Overview

• Discuss industry and FDA perspective on FDARA changes related to inspection process, non-binding feedback and export certificates

• Panelists
  – Amanda Klingler, King and Spalding
  – Gina Brackett, FDA
  – Monica Wilkins, Abbott
Section 704: Export Certification

• Foreign governments often seek assurance from FDA that exported devices comply with U.S. laws and regulations.

• FDA supplies reassurance in the form of Certificates to Foreign Government (CFGs).
  – Industry must request directly from Agency.
Section 704: Export Certification

• Section 704 provides for three important changes:
  – (1) Requires FDA to provide a written explanation for the reason(s) that a CFG request is denied.
    • 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.
  – (2) Prohibits FDA from denying CFGs based solely on FDA-483 observations if the firm has agreed to a corrective action plan with the Agency.
Section 704: Export Certification

• Section 704 provides for three important changes:

  – (3) 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.
Section 704 Draft Guidance

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

• Issued on August 17, 2018
• Provides clarity to industry on FDARA’s 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.
Section 704 Draft Guidance

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

• Draft guidance identify four potential reasons that FDA may deny a request:
  – (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.
Section 704 Draft Guidance:
Process to Request Review of FDA’s Decision Not to Issue Certain Export Certificates for Devices

• Draft guidance outlines review process.
  – FDA did not create a new review process specific to CFGs.

• Firms may request review of a CFG denial by contacting the CDRH’s Exports Branch or the CBER Import and Export Staff.
Draft Export Certificate Guidance

- Draft guidance published on 8/17/2018
  (comment period ended 60 days after publication)

Draft Guidance Process to Request a Review of FDA's Decision to Issue Certain Export Certificates for Devices
FDARA 701: RISK-BASED INSPECTIONS
FDARA 702: UNIFORM PROCESS AND STANDARDS
Section 701
Risk-Based Inspections

Factors to Consider:

(A) Compliance History

(B) Recall History and Nature of Recalls

(C) Inherent Risk of the device

(D) Inspection History of establishment, including whether inspected in last 4 years

(E) Whether the establishment has been inspected by a foreign gov or an agency of a foreign gov recognized by section 809 (e.g. MDSAP)
Section 702
Improvements to Inspection Process

Uniform Process and Standards
Uniform Process and Standards

• Requires FDA to establish uniform process for routine inspections (not for cause) to include:
  
  – Pre-announcement of routine inspections
    • Within a “reasonable time”
    • Notification of type and nature of the inspection
  
  – Estimate of inspection timeframe
Uniform Process and Standards

• Opportunity for advance communication regarding working hours; and to the extent possible advance notice of some records to be requested.

• Regular communication during the inspection regarding the inspection status, which may be recorded by either party with advanced notice and mutual consent.
Draft Inspection Guidance

• Draft guidance published on 3/29/2019
  (comment period ends 60 days after publication)

FDARA 702: INSPECTION NON-BINDING FEEDBACK
FDARA Section 702: Non-Binding Feedback

Amended section 704 by adding:

• 704h(2)(A) The Secretary shall, with respect to a request described in subparagraph (B), provide nonbinding feedback with respect to such request not later than 45 days after the Secretary receives such request.

• 704h(2)(B) A request described in this subparagraph is a request for feedback
  – (i) that is made by the owner, operator, or agent in charge of such establishment in a timely manner; and
  – (ii) with respect to actions proposed to be taken by a device establishment in a response to a report received by such establishment pursuant to subsection (b) that involve a public health priority, that implicate systemic or major actions, or relate to emerging safety issues (as determined by the Secretary).
Draft Guidance

Submitting a Timely Request

• Originate from person to whom 483 issued, or owner, operator, agent in charge (or designated representative)
• No later than 15 business days after 483 issuance
• Submitting requests for non-binding feedback at the same time as response to 483, but as two distinct documents
• Send to the same FDA contact who would receive a response to the 483
Draft Guidance

Submitting a Timely Request

• Include a cover letter addressing:
  – A header that clearly and conspicuously states “Request for Nonbinding FDA Feedback After a Device Inspection”
  – The name, address, phone number, and email address of the person submitting the request
  – The name, address, and FDA Establishment Identification (FEI) number of the establishment that was inspected and the date(s) of the inspection; and
  – A justification describing how the request meets at least one of the eligibility criteria specified in FD&C Act section 704(h)(2)(B)(ii)), as described in Section IV below.
Draft Guidance

Eligibility Criteria

• Observations must
  – Involve a public health priority,
  – Implicate systemic or major actions, or
  – Relate to emerging safety issues (as determined by the Secretary)
Draft Guidance

Justification

• How at least one of the eligibility criteria is met
• May relate to one, multiple or all observations
• Explain how each observation meets the eligibility criteria
• FDA required to provide non-binding feedback if at least one criteria is met
• FDA is not required to provide non-binding feedback if criteria are not met
Draft Guidance

Proposed Responsive Actions

• State the inspectional observations
• Detailed descriptions and timeline of activities of the proposed actions in response to the observations
• Include supporting documentation
Draft Guidance

FDA Non-binding Feedback

• Verifies the request was made by the owner, operator or agent
• Determines if one or more of the eligibility criteria are met
• Considers the justification provided
• FDA notifies requestor within 45 calendar days of receipt of request, advising
  – If not met, notifies request is not eligible to receive non-binding feedback
  – If met, FDA provides non-binding feedback about proposed actions
Draft Guidance

FDA Non-binding Feedback

• Evaluates to determine if the proposed actions to address inspectional observations are:
  – Adequate
  – Partially adequate
  – Inadequate

• If proposed actions appear partially adequate or inadequate, FDA intends to:
  – Acknowledge the submitted proposed actions submitted, including references (where appropriate) to sections, page numbers, or tables;
  – Explain why the proposed actions (or elements of the proposed actions) do not appear adequate; and
  – Provide a recommendation on what may be needed for FDA to consider the proposed actions (or elements of the proposed actions) adequate.

• If proposed actions appear adequate, FDA intends to notify the requestor.
Draft Guidance

FDA Non-binding Feedback

- Intended to be used to inform on the firm’s implementation of actions in response to inspectional observations.
- Firms are not required to adhere to non-binding feedback provided and may use an alternative approach.
- Implementing the FDA non-binding feedback may not address the cause of problems that led to the observations and may require additional action.
- Implementation of non-binding feedback does not prevent FDA from citing observations or taking action.
- Does not preclude or limit FDA’s regulatory options.
- Firms are responsible for adherence to laws and regulations.
Non-Binding Feedback

• Draft guidance published on 2/19/2019 (Comment period has ended)

Nonbinding Feedback After Certain FDA Inspections of Device Establishments