

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

Guidance for Industry and Food and Drug Administration Staff

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

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. 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.

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CDRH

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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>.

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

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. Introduction¹

The FDA is issuing this guidance document 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 for a device is denied, and the process for seeking review of such a denial.

FDA's guidance documents, including this 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.

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.

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 for devices manufactured in an establishment registered under section 510 of the FD&C Act (e.g., FDA-approved, cleared, or exempted devices) that are exported from the United States. Specifically, this guidance describes the information that CDRH and CBER, in collaboration with ORA, will provide to a person whose request for a CFG is denied, and the process for seeking review of such a denial.²

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 certificates provide written attestation that the exported product meets applicable requirements of the FD&C Act.³ Revisions to section 801(e)(4)(E)(iii) of the FD&C Act as part of the [Coronavirus Aid, Relief, and Economic Security \(CARES\) Act](#)⁴ 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)(E)(iii) 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 of Device Not Exported from the United States (CDNE).⁵

III. Denial of a Request to Issue a CFG

A. Grounds for Denial

Among the reasons FDA may deny a request for issuance of a CFG are those 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 compliance⁶ 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 via email, identify the basis for denying the request, and specifically identify the finding upon

² For additional information regarding FDA export certificates, see the FDA guidance entitled "[FDA Export Certificates](#)" at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-export-certificates>.

³ Section 801(e)(4)(A)(ii) of the FD&C Act.

⁴ Section 3856(a) of the CARES Act contained a technical amendment to section 801(e)(4)(E)(iii) of the FD&C Act regarding devices not exported from the United States.

⁵ See <https://www.fda.gov/medical-devices/importing-and-exporting-medical-devices/devices-not-exported-united-states> for information about FDA's CDNE process.

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>.

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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 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 is requested by a party that has a business relationship with an establishment that has a different owner/operator number. If the CFG is denied because such establishment is found to be out of compliance, the CFG 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 requestor, but to the out-of-compliance establishment via the owner, operator, or agent in charge of the establishment, if the CFG requestor agrees that its pending CFG request can be made known to the other establishment.

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

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

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) of the FD&C Act 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 (Form FDA 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. 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.

⁷ See section 801(e)(4)(E)(i)(I) of the FD&C Act; 21 U.S.C. § 381(e)(4)(E)(i)(I).

⁸ See section 801(e)(4)(E)(i)(II) of the FD&C Act, 21 U.S.C. § 381(e)(4)(E)(i)(II).

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).

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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, 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. The 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 application is currently under review¹⁰ or subsequently submitted to the Agency, FDA will issue a CFG, if no other grounds for denial are present.

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 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 may request

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; 21 U.S.C. 381(e)(4)(A)(ii)). As such, it may be necessary for the establishment to submit a new CFG application. As indicated in the Guidance “[FDA Export Certificates](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-export-certificates)” (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-export-certificates>), the FDA “has interpreted the 20-day period to mean 20 government working days.”

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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) 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 process¹¹ 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 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 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 process¹² 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 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 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 denial should include the following:

- An email subject line that states: "Request for Review of FDA's Decision to Deny a CFG" and the CFG application number;
- 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 was denied;
- A clear reference to the inspectional observation(s) as noted in the substantive summary of the denial; and

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](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-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](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/formal-dispute-resolution-sponsor-appeals-above-division-level-guidance-industry-and-review-staff)," 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>.

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- Information demonstrating why the request for CFG 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 “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], 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 such a review by contacting the Exports Team within CDRH’s Office of Regulatory Programs (ORP), Division of Establishment Support 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 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 the FDA.

A request for review of new information pertaining to a CFG 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” and the CFG 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.