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Client Alert

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FDA Releases Draft Guidance on Agency Decisions Not to Issue Certificates to Foreign Governments

On August 16, 2018, the U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) announced (by tweet!) that it was issuing a draft guidance that provides information regarding new processes associated with FDA's denial of requests for Certificates to Foreign Government (CFGs). *FDA, Draft Guidance, Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices* (Aug. 17, 2018) (hereinafter "CFG Draft Guidance"). The draft guidance was issued in compliance with § 704 of the FDA Reauthorization Act of 2017 (FDARA), P.L. 115-52, which required the Agency to issue the document in draft form by August 18, 2018. The draft guidance provides important clarity to industry on the Agency's implementation of FDARA's statutory changes regarding (1) the information to be supplied to CFG applicants whose requests are denied, (2) the potential bases for CFG denials, and (3) the review process for CFG denials.

By way of background, foreign governments often seek assurance from FDA that products exported to their countries from the United States comply with U.S. laws and regulations, such as the Quality System Regulation (QSR) in 21 C.F.R. Part 820. FDA supplies this reassurance in the form of CFGs, which industry must request directly from the Agency. FDARA and the draft guidance identify four potential reasons that FDA may deny a request, although the draft guidance does not limit FDA to these four categories of denials:

1. There firm is subject to an FDA injunction proceeding;
2. The device is subject to a seizure action;
3. The device is the subject of a Class I or Class II recall; or
4. The establishment where the device is manufactured is out of compliance with FDA's QSR.

See 21 U.S.C. § 381(e)(4)(E)(i)(II); CFG Draft Guidance at 5.

A frustration for industry has been the Agency's denial of requests for CFGs based solely on FDA-483 observations with the rationale that such observations demonstrate that the establishment is out of compliance with the QSR. In addition, past denials of these certificates by the Agency provided very little insight into the reason for the denial, or the options that the requesting firm had for correcting any deficiencies leading to the denial. Section 704 of FDARA provided a welcome change that could help address these issues.

Section 704 provides for three important changes to the CFG process. First, it requires FDA to provide a written explanation for the reason(s) that a CFG request is denied. FDA Reauthorization Act of 2017, P.L. 115-52 § 704 (2017). If a denial is based on QSR non-compliance, then FDA must include a substantive summary of the specific deficiency, unless the denial is due to an injunction, seizure, or Class I or II recall. *Id.* Second, FDARA prohibits FDA from denying CFGs based solely on FDA-483 observations if the firm has agreed to a corrective action plan with the Agency. *Id.* Finally, § 704 requires FDA to implement a process for firms to request review of CFG denials, under which firms can submit new information, such as evidence of corrective actions that address the non-compliance identified in the CFG denial notice. *Id.* The draft guidance incorporates all three new statutory requirements.

IDENTIFICATION OF THE REASON FOR CFG DENIAL

With respect to the first modification mandated by § 704, FDA's draft guidance states that, if the Agency denies the CFG request, then it will "identify its basis for denying the request, and specifically identify the finding upon which such denial is based." CFG Draft Guidance at 5. In addition, the draft guidance notes that for denials that are based solely on a facility's non-compliance with the QSR, the Agency will also provide "a substantive summary of the specific grounds for noncompliance identified by FDA." *Id.* This added transparency into the CFG decision-making process should allow firms to more quickly address issues leading to denial and better understand the Agency's thinking on the topic, which should be very beneficial when submitting future requests for issuance of these and similar certificates.

NO DENIALS DUE TO FDA-483 OBSERVATIONS, IF THERE IS AN AGREED-UPON PLAN OF CORRECTION

Perhaps most importantly, the second change in the CFG process stemming from FDARA is that FDA may not deny a request for issuance of 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 (FDA Form 483) . . . 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." *Id.* Similarly, FDA notes that it does not intend to deny issuance of a CFG based solely on inspectional findings from FDA-recognized audit programs, such as the Medical Device Single Audit Program (MDSAP), so long as FDA and the firm agree to a corrective action plan in response to the report. *Id.* at 5-6.

The draft guidance helps clarify, to some degree, what it means to "agree" to corrective actions. To agree to a plan of correction in response to FDA-483 observations, FDA states that there are two required steps. First, the firm should submit a plan of correction in writing to the Agency that includes steps that the establishment will take to correct the observations and timeframes for doing so. *Id.* at 6. Second, FDA will review the plan and notify the firm whether it is "sufficient to address the violations documented in the inspectional observations." *Id.* If the Agency believes that it is sufficient, then it will issue the CFG. *Id.* Notably, the draft guidance is not clear on what suffices as a plan for corrective actions. FDA does not explain whether the establishment's FDA-483 response may satisfy this requirement, or if it will require a separate corrective action plan specifically tailored to the CFG request. The draft guidance also does not explain the process for submitting this plan for corrective action; it simply states that the plan should be submitted "to the appropriate FDA office," without specifying whether that office is a Division of the Office of Medical Device and Radiological Health Operations (OMDRHO) or some other office within CDRH.

PROCESS FOR REQUESTING REVIEW OF CFG DENIALS

Finally, FDARA § 704 requires FDA to provide a review process for CFG denials and specifies that a firm "may at any time request a review to present new information relating to actions taken . . . 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]." *Id.* The draft guidance does outline a process for such review, but FDA did not create a new review process specific to CFGs; rather, the Agency is applying existing review processes to requests for review of CFG denials.

Under the process described in the draft guidance, firms may request review of a CFG denial by contacting the Exports Branch within CDRH's Division of International Compliance Operations or the CBER Import and Export Staff within the Office of Compliance and Biologics Quality (OCBQ), Division of Case Management (DCM). *Id.* If these offices are unable to resolve the issue, then FDA plans to follow each Center's existing review process for continued review of the CFG denial. *Id.* at 6-7.

Importantly, this guidance is in draft form, and FDA is accepting comments on the document until November 15, 2018. Industry participants may wish to consider submitting comments on these proposed processes and other issues as the Agency further develops its policy positions and works toward issuing a final guidance document. FDARA requires that FDA issue the final guidance no later than one year after the end of the comment period, so we expect to see that final guidance in late 2019, provided FDA does not extend the comment period for the draft guidance.

King & Spalding would be pleased to provide you with additional information as you consider these new developments.