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Appealing a denial of a drug/medical device export certificate: FDA final guidance

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Drug and medical device manufacturers seeking to export a product from the United States may need to obtain from the U.S. Food and Drug Administration (FDA) a Certificate to Foreign Government (CFG) in order to satisfy the requirements of the importing jurisdiction. Newly released final guidance explains on what basis the agency will deny an export certificate request and outlines the procedure for appealing an adverse decision.

On 14 November 2019 FDA published the final guidance document, "Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices" (final guidance), which updates a draft version released 17 August 2018. The final guidance clarifies and details the agency's decision-making and provision of information for a denial of a CFG. The guidance also establishes a process for seeking a review of a denial.

Background

FDA may deny a request for issuance of a CFG in the following cases:

- An injunction.
- A seizure involving the subject product.
- Class I or Class II recall involving the subject product.
- Major noncompliance with FDA's Quality System Regulation (QSR)/Current Good Manufacturing Practice (CGMP) requirements.

FDA's final guidance is intended to comply with section 704 of the FDA Reauthorization Act of 2017 (FDARA), which mandates that the agency provide reasons with specificity for a CFG denial and requires a process for appealing the denial of a CFG request.

Rationale for denial

The final guidance clarifies that if the agency denies a CFG request, an email will be sent to the requester identifying the basis for the denial and providing a substantive summary specifying the finding underlying the decision. For example, in cases where noncompliance with the QSR/CGMP requirements is the basis for the denial, FDA will summarize the specific grounds, describing the major noncompliance issues as warranted based on the specific facts of each case. The final guidance states that the agency does not intend to deny CFGs for quality system

inspections that result in a No Action Indicated (NAI) or Voluntary Action Indicated (VAI) classification. The final guidance does not provide a timeline for FDA to issue its summary of the basis for denial.

After receiving a substantive summary of the grounds for denial, a requester may submit a "plan of correction." If FDA and the recipient of an FDA Inspectional Observations form (Form FDA 483) have agreed on the actions to be taken to remediate the 483 observations – a "plan of correction" for CFG decision purposes – the agency will not deny the request.

With respect to CFGs involving products for which there is an open recall, FDA intends to base its decision to issue a CFG on the current status of the recalled products. For example, if the subject product is being reworked, FDA will review the rework documentation and final product testing to determine whether the CFG will be issued.

Appeal process

The final guidance delineates two avenues for a requester seeking agency review of a decision to deny a CFG request. The request for review must be submitted within 60 calendar days from the denial date.

Supervisory review

a) This review appears to be appropriate where the firm maintains that, based on existing information, the CFG should not have been denied (e.g., FDA denied a CFG because it erroneously believed the previous inspection was classified Official Action Indicated (OAI) when in fact it was classified VAI or NAI).

b) The supervisory review includes an in-person meeting or teleconference, if requested.

c) The request for review must reference the inspectional observations from the substantive summary of FDA's denial letter and provide information demonstrating why the CFG request should not have been denied.

Review of new information

a) Per FDA's final guidance, a person who has been denied a CFG may at any time request a review of new information involving actions taken by the CFG requester that address the reasons identified by FDA for the CFG denial. As an example, new information could include evidence that corrective actions are being or have been implemented to address grounds for noncompliance identified by FDA.

b) The final guidance explains that FDA intends 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 firm.

Both types of review are to be solicited via email. The final guidance sets out specific contents for the review request emails and provides agency contact information.

Conclusion

In FDA's final guidance, the agency has defined a clear process for addressing CFG denials, including timelines for when decisions can be appealed and when such issues should be resolved. Moreover, the final guidance clearly explains that inspections classified as NAI or VAI should not be the basis for a CFG denial. When FDA denies a CFG, the summary of the basis for the denial will provide companies with additional information regarding the agency's view of a facility's compliance situation through detailed information as to the remaining gaps. This additional data

point will be hugely beneficial as companies can at times go many, many months without a clear understanding as to whether the agency views its proposed remediation plans to be adequate. The information provided in the final guidance also can be used to provide firms with clear guidelines as to when it would not be appropriate to seek a CFG as well as better predictability regarding whether a request for a CFG should be granted.

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