January 13, 2022

Contemplating a Post-COVID Return to "Normal Operations": FDA's Transition Plans for Devices Marketed Under Emergency Use Authorizations and Enforcement Policies

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In late December 2021, FDA issued two draft guidance documents regarding unapproved medical devices that FDA has allowed to be marketed during the COVID-19 pandemic: one details transition plans for devices issued emergency use authorizations ("EUAs") under section 564 of the Federal Food Drug & Cosmetic Act ("FDCA"); the other addresses devices subject to FDA COVID-related enforcement policies.

The two companion documents aim to prepare manufacturers and other stakeholders for a return to "normal operations," *i.e.*, "when the COVID-19 PHE under . . . the Public Health Service Act has expired and/or the relevant device COVID-19 emergency use declarations under [the FDCA] are terminated."

This alert reviews the expectations underlying FDA's new draft guidances as well as the Agency's key recommendations for how manufacturers can prepare themselves for a post-emergency reality. Manufacturers of devices marketed under EUAs or enforcement discretion policies should be familiar with these guidance documents and begin to plan accordingly.

Background

Since the outset of the COVID-19 pandemic, FDA has taken action to help alleviate supply chain issues associated with the pandemic and facilitate the availability of devices intended to diagnose, treat, and prevent COVID-19 and associated conditions. It has done so both by granting EUAs for certain unapproved or uncleared devices, including for unapproved uses of otherwise legally marketed devices, and through the enactment of enforcement policies recognizing FDA's "non-objection" to the distribution of certain unapproved or otherwise non-compliant devices. See, for example, a prior Ropes & Gray analysis of FDA's actions during the early stages of the pandemic.

Notwithstanding that the COVID-19 PHE is approaching its two-year anniversary in the United States with no clear end in sight, the EUA declarations and FDA enforcement policies that have been issued are intended to be temporary. While there is increasing recognition that we will have to factor COVID-19 into our new "normal," manufacturers of devices currently on the market pursuant to EUAs or FDA's COVID-19-related enforcement policies will, nevertheless, ultimately need to either cease distribution of those devices or bring them into compliance with FDA requirements that will apply in full force when the current emergency ends.

Transition Plan for Medical Devices Issued EUAs During the COVID-19 PHE

This draft guidance describes pathways available to device manufacturers following the termination of relevant EUA declarations: manufacturers can cease distribution of affected devices, submit appropriate marketing applications seeking FDA authorization to continue distribution, or return devices to their previously cleared or approved state, if applicable. FDA advises manufacturers to begin preparing now for post-EUA regulatory and disposition strategies.

FDA-issued EUAs will remain in effect until either their authorizing declaration is terminated by the HHS Secretary through notice and publication in the Federal Register or FDA determines that a particular EUA should be revoked. Three EUA declarations for medical devices have been issued during the COVID-19 pandemic: one for COVID-19 diagnostics (Feb. 4, 2020); one for personal respiratory protective devices (March 2, 2020); and one for medical devices more generally (March 24, 2020). The draft guidance advises that 180 days' advance notice will be provided prior to

termination of each EUA declaration. Once a declaration is terminated, all EUAs issued under that declaration also terminate, and emergency use of such products is no longer authorized.

When an EUA terminates, FDA is required to consult with the product manufacturer to determine the appropriate disposition of the product. FDA believes that issuance of the draft guidance and the accompanying request for public comment may help the Agency satisfy (or determine how to satisfy) this requirement while conserving Agency resources.

Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the COVID-19 PHE

The enforcement policies FDA has issued in response to the pandemic state that they will remain in effect only for the duration of the PHE. However, given the magnitude and duration of the COVID-19 PHE, FDA's draft guidance proposes a phased approach for transition back to "normal operations," acknowledging "unique considerations" such as device manufacturing by non-traditional manufacturers. The draft guidance applies to a host of devices subject to FDA COVID-19 enforcement policies, including digital pathology devices, ventilators, and face masks – enforcement policies referred to collectively as "List 1." List 1 is subject to change as the pandemic continues, and FDA intends to remove policies from the list when they are withdrawn.

FDA proposes a 180-day transition period that would begin on the "implementation date" of the final guidance and would end with the enforcement policies on List 1 being withdrawn. Should FDA finalize the guidance before the expiration of the COVID-19 PHE declaration, the implementation date would be the date the COVID-19 PHE declaration expires. However, if the COVID-19 PHE declaration expires in advance of guidance finalization, the implementation date would be announced in the final guidance and would be at least 45 days after finalization.

Regardless of whether manufacturers pursue marketing authorization for their devices, FDA expects that all manufacturers of devices distributed pursuant to a List 1 enforcement policy will abide by expectations keyed to the following three phases:

- *Phase 1 beginning on implementation date*. If not already doing so, manufacturers should comply with medical device adverse event reporting requirements and the conditions of the applicable enforcement policy. Manufacturers should also submit any adverse event reports that were delayed (e.g., due to pandemic-related employee absenteeism) consistent with FDA guidance

- *Phase 2 beginning 90 days after implementation date*. If not already doing so, manufacturers should comply with device correction and removal (*i.e.*, recall) reporting requirements. If planning to continue to distribute devices after the transition period, manufacturers should register and list their devices. If applicable, manufacturers should submit to FDA and have accepted a marketing submission before the start of Phase 3.

- *Phase 3 beginning 180 days after implementation date*. FDA intends to withdraw the List 1 guidances. Manufacturers will be expected to comply with all statutory and regulatory requirements applicable to their devices (e.g., quality system regulation; unique device identification), except as discussed below regarding devices subject to ongoing premarket review.

Common Characteristics of Both Transition Plans

In addition to sharing 180-day transition timelines, the guidances mirror each other in other ways. For example, FDA expects manufacturers who intend to distribute devices after either the applicable EUA termination or relevant guidance withdrawal to have completed necessary steps to transition into compliance with all applicable FDCA requirements once "normal operations" resume. The guidances outline the following common recommendations.

"Notifications of intent" for certain reusable life-supporting or life-sustaining devices

FDA requests that manufacturers of certain reusable life-supporting or life-sustaining devices, such as ventilators and anesthetic gas machines, notify FDA regarding whether or not they intend to submit a marketing submission to continue product distribution during normal operations. For devices marketed under EUAs, FDA is requesting these notifications of intent "as soon as possible" after FDA's guidance is finalized. For devices marketed under enforcement policies, FDA is requesting the notifications prior to the start of "Phase 2" discussed above. If a manufacturer does not plan to submit a marketing submission, such notification should include the manufacturer's plans to discontinue distribution of the device, restore the device to a previously FDA-cleared or approved version, and provide a physical copy or electronic version of updated labeling to customers. The guidances provide a more comprehensive description of the information that should be included in these notifications.

Considerations for continuing device distribution during normal operations

Manufacturers that intend to continue device distribution during normal operations should submit marketing submissions to FDA with sufficient time for acceptance prior to the applicable EUA termination or guidance withdrawal date. After such dates, whether a marketing authorization is still under review or has been granted, FDA expects manufacturers to comply with all other applicable regulatory requirements.

FDA does not intend to object to continued device distribution following an EUA termination or guidance withdrawal if, prior to such time, the manufacturer has submitted a marketing submission to FDA and had it accepted, and FDA has not taken a final action on the marketing submission. For EUA devices, during the period after the EUA termination date, labeling should be updated to accurately state that the product was authorized under an EUA issued during the COVID-19 PHE and remains under FDA review for clearance or approval. If the manufacturer receives a negative decision on its marketing submission, withdraws its submission, or fails to provide a timely complete response to an FDA request for additional information, the manufacturer should cease distribution of the affected device on the date the negative decision is received, the withdrawal is effectuated, or the deadline passes for the complete response.

In marketing submissions, manufacturers should include a "transition implementation plan" for already-distributed devices. This plan should address the estimated number of EUA or enforcement policy devices currently in U.S. distribution, the manufacturer's benefit-risk plan for disposition of already-distributed product in the event of a negative marketing submission decision (with further details required if the plan is to leave product in place), and the manufacturer's plan for addressing already-distributed products in the event the marketing authorization is granted (such as notifying customers of the new regulatory status and providing updated labeling). FDA may engage with manufacturers during review to discuss the disposition of already-distributed devices. If device changes have been made, manufacturers should discuss with FDA possible correction or removal approaches for devices already distributed to end users, and FDA may request a recall for some devices if appropriate.

FDA acknowledges that some non-traditional device manufacturers may face transition challenges. To that end, the draft guidances state that manufacturers may request an exemption or variance from a quality system regulation requirement under specified timelines prior to the applicable EUA termination or guidance withdrawal.

Considerations if not continuing device distribution during normal operations

Manufacturers are expected to discontinue device distribution on, as relevant, the EUA termination date or withdrawal of the applicable PHE enforcement policy if no required marketing submission has been submitted and accepted by FDA. Additionally, manufacturers should be aware of and comply with any applicable requirements for their device that may extend beyond the cessation of distribution, such as adverse event reporting.

If a manufacturer does not plan to continue distribution of its device during normal operations, FDA does not intend to request market removal of certain types of already-distributed devices if they were distributed before either the applicable EUA termination or guidance withdrawal. FDA's expectations for such devices vary, however, based on device type. For example, FDA will not request market removal of single-use, non-life-supporting/non-life-sustaining devices that are consumed by the end user, such as face masks. But for reusable devices, FDA expects the device to be restored by the manufacturer to the previously FDA-cleared or approved version, or the manufacturer to have both a publicly available electronic copy and a physical copy of labeling that accurately describes the product features and regulatory status (i.e., that the product lacks FDA clearance or approval).

What's Next for Manufacturers of Affected Devices?

Now that FDA has issued these two draft guidances explaining the Agency's intentions for medical devices once the PHE and EUA declarations terminate, it is important for medical device manufacturers to develop disposition plans for devices that will become legally non-compliant upon a return to normal operations.

Manufacturers may find FDA's disposition expectations burdensome in that they request notice of detailed plans before manufacturers may have all the information or ask manufacturers to make decisions about their future intentions before they may be ready to do so. Likely for this reason, FDA is urging manufacturers to start planning now, so they can begin collecting all the information the Agency expects and developing submission-ready transition plans.

Additionally, the implications of the recall-related discussions in the draft guidances suggest that FDA anticipates that field actions (e.g., updated labeling, software updates, and potentially product removals) are likely to be warranted in many cases, especially for those devices not fitting into the device categories for which FDA does not intend to request removal. Even manufacturers that simply wish to cease marketing their devices once the applicable EUA terminates or guidance is withdrawn will need to carefully evaluate the draft guidances to understand FDA's expectations.

While neither HHS nor FDA has provided a timeline with respect to when the process of terminating the PHE or EUA declarations will begin, the mere fact that FDA is encouraging manufacturers to start planning their post-emergency regulatory and disposition strategies now is an important signal that FDA expects such terminations could occur in the foreseeable future. Additionally, FDA's plan to use the public comment process for the draft guidance to satisfy (at least in part) its statutory obligation to consult with EUA holders about product disposition is further evidence that FDA is preparing for a post-pandemic future.

Individual consultations with each EUA holder would be a massive drain on Agency resources considering the large number of device EUAs FDA has granted since the onset of the pandemic. To the extent manufacturers have disposition-related questions, commenting on the draft guidance may be one way to get such questions before the Agency as it works on its transition planning and may enable manufacturers to be better prepared to provide a disposition plan that will be acceptable to the Agency later. Alternatively or in addition to commenting on the draft guidances, FDA is also inviting manufacturers to discuss their particular circumstances through the Q-Submission Program.

The comment periods for the two draft guidances will close on March 23, 2022. Ropes & Gray will be closely tracking any changes in FDA's position on the return-to-normal operations as the circumstances of the pandemic continue to evolve. If you have any questions on these draft guidances or anything else, please contact any member of our FDA regulatory practice or your usual Ropes & Gray advisor.