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Be Prepared: FDA Signals Transition Countdown for Medical Devices Marketed Under COVID-Era Enforcement Policies, EUAs

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On October 17, 2022, the U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) released the list of guidance documents proposed for publication in fiscal year 2023. While it is unclear if FDA has ranked the released list, it is notable that the Agency has included two COVID-19 Public Health Emergency Transition plans at the top of its A-list for finalization. The first is intended to address medical devices that entered the marketplace under one of the enforcement policies that FDA established during the crisis, and the second is directed at those devices that were granted an Emergency Use Authorization (EUA) during the pandemic, rather than proceeding through the usual approval pathways. Draft guidance documents for both topics were issued as companion documents on December 22, 2021, with comment periods ending in March 2022. With the final guidance hitting the shelves in the coming months, and FDA's history of (usually) changing little from draft to final guidance documents, it is not too early for device manufacturers to begin preparations for the transition.

COVID-19 Enforcement Policies Transition Guidance

The draft guidance, *Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency* (Enforcement Policy Transition Guidance) was a comprehensive guidance that outlined a three-phase approach to transition medical devices introduced under one of the "pandemic-related" device-specific enforcement policy guidance documents to an appropriate clearance pathway (what FDA calls "normal operations"). Throughout the pandemic, FDA

Authors

Ann M. Begley
Partner
202.719.4585
abegley@wiley.law

Practice Areas

Food & Drug
Medical Devices

released a number of guidance documents that provided enforcement policies with respect to specific device classes, which permitted many devices to come to the market while bypassing the traditional regulatory pathways (e.g., 510(k) or Premarket Approval (PMA) pathways). FDA was clear in these guidance documents that the enforcement policies were temporary and would be rescinded when no longer needed, and the Enforcement Policy Transition Guidance was developed to assist manufacturers with bringing their products to market following the FDA withdrawal of these guidance documents.

The three phases occur relatively quickly over a 180-day period once an **implementation date** is set, culminating in the withdrawal of the guidance documents which described the enforcement policies. The implementation date is dependent on two factors: the date FDA finalizes the Enforcement Policy Transition Guidance, and the expiration date of the Secretary of Health and Human Services (HHS) COVID-19 Section 319 Public Health Emergency Declaration (the Declaration). If the draft Enforcement Policy Transition Guidance is finalized *before* the Declaration expires, the implementation date would be the expiration date. If the Enforcement Policy Transition Guidance is finalized after the Declaration expires, FDA would propose an implementation date at least 45 days after the date the guidance is finalized, and the guidance withdrawal date (Phase 3) would be at least 180 days after the implementation date.

Given the fluidity of the implementation date, medical device manufacturers, especially those who intend to continue distribution of their device after the withdrawal of the enforcement policy guidance documents, need to be prepared to execute the recommended actions in the Enforcement Policy Transition Guidance. The recommended actions, and appropriate regulatory requirements, are outlined in the table below. It is critical to mention that submission and acceptance of an appropriate marketing application is required at the end of Phase 2, which is only 90 days after the implementation date.

Table 1. Enforcement Policy Transition Guidance Timelines and Tasks

Phase

Start Date Relative to Implementation Date

Recommended Actions

Applicable Regulations and Guidance Documents

1

Implementation Date

- Continue to report adverse events
- Submit any stored adverse event reports
- Begin preparation of marketing submission (if plan is to continue distribution after guidance withdrawal and marketing application required)

- Develop transition implementation plan to accompany marketing application

- 21 CFR Part 803 (Adverse Event Reporting)
- Guidance: Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic
- 21 CFR Part 807 Subpart E (510k)
- Part 814 (PMA)
- Part 860.220 (De Novo Classification Request)

2

90 days after Implementation Date

- Submit reports of corrections or removals
- Register and list (or update if previously registered)
- **Submit marketing application and transition implementation plan and receive acceptance of the submission from FDA**
- Submit notification of intent for certain reusable life-supporting or life-sustaining devices (if applicable)[1]
- Discontinue distribution if not submitting a marketing application

- 21 CFR Part 806 (Corrections/Removals)
- 21 CFR Part 807 (Registration and Listing)
- Guidance: Refuse to Accept Policy for 510(k)s
- Guidance: Acceptance and Filing Reviews for Premarket Approval Applications (PMAs)
- Guidance: Acceptance Review for De Novo Classification Requests

3

180 days after Implementation Date

- Continued device distribution permitted in certain circumstances if application has been accepted and no final action taken on the application
- Continued compliance with applicable statutory requirements for devices (including quality systems regulations (QSR) and Unique Device Identification (UDI) requirements)

- 21 CFR Part 820 (QSR)
- 21 CFR Part 830 (UDI)

While many companies have begun the preparations for these tasks, it is time to implement the preparations and begin finalizing the reports and submissions that are coming due. Premarket applications are often data-heavy, format specific applications that require a tremendous amount of time and effort to prepare. Equally important is for the medical device manufacturer to determine which clearance pathway is most appropriate, as the available applications vary greatly with regard to the amount and format of the data and information that needs to be provided. FDA has numerous guidance documents to assist in the determination, as well as a classification request pathway, for those unsure of the appropriate regulatory pathway. In addition, the Enforcement Policy Transition Guidance requires not only submission of the marketing application but acceptance of the filing. This is a separate review process directed at the format and content (but not substantive issues) of the application, to ensure that the application is complete and ready for review. Relevant guidance documents that discuss the criteria for an acceptance for filing are referenced in Table 1 above.

It is also important to note that those manufacturers who do not intend to continue distribution of devices introduced under one of the enforcement policy guidance documents remain responsible for certain actions under the Enforcement Policy Transition Guidance, particularly with regard to reporting of adverse events. Further, FDA can inspect any establishment where medical devices are stored, manufactured, processed, or packed before or after introduction into commerce.

It is recommended that medical device manufacturers promptly assess the status of completion of the recommended actions in the Enforcement Policy Transition Guidance. Manufacturers should also determine if there is a need to communicate with the FDA, to discuss possible exemptions or variances from regulatory requirements if needed, for example, and should begin that engagement soon through the Q-submission program. Manufacturers that wait too long to engage in necessary communications with the Agency may find themselves lost in the deluge of meeting requests that FDA will likely receive when the guidance is finalized.

COVID-19 EUA Transition Guidance

Unlike the phased approach set forth in the Enforcement Policy Transition Guidance, FDA's *Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency* (EUA Transition Guidance) relies on a statutory provision of advanced notice of termination of the EUA declaration, described in Section 564 of the Federal Food, Drug, and Cosmetic Act (FFDCA). The FFDCA requires the HHS Secretary to publish the intent to withdraw the EUA declaration in the Federal Register prior to termination. Like the Enforcement Policy Transition Guidance indicates, once an EUA declaration has been terminated, the medical devices that were covered by that declaration are no longer authorized for emergency use. FDA provides a time frame of 180 days from the Federal Register to the termination, using the same time frame as is suggested for devices permitted under the enforcement policy guidance documents. It is important to note that during the 180-day period, all devices under the EUA must continue to comply with the conditions set forth in the EUA.

For manufacturers intending to continue marketing EUA-cleared medical devices after the EUA termination, FDA recommends that they file, and have accepted for review, an appropriate marketing application prior to the termination date.[2] Like those devices permitted under an enforcement policy guidance, FDA does not intend to object to the continued distribution of devices for which a marketing application has been accepted for review (and for which no final action on the application has been taken). However, an important distinction is that the EUA Transition Guidance indicates that the medical device labeling should be updated to explain that the device was authorized under an EUA during the COVID-19 public health emergency, but is currently under review for clearance or approval. Further, during the period between the termination of the EUA and while the product is under review, continued compliance with all regulatory requirements, including adverse event reporting, registration and listing, and quality systems regulations, is required.

The Transition Implementation Plan

The FDA has requested that manufacturers of devices permitted under an EUA, as well as those with devices permitted under the enforcement policy guidance documents, submit a Transition Implementation Plan (TIP) with their marketing applications. The TIP is intended to proactively engage manufacturers to develop a plan to deal with devices in the marketplace should they receive a positive or negative decision from the FDA on the marketing submission. The FDA recommends the following elements be included in the TIP:

1. An estimate of the number of devices that are currently in distribution in the United States.
2. Disposition plan, developed using a risk-benefit decision-making process, for devices in distribution should the manufacturer receive a negative decision from FDA on the marketing submission. The plan should address how the decision will be communicated to end users (patients, health care facilities, etc.), the process to restore the device to a previously FDA-cleared version (if applicable) or the plan to update labeling that identifies change in regulatory status and features of the device, and finally, a maintenance plan for those devices already in distribution.
3. Plan to update the device, labeling, and components of devices already in distribution should the manufacturer receive a positive decision from the FDA on its marketing submission. This would include a plan to update the labeling to reflect the change in regulatory status and to reflect any changes that resulted from the review process.

Manufacturers should realize that FDA may request additional actions, such as a recall, depending on the outcome of the review of the marketing submission and other risk factors and circumstances. Manufacturers should assess their internal abilities to complete the actions in the TIP, and ensure that relevant policies and standard operating procedures to complete the tasks in the TIP are developed and ideally finalized prior to the submission. Submission of a detailed and thorough TIP will contribute to a productive discussion with the FDA, and could aid in the development of a plan that is most beneficial to the manufacturer.

Further, as with devices introduced under the enforcement policies, manufacturers who do not intend on continued distribution of their devices once the EUA has been terminated must continue to comply with regulatory requirements until termination and beyond (as applicable), particularly with regard to reporting of

adverse events.

Summary

The FDA has published its intention to finalize the guidance documents, *Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency* and *Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*. These documents outline the steps FDA expects manufacturers to take in preparation for the end of enforcement policies and EUAs which were granted during the pandemic, and provides strategies for medical devices that entered the marketplace under these policies to achieve clearance or approval. While the guidance documents take two different approaches, the end result is the same, requiring manufacturers to submit a transition implementation plan and a marketing submission. These activities are time consuming and require a great deal of data. Therefore, manufacturers should start their development now, rather than waiting for the documents to be finalized. This early preparation is critical, as the date the guidance is finalized could start the clock on the deadlines for submission of the application (as short as 90 days for devices under the enforcement policies) if the public health emergency declaration for COVID-19 has expired. The countdown is on, and the risk of waiting to begin the transition activities could be the difference between clearance and continued marketing, or rejection.

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[1] Applicable for product codes BSZ (Gas machine, anesthesia), CAW (Generator, oxygen, portable), BTT (Humidifier, respiratory gas (Direct Patient Interface)), QAV (High flow/high velocity humidified oxygen delivery device), CBK (Ventilator, continuous, facility use), MNT (Ventilator, continuous, minimal ventilatory support, facility use), NOU (Continuous, ventilator, home use), MNS (Ventilator, continuous, non-life-supporting), ONZ (Mechanical ventilator), BTL (Ventilator, emergency, powered (Resuscitator)).

[2] FDA is requesting that manufacturers of certain life supporting or sustaining devices provide the Agency with a notification of the manufacturers' intent on whether they will continue to market their products after the termination of the EUA to avoid shortages. Notifications of intent are recommended for the following product codes: BSZ (Gas-machine, anesthesia), CAW (Generator, oxygen, portable), BTT (Humidifier, respiratory gas (Direct Patient Interface)), QAV (High flow/high velocity humidified oxygen delivery device), CBK (Ventilator, continuous, facility use), MNT (Ventilator, continuous, minimal ventilatory support, facility use), NOU (Continuous, ventilator, home use), MNS (Ventilator, continuous, non-life-supporting), ONZ (Mechanical ventilator), BTL (Ventilator, emergency, powered (Resuscitator)), QOO (Tubing connector for co-venting).