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

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Guidance for Industry and Food and Drug Administration Staff

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This document supersedes Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices, issued November 2020.

For questions about this document regarding CDRH-regulated devices, contact the Exports Team within ORP: Office of Regulatory Programs/DRP2: Division of Establishment Support at exportcert@cdrh.fda.gov or 301-796-7400, option 3.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

U.S. FOOD & DRUG ADMINISTRATION

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

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Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852-1740. Identify all comments with the docket number FDA-2018-D-2310. Comments may not be acted upon by the Agency until the document is next revised or updated.

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 include the document number GUI00017044 and complete title of the guidance in the request.

CBER

Additional copies are available from the Center for Biologics Evaluation and Research (CBER), 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/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.

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Guidance for Industry and Food and Drug Administration Staff

This guidance represents 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[1]

FDA is reissuing this guidance document to make minor updates to align with section 3304 of the Consolidated Appropriations Act, 2023, Pub. L. No. 117-32.[2] The original version of this guidance was issued to comply with section 704 of the FDA Reauthorization Act of 2017 (FDARA) (Public Law 115-52), which amended section 801(e)(4) 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), in collaboration with the Office of Regulatory Affairs (ORA), will provide to a person whose request for a CFG or CFG-NE for a device is denied, and the process for seeking review of such a denial.

In general, FDA's guidance documents 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

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[1] This guidance has been prepared by the Center for Devices and Radiological Health and the Center for Biologics Evaluation and Research in consultation with Office of Regulatory Affairs.

[2] Section 3304 of the Consolidated Appropriations Act, 2023 directs FDA to provide certification for devices that are not exported from the United States if certain conditions are met. Section 3304 strikes clause iii of section 801(e)(4)(E) of the FD&C Act and adds subparagraph (F), to provide that the requirements and procedures of subparagraph (E) apply to a denial of a certification under subparagraph (F) for a device not exported from the United States.

the word *should* in Agency guidances 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)(ii) of the FD&C Act or denied CFG-NEs requested pursuant to section 801(e)(4)(F) of the FD&C Act for devices manufactured in an establishment registered under section 510 of the FD&C Act (e.g., FDA-approved, cleared, or exempted devices). Specifically, this guidance describes the information that CDRH and CBER, in collaboration with ORA, will provide to a person whose request for a CFG or CFG-NE is denied, and the process for seeking review of such a denial.[3]

Section 801(e)(4)(A)(ii) 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. Such FDA export certifications provide information concerning a product and/or establishment's regulatory or marketing status, based on available information at the time FDA issues the certification (including, as appropriate, attestations provided by the person seeking the export certification). Upon issuance, FDA certifies in writing that the exported product meets applicable requirements of the FD&C Act.[4] Revisions to section 801(e)(4) of the FD&C Act as part of the Consolidated Appropriations Act, 2023, direct FDA to provide certification for devices that are not exported from the United States. Manufacturers of devices not exported from the United States, as described in section 801(e)(4)(F) of the FD&C Act, may not request CFGs pursuant to section 801(e)(4)(A)(ii) of the FD&C Act, but may request a Certificate to Foreign Government for Device Not Exported from the United States (CFG-NE).[5] Although CFG-NEs apply to devices not exported from the United States, the processes referenced below also apply to CFG-NEs, pursuant to section 801(e)(4)(F)(iv) of the FD&C Act, unless otherwise specified.

III. Denial of a Request to Issue a CFG or CFG-NE

A. Grounds for Denial

Among the reasons FDA may deny a request for issuance of a CFG or CFG-NE are those referenced in section 801(e)(4)(E)(i)(II) of the FD&C Act:

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 FDA as Class I or Class II (in accordance with 21 CFR part 7); or

[3] For additional information regarding FDA export certificates, see the FDA guidance entitled "FDA Export Certification" at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-export-certification

[4] Section 801(e)(4)(A)(ii) of the FD&C Act.

[5] See https://www.fda.gov/medical-devices/exporting-medical-devices/devices-not-exported-united-states for information about FDA's CFG-NE process.

4. An establishment is out of compliance[6] with FDA's Quality System regulation (also known as current Good Manufacturing Practices (cGMPs)) under 21 CFR part 820.

In addition to the above reasons, FDA may deny a request for issuance of a CFG-NE if any of the conditions specified in section 801(e)(4)(F)(i) of the FD&C Act are not met, such as the device is not imported or offered for import into the United States.

If FDA denies a request for a CFG or CFG-NE for these or other reasons, FDA will notify the requestor via email, identify the basis for denying the request, and specifically identify the finding upon which such denial is based.[7] For denials based on a facility being out of compliance with cGMPs (reason 4, above), and not on the basis of an injunction, seizure, or recall, FDA will include a substantive summary of the specific grounds for noncompliance with the email.[8] Within the summary, FDA will describe the major noncompliance issues that are the basis for the denial and associated reference to the Quality System regulation. The level of detail will vary based on the specific facts of each individual case. FDA does not intend to deny a CFG or CFG-NE for an establishment with a No Action Indicated (NAI) or Voluntary Action Indicated (VAI) classification for the most recent quality system inspection.

There may be instances where a CFG or CFG-NE is requested by a party that has a business relationship with an establishment that has a different owner/operator number. If the CFG or CFG-NE is denied because such establishment is found to be out of compliance, the CFG or CFG-NE requestor will receive a denial email indicating that the denial is based on matters pertaining to that establishment. However, pursuant to applicable disclosure requirements,[9] the substantive summary will not be emailed to the CFG or CFG-NE requestor, but to the out-of-compliance establishment via the owner, operator, or agent in charge of the establishment, if the CFG or CFG-NE requestor agrees that its pending CFG or CFG-NE request can be made known to the other establishment.

For open recalls, the Agency intends to base its decision to issue a CFG or CFG-NE on the current status of the recalled products. For example, if a party requests a CFG or CFG-NE for a recalled product that has been corrected, FDA will review documentation of the correction and final testing of the product, per the current recall review process, to determine whether a CFG or CFG-NE should be issued.

For a product line with an open lot-specific recall, lots not under recall may be included on a CFG or CFG-NE provided the firm signs a statement indicating that it will not ship the lots of the product that are subject to the recall.

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[6] For the purposes of this guidance, "out of compliance" is synonymous with "noncompliance." "Out of compliance" means having one or more major deficiencies with the Quality System regulation, per Compliance Program Guidance Manual 7382.845 Part V, available at https://www.fda.gov/media/80195/download.

[7] See section 801(e)(4)(E)(i)(I) of the FD&C Act.

[8] See section 801(e)(4)(E)(i)(II) of the FD&C Act.

[9] Trade secrets and confidential commercial information (CCI) are protected from public disclosure by the Trade Secrets Act (18 USC 1905), Exemption 4 of the Freedom of Information Act (5 USC 552(b)(4)), and FDA's disclosure regulations (21 CFR 20.61).

B. Plan of Correction

The firm may submit a plan of correction after it has received the substantive summary of the specific grounds for noncompliance (reason 4, described above). Section 801(e)(4)(E)(i)(III) and section 801(e)(4)(F)(iv) of the FD&C Act provide that FDA shall not deny a request for a CFG or CFG-NE based solely on the grounds that the device at issue was manufactured in an establishment that has received an FDA Inspectional Observations form (Form FDA 483), issued under section 704(b) of the FD&C Act, if 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 purposes of this guidance, FDA interprets "plan of correction" to mean a response to an FDA Inspectional Observations, issued under section 704(b) of the FD&C Act.

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 or CFG-NE consideration, the following steps should occur:

1. The owner, operator, or agent in charge of the establishment should submit, via email, a plan that includes steps the owner, operator, or agent in charge of the establishment is taking to address, and prevent the recurrence of, the inspectional observations, and timeframes for completing such actions. This "plan of correction" should also include documentation demonstrating the corrective/preventative actions that have been taken and/or will be taken.

    - To submit a plan of correction, the owner, operator, or agent in charge of the establishment should email the FDA contact identified by the investigator at the end of the inspection for submission of a response to the Form FDA 483.

    - The email subject line should clearly state "Plan of Correction," along with the establishment name and FDA Establishment Identifier (FEI) number.

2. FDA will review the plan and notify the owner, operator, or agent in charge of the establishment via email whether the plan is sufficient to address the violations documented in the inspectional observations. If the Agency finds that clarification on the submitted plan of correction is needed, the Agency may, at its discretion, initiate further communication with the owner, operator, or agent in charge of the establishment prior to making a decision. Generally, depending upon the Agency's resources, the complexity of the noncompliance issues presented, and the responsiveness of the owner, operator, or agent in charge of the establishment, FDA intends to provide a response to a plan of correction within 90 days.

3. If the plan is determined to be sufficient, and a CFG or CFG-NE application is currently under review[10] or subsequently submitted to the Agency, FDA will issue a CFG or CFG-NE, if no other grounds for denial are present.

[10] The FD&C Act limits the processing of a CFG request to within 20 working days of receipt of the request (section 801(e)(4)(A)(ii) of the FD&C Act. As such, it may be necessary for the establishment to submit a new CFG application. As indicated in the Guidance "FDA Export Certification" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-export-certification), FDA "has interpreted the 20-day period to mean 20 government working days."

If an establishment is implementing a plan of correction and determines that modifications to the plan are necessary, it should notify FDA of the modifications via the previously identified contact information.

IV. Review of FDA Denial of a CFG or CFG-NE Request

The CDRH Exports Team and the CBER Import and Export Staff will make every effort to directly resolve issues. In addition, the statute provides that persons denied a CFG or CFG-NE may request review of the Agency's decision, and outlines two distinct types of review. The process for requesting such reviews is outlined below.

A. Review Pursuant to Section 801(e)(4)(E)(ii)(I)

Section 801(e)(4)(E)(ii)(I) and section 801(e)(4)(F)(iv) of the FD&C Act direct FDA to provide a process for a person who is denied a CFG or CFG-NE 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[11] follows the standards of section 517A by providing for supervisory review, opportunity for a meeting or teleconference, and timeframes, except it does not adopt the specific timeframes set forth in section 517A(b)(2)&(3). FDA will strive to meet the timeframes outlined in 517A(b)(3); however, efforts to resolve any issues raised by a person whose request for a CFG or CFG-NE is denied may take up to, or more than, 30 days to be completed. In addition, since the denial of a request to issue a CFG or CFG-NE is not a "significant decision" as defined in section 517A(a)(1), CDRH's review process will not include the 30-day timeframe for submitting a request for review. Similarly, CBER will use the Formal Dispute Resolution process[12] for submitting a request 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 or CFG-NE is denied may take up to, or more than, 30 days to be completed.

The request for a review of FDA's decision not to issue a CFG or CFG-NE should be submitted no later than 60 calendar days from the denial date by emailing the Exports Team within CDRH's Office of Regulatory Programs (ORP), Division of Establishment Support using exportcert@cdrh.fda.gov, or the CBER ombudsman using cberombudsman@fda.hhs.gov.

A request for review of a CFG or CFG-NE denial should include the following:

- An email subject line that states: "Request for Review of FDA's Decision to Deny a CFG or CFG-NE" and the CFG or CFG-NE application number;

[11] 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 (CDRH) Appeals Processes," available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes

[12] For additional information regarding appeal review processes in CBER, please see the guidance, "Formal Dispute Resolution: Sponsor Appeals Above the Division Level," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/formal-dispute-resolution-sponsor-appeals-above-division-level-guidance-industry-and-review-staff

- The name, title, firm, address, phone number, and email address of the person submitting the request;
- The name, address, and FEI number of the establishment for which the CFG or CFG-NE was denied;
- A clear reference to the inspectional observation(s) as noted in the substantive summary of the denial; and
- Information demonstrating why the request for CFG or CFG- NE should not have been denied, referencing previously submitted documentation.

This review process consists of a supervisory review, including an in-person meeting or teleconference, if requested.

B. Review of New Information Pursuant to Section 801(e)(4)(E)(ii)(II)

A person who has been denied a CFG or CFG-NE "may at any time request a review in order to present new information relating to actions taken by such person to address the reasons identified by [FDA] for the denial of [the CFG or CFG-NE], 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) and section 801(e)(4)(F)(iv) of the FD&C Act.

The owner, operator, or agent in charge of the establishment can request such a review by contacting CDRH's Exports Team 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 CBERBECATS@fda.hhs.gov. A person requesting a review of new information should reference, but need not re-submit, inspection related documentation previously submitted to FDA.

A request for review of new information pertaining to a CFG or CFG-NE denial should include the same information as listed above in section IV.A., except the email subject line should state: "New Information – Denial of a CFG or CFG-NE" and the CFG or CFG-NE application number. CBER and CDRH will review the new information in collaboration with ORA and intend to provide a response within 90 days, depending upon the Agency's resources, the complexity of the noncompliance issues presented, and the responsiveness of the establishment.