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

Agency guidances at any time as follows:

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–D–2310 for ''Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Joann Belt, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1463, Silver Spring, MD 20993–0002, *exportcert@cdrh.fda.gov,* 301–796–7400, option 3; 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, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this guidance to comply with section 704 of FDARA (Pub. L. 115–52), which amended section 801(e)(4) of the FD&C Act (21 U.S.C. 381(e)(4)), to specify the process afforded to persons denied a CFG for a device. This guidance describes the information that CDRH and CBER, in collaboration with 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. This guidance applies to the process for persons denied CFGs requested pursuant to section 801(e)(4)(A) of the FD&C Act for devices manufactured in an establishment registered under section 510 of the FD&C Act (21 U.S.C. 360) (*i.e.,* FDA-approved, cleared, or exempted devices) that are exported from the United States. This guidance supplements the FDA's guidance ''FDA Export Certificates,'' which is available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-export-certificates.* FDA considered comments received on the draft guidance that appeared in the **Federal Register** of August 17, 2018 (83 FR 41078). FDA revised the guidance as appropriate in response to the comments.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all

Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.* Persons unable to download an electronic copy of ''Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 17044 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

FD&C Act section; 21 CFR part; or guidance	Topic	OMB control No.
FD&C Act sections 801(e) and 802 (21 U.S.C. 382)	Export certificates for FDA regulated products	0910–0498
21 CFR part 820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
21 CFR part 807, subparts A through E	Electronic Submission of Medical Device Registration and Listing.	0910–0625
''Center for Devices and Radiological Health Appeals Processes''.	Appeals process	0910–0738

Dated: November 5, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24717 Filed 11–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Standardized Work Plan (SWP) Form for Use With Applications to the Bureau of Health Workforce (BHW) Research and Training Grants and Cooperative Agreements, OMB No. 0906–xxxx–New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR have been provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this Notice has closed.

DATES: Comments on this ICR should be received no later than December 16, 2019.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: SWP Form for Use with Applications to BHW Research and Training Grants and Cooperative Agreements, OMB No. 0906–xxxx–NEW

Abstract: BHW requires applicants for training and research grants and cooperative agreements to submit a work plan that describes the timeframes and deliverables required during the grant period of performance to address each of the needs detailed in the Purpose and Need section of the application, as required in the Notice of Funding Opportunity announcement. Applicants are currently able to submit work plans in a non-standardized format.

In order to standardize the data provided by applicants to make informed decisions about funding and assist with monitoring awardee progress, BHW plans to require applicants to complete a SWP form in lieu of submitting a work plan in the applicant's own format. Applicants will use the SWP form when they submit their proposals, and grantees and Project Officers will use the SWP information to assist in monitoring progress once HRSA makes the awards.

A 60-day notice was published in the **Federal Register** on June 19, 2019, Vol. 84, No. 118, pp.28560–28561. There was one public comment and it was thoroughly addressed.

Need and Proposed Use of the Information: The information collected by the SWP form is necessary to standardize and streamline the data used by HRSA in reviewing applications and monitoring awardees. The form will ask applicants to provide a description of the activities or steps the recipient will take to achieve each of the objectives proposed during the entire period of performance. The current variation in formats and data submitted by applicants reduces efficiency in reviewing, awarding, and monitoring each project, so this change will remedy that inefficiency. In addition, seeking OMB approval comports with the regulatory requirement imposed by 45 CFR 75.206(a), Paperwork clearances.

The proposed SWP form will be used to provide information to assess applications for awards including ranking applications as part of the grant review process. BHW will also use the information to assess whether current recipients of grant funding have met statutory and programmatic requirements.

Likely Respondents: Respondents will be applicants to HRSA's research and training programs in BHW.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose