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*Draft – Not for Implementation*

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

## Draft Guidance for Industry and Food and Drug Administration Staff

### *DRAFT GUIDANCE*

**This draft guidance document is being distributed for comment purposes only.**

**Document issued on August 17, 2018.**

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance.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](mailto: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**

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### **Additional Copies**

#### **CDRH**

Additional copies are available from the Internet. You may also send an e-mail request to [CDRH-Guidance@fda.hhs.gov](mailto: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](mailto:ocod@fda.hhs.gov), or from the Internet at <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

**Table of Contents**

58

59

60

61 I. Introduction ..... 4

62 II. Scope ..... 5

63 III. Denial of a Request to Issue a CFG ..... 5

64 IV. Review of FDA Denial of a Request to Issue a CFG ..... 6

65  
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# Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices

## Draft Guidance for Industry and Food and Drug Administration Staff

*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.

## 102 **II. Scope**

103  
104 This guidance applies to the process for persons denied CFGs requested pursuant to section  
105 801(e)(4)(A) of the FD&C Act for devices manufactured in an establishment registered under  
106 section 510 of the FD&C Act (i.e., FDA-approved, cleared or exempted devices) that are  
107 exported from the United States. Specifically, this guidance describes the information that  
108 CDRH and CBER will provide to a person whose request for a CFG is denied, and the process  
109 for seeking review of such a denial.<sup>1</sup>

110  
111 Section 801(e)(4)(A) of the FD&C Act applies to export certificates for devices, as well as other  
112 FDA-regulated products, that are exported from the United States. Because section 801(e)(4)(A)  
113 does not apply to a device that is not exported from the United States, the FDA will notify the  
114 submitter of any request for an export certificate for such a device (including requests  
115 referencing section 801(e)(4)(E), which cites subparagraph (A)(ii) that the device is ineligible  
116 for consideration for an export certificate because it is outside the scope of section 801(e)(4)(A).  
117

## 118 **III. Denial of a Request to Issue a CFG**

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

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

128  
129 If FDA denies a request for a CFG for these or other reasons, the FDA will notify the requestor  
130 in writing, identify its basis for denying the request, and specifically identify the finding upon  
131 which such denial is based. If FDA denies a request based on a facility being out of compliance  
132 with cGMPs (reason 4, above), and not on the basis of an injunction, seizure, or recall, it will  
133 also provide a substantive summary of the specific grounds for noncompliance identified by  
134 FDA.

135  
136 Section 801(e)(4)(E)(i)(III) of the FD&C Act further provides that FDA shall not deny a request  
137 for a CFG based solely on the grounds that the device at issue was manufactured in an  
138 establishment that has received an FDA Inspectional Observations form (FDA Form 483), issued  
139 under section 704(b) of the FD&C Act, if the FDA and the owner, operator, or agent in charge of  
140 such establishment have agreed to a plan of correction in response to the report. Additionally,  
141 the FDA does not intend to deny a CFG based solely on observations documented in a report

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<sup>1</sup> For additional information regarding FDA export certificates, see the FDA guidance entitled “FDA Export Certificates” at <https://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm>

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

145  
146 For FDA and the owner, operator, or agent in charge of the establishment to agree on a plan of  
147 correction in response to the inspectional observations, for CFG consideration, the following  
148 steps should occur:

- 149
- 150 1. The owner, operator, or agent in charge of the establishment should submit a plan of  
151 correction in writing to the appropriate FDA office. The plan should include steps the  
152 owner, operator, or agent in charge of the establishment will take to correct observations  
153 documented and timeframes for completing such steps.
  - 154 2. The FDA will review the plan and notify the owner, operator, or agent in charge of the  
155 establishment whether the plan is sufficient to address the violations documented in the  
156 inspectional observations. If the plan is agreed to, FDA will issue a CFG.  
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#### 159 **IV. Review of FDA Denial of a Request to Issue a CFG**

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161 A person who has been denied a CFG “may at any time request a review to present new  
162 information relating to actions taken by such person to address the reasons identified by [FDA]  
163 for the denial of [the CFG], including evidence that corrective actions are being or have been  
164 implemented to address grounds for noncompliance identified by [FDA]” (section  
165 801(e)(4)(E)(ii)(II) of the FD&C Act; 21 U.S.C. 381(e)(4)(E)(ii)(II)). The owner, operator, or  
166 agent in charge of the establishment can request a review by contacting the Exports Branch  
167 within CDRH’s Division of International Compliance Operations by email at  
168 [exportcert@cdrh.fda.gov](mailto:exportcert@cdrh.fda.gov) or CBER Import and Export Staff within the Office of Compliance and  
169 Biologics Quality (OCBQ), Division of Case Management (DCM) at  
170 [CBERExportCert@fda.hhs.gov](mailto:CBERExportCert@fda.hhs.gov).

171  
172 The CDRH Exports Branch and the CBER Import and Export Staff will make every effort to  
173 directly resolve issues. If the issue cannot be resolved by the CDRH Exports Branch or the  
174 CBER Import and Export Staff, each Center’s review process will be followed. Section  
175 801(e)(4)(E)(ii)(I) directs the FDA to provide a process for a person who is denied a CFG for a  
176 device to request a review that conforms to the standards of section 517A(b) of the FD&C Act.  
177 CDRH’s review process<sup>2</sup> follows the standards of section 517A, except as necessary to account  
178 for differences in nature and degree of importance between CDRH’s denial of a request for a  
179 CFG, and a significant decision by CDRH. For example, CDRH does not consider the denial of

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<sup>2</sup> 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>

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180 a request to issue a CFG to be a “significant decision” as defined in section 517A(a)(1), and  
181 CDRH’s review process will not include the 30-day timeframe for submitting a request for  
182 review because efforts by the CDRH Exports Branch to resolve any issues raised by a person  
183 whose request for a CFG is denied may take up to or more than 30 days to be completed.  
184 Similarly, CBER will use the Formal Dispute Resolution process<sup>3</sup> to process requests for  
185 review, but the efforts by the CBER Import and Export Staff to resolve any issues raised by a  
186 person whose request for a CFG is denied may take up to or more than 30 days to be completed.

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<sup>3</sup> 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>