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ALERTS

FDA Draft Guidance For Medical Devices Prepares For End Of Pandemic

March 16, 2022

Highlights

The FDA has issued two separate draft guidance documents for medical devices being marketed subject to 1) an Emergency Use Authorization and 2) enforcement discretion

Both guidance documents propose transition plans of at least 180 days; public comments are being accepted until March 23, 2022

Different types of devices will be treated differently, so manufacturers should consider carefully reviewing the guidance documents

The FDA's Center for Devices and Radiological Health (CDRH) has published two draft guidance documents in anticipation of the end of the public health emergency brought about by the COVID-19 pandemic. One addresses the transition plan for medical devices being marketed under an Emergency Use Authorization (EUA) and the other describes the transition plan for medical devices on the market subject to enforcement discretion.

The EUA draft guidance document is just over 18 pages and the enforcement discretion guidance stretches to 27 pages. Any manufacturer

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with devices subject to the guidances should consider reviewing these documents carefully, because they address many types of devices differently.

Public comments are being accepted until March 23, 2022.

EUA Guidance

The proposed guidance outlines these parameters:

- After the draft guidance is finalized, the FDA will provide advance notice of termination of each EUA declaration pertaining to devices in the Federal Register 180 days before the day on which the EUA declaration is terminated.
- Manufacturers who intend to continue distributing devices authorized under an EUA should submit marketing submissions to the FDA with sufficient time for them to be accepted (not necessarily approved) by the FDA before the EUA termination date. While an accepted marketing submission is under consideration, the FDA expects that manufacturers will comply with all applicable regulatory requirements, including the applicable marketing submission requirements, Quality System Regulation, adverse event reporting, registration and listing, and Unique Device Identification.
- The FDA will permit the continued distribution of devices after the EUA termination date where:
    - The manufacturer has submitted a marketing submission to the FDA and the FDA accepted it before the EUA termination date
    - The FDA has not taken a final action on the marketing submission.
- The FDA expects manufacturers to discontinue distribution of a device
    - On the EUA termination date if the manufacturer has not submitted a required marketing submission for its device and had it accepted by FDA before the EUA termination date; or
    - On the date the manufacturer receives a negative decision on its marketing submission as FDA's final action, or on the date the manufacturer withdraws its submission or fails to provide a complete and timely response to an FDA request for additional information.

Enforcement Discretion Guidance

This guidance applies to devices subject to 16 other listed guidance documents that stated certain devices would be subject to enforcement discretion during the public health emergency.

- The FDA is proposing a 180-day transition period that will begin on the “implementation date” and end on the date that the 16 listed guidances are withdrawn. If the guidance is finalized before the COVID-19 public health emergency ends, the “implementation date” will be the date the 16 listed guidances are withdrawn. If it is not finalized in time, it will be one of two alternative dates.

- The transition period has three phases:

    - **Phase 1** begins on the implementation date. If not already doing so, manufacturers should follow adverse event reporting requirements to prepare for Phase 3.

    - **Phase 2** begins 90 days after the implementation date. Before the start of Phase 2 and to prepare for Phase 3, if not already doing so, manufacturers should follow reports of corrections and removals requirements, and if planning to continue to distribute their devices after the transition period should also follow the registration and listing requirements.

    - **Phase 3** begins 180 days after the implementation date. At the start of Phase 3, the FDA intends to withdraw the 16 listed guidances and manufacturers will be expected to comply with all statutory and regulatory requirements applicable to their devices, except as discussed below regarding premarket authorization.

- Prior to the start of Phase 3, the FDA expects any marketing submission for a device to have been submitted and accepted if the manufacturer intends to continue distribution of the device after the 16 listed guidances are withdrawn. Upon receiving marketing authorization or any final action on a marketing submission, manufacturers must comply with all applicable statutory and regulatory requirements for their devices.

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