Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

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You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document regarding CDRH-regulated devices, contact the Exports Branch within the Division of International Compliance Operations at Food and Drug Administration's Center for Devices and Radiological Health (CDRH) at exportcert@cdrh.fda.gov or call 301-796-7400, option 3.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Preface

Additional Copies

CDRH

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 17044 to identify the guidance you are requesting.

CBER

Additional copies are available from the Center for Biologics Evaluation and Research (CBER) by written request, Office of Communication, Outreach, and Development (OCOD), 10903 New Hampshire Ave., WO71, Room 3128, Silver Spring, MD 20903, or by calling 1-800-835-4709 or 240-402-8010, by email, ocod@fda.hhs.gov, or from the Internet at https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The FDA is issuing this draft guidance document to comply with section 704 of the FDA Reauthorization Act of 2017 (FDARA) (Public Law 115-52), which amended section 801 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to specify 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) 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.

The FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Scope

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 (i.e., FDA-approved, cleared or exempted devices) that are exported from the United States. Specifically, this guidance describes the information that CDRH and CBER will provide to a person whose request for a CFG is denied, and the process for seeking review of such a denial.[1]

Section 801(e)(4)(A) of the FD&C Act applies to export certificates for devices, as well as other FDA-regulated products, that are exported from the United States. Because section 801(e)(4)(A) does not apply to a device that is not exported from the United States, the FDA will notify the submitter of any request for an export certificate for such a device (including requests referencing section 801(e)(4)(E), which cites subparagraph (A)(ii)) that the device is ineligible for consideration for an export certificate because it is outside the scope of section 801(e)(4)(A).

III. Denial of a Request to Issue a CFG

Among the reasons FDA may deny a request for issuance of a CFG are the following reasons referenced in section 801(e)(4)(E)(i)(II) of the FD&C Act; 21 U.S.C. 381(e)(4)(E)(i)(II):

1. There is an injunction proceeding pursuant to section 302 of the FD&C Act; or
2. There is a seizure action pursuant to section 304 of the FD&C Act; or
3. The device is the subject of a recall designated by the FDA as Class I or Class II (in accordance with 21 CFR part 7); or
4. An establishment is out of compliance with FDA's Quality System Regulation (also known as current Good Manufacturing Practices (cGMPs)) under 21 CFR part 820.

If FDA denies a request for a CFG for these or other reasons, the FDA will notify the requestor in writing, identify its basis for denying the request, and specifically identify the finding upon which such denial is based. If FDA denies a request based on a facility being out of compliance with cGMPs (reason 4, above), and not on the basis of an injunction, seizure, or recall, it will also provide a substantive summary of the specific grounds for noncompliance identified by FDA.

Section 801(e)(4)(E)(i)(III) of the FD&C Act further provides that FDA shall not deny a request for a CFG based solely on the grounds that the device at issue was manufactured in an establishment that has received an FDA Inspectional Observations form (FDA Form 483), issued under section 704(b) of the FD&C Act, if the FDA and the owner, operator, or agent in charge of such establishment have agreed to a plan of correction in response to the report. Additionally, the FDA does not intend to deny a CFG based solely on observations documented in a report

[1] For additional information regarding FDA export certificates, see the FDA guidance entitled " FDA Export Certificates" at https://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm

issued to an establishment that participates in an audit program in which the United States participates or recognizes, if the FDA and the owner, operator, or agent in charge of such establishment have agreed to a plan of correction in response to the report.

For FDA and the owner, operator, or agent in charge of the establishment to agree on a plan of correction in response to the inspectional observations, for CFG consideration, the following steps should occur:

1. The owner, operator, or agent in charge of the establishment should submit a plan of correction in writing to the appropriate FDA office. The plan should include steps the owner, operator, or agent in charge of the establishment will take to correct observations documented and timeframes for completing such steps.

2. The FDA will review the plan and notify the owner, operator, or agent in charge of the establishment whether the plan is sufficient to address the violations documented in the inspectional observations. If the plan is agreed to, FDA will issue a CFG.

IV. Review of FDA Denial of a Request to Issue a CFG

A person who has been denied a CFG "may at any time request a review to present new information relating to actions taken by such person to address the reasons identified by [FDA] for the denial of [the CFG], including evidence that corrective actions are being or have been implemented to address grounds for noncompliance identified by [FDA]" (section 801(e)(4)(E)(ii)(II) of the FD&C Act; 21 U.S.C. 381(e)(4)(E)(ii)(II)). The owner, operator, or agent in charge of the establishment can request a review by contacting the Exports Branch within CDRH's Division of International Compliance Operations by email at exportcert@cdrh.fda.gov or CBER Import and Export Staff within the Office of Compliance and Biologics Quality (OCBQ), Division of Case Management (DCM) at CBERExportCert@fda.hhs.gov.

The CDRH Exports Branch and the CBER Import and Export Staff will make every effort to directly resolve issues. If the issue cannot be resolved by the CDRH Exports Branch or the CBER Import and Export Staff, each Center's review process will be followed. Section 801(e)(4)(E)(ii)(I) directs the FDA to provide a process for a person who is denied a CFG for a device to request a review that conforms to the standards of section 517A(b) of the FD&C Act. CDRH's review process[2] follows the standards of section 517A, except as necessary to account for differences in nature and degree of importance between CDRH's denial of a request for a CFG, and a significant decision by CDRH. For example, CDRH does not consider the denial of

[2] For additional information regarding appeal review processes in CDRH, specifically appeals of actions that are not significant decisions, please see the guidance "Center for Devices and Radiological Health Appeals Processes: Guidance for Industry and Food and Drug Administration Staff," available at: https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284670.pdf

a request to issue a CFG to be a "significant decision" as defined in section 517A(a)(1), and CDRH's review process will not include the 30-day timeframe for submitting a request for review because efforts by the CDRH Exports Branch to resolve any issues raised by a person whose request for a CFG is denied may take up to or more than 30 days to be completed. Similarly, CBER will use the Formal Dispute Resolution process[3] to process requests for review, but the efforts by the CBER Import and Export Staff to resolve any issues raised by a person whose request for a CFG is denied may take up to or more than 30 days to be completed.

[3] For additional information regarding appeal review processes in CBER, please see the guidance, "Dispute Resolution: Sponsor Appeals Above the Division Level Guidance for Industry and Review Staff," available at https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm343101.pdf