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ALERTS

FDA Issues Final Guidance On Review Of Denial Of Medical Device Export Certificates

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Before certain medical devices can be lawfully exported from the United States, some countries require American companies to obtain a Certificate to Foreign Government (CFG). The FDA recently issued a final guidance titled "Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices," which details how to seek review of the denial of a CFG request, as well as the reasons the FDA will deny such a request and how to rectify them.

Reasons for Denial

According to the final guidance, the FDA may deny a request for a CFG for one or more of the following reasons:

- There is an injunction proceeding pursuant to Section 302 of the Food, Drug & Cosmetic (FD&C) Act
- There is a seizure action pursuant to Section 304 of the FD&C Act
- 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)
- An establishment is not in compliance with FDA's Quality System regulations, also known as current Good Manufacturing Practices (cGMPs), under 21 CFR Part 820

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When the denial is based on reason 4 only, the guidance states that the FDA's response will include a substantive summary describing the major noncompliance issues that are the basis for the denial and the related reference to the Quality System regulations.

Plan of Correction

If the FDA denies a request for a CFG solely because the device at issue was manufactured in an establishment that has received an FDA Form 483, the company can submit a plan of correction in response. Once the FDA agrees to the plan of correction, it will issue the CFG.

To pursue a plan of correction, the guidance outlines the following steps that should be taken:

1. The establishment should submit, via email, a plan that includes steps it is taking to address, and prevent the recurrence of, the inspectional observations, and timeframes for completing such actions. The plan of correction should also include documentation demonstrating the corrective/preventative actions that have been taken and/or will be taken.
2. The FDA will review the plan and notify the establishment via email, generally within 90 days, whether the plan is sufficient to address the violations in the Form 483.
3. If the FDA approves the plan, and a CFG application is currently under review or subsequently submitted to the agency, the FDA will issue a CFG, if none of the other grounds for denial is present.

Review of Denial of a Request for a CFG

The final guidance discusses two distinct types of review:

1. The first, under FD&C Act Section 801(e)(4)(E)(ii)(I), provides for supervisory review, an opportunity for a meeting or teleconference, and timeframes. The request for review should be submitted within 60 days of denial of the CFG request. The final guidance specifies the information to be included in the request for review. The FDA states resolving the review may take 30 days or more.
2. The second type of review, under FD&C Act Section 801(e)(4) (E) (ii)(II), allows the entity to present new information relating to its actions to address the reasons identified by the FDA for denying the CFG. In this case, the FDA states generally it intends to provide a response within 90 days.

For more information, please contact the Barnes & Thornburg attorney with whom you work or Lynn Tyler, chair of the Food, Drug & Device group, at 317-231-7392 or lynn.tyler@btlaw.com.