



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 [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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.

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