with changes to the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Reauthorization Act of 2017 (FDARA), which specifies the process afforded to persons denied a Certificate to Foreign Government (CFG) for a device. This guidance describes the information that the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER), in collaboration with the Office of Regulatory Affairs (ORA), will provide to a person whose request for a CFG for a device is denied, and the process for seeking review of such a denial.

DATES: The announcement of the guidance is published in the **Federal Register** on November 14, 2019.

ADDRESSES: You may submit either electronic or written comments on