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FDA Issues Draft Device Guidance in Preparation for the End of the Public Health Emergency

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We recently published a post describing FDA's recent actions to roll back enforcement policies implemented in response to the COVID-19 pandemic. On December 22, 2021, FDA took another step in that process by publishing guidance documents describing the regulatory requirements for devices that were authorized under the emergency use authorization (EUA) process (EUA Devices) and those under temporary FDA policies implementing specific enforcement discretion during the pandemic (Enforcement Policy Devices) once the Public Health Emergency for COVID-19 (PHE) ends. These guidance documents, Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency and Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Transition Plan Guidances), are critically important for manufacturers that developed and produced new devices or modified legally marketed devices specifically in response to the pandemic to help diagnose, cure, treat, or mitigate the symptoms of COVID-19. Both EUAs and FDA's enforcement policies are temporary and designed to terminate once the PHE ends, and at that time, any device that received an EUA or was developed, manufactured, labeled, and distributed in accordance with FDA's enforcement policies will suddenly lose any marketing authorization or enforcement discretion. The Transition Plan Guidances will help device manufacturers prepare for the end of the PHE and continue to commercialize devices necessary for the long-term response to COVID-19.

The Transition Plan Guidances establish similar transition frameworks for EUA and Enforcement Policy Devices, each with a notice to manufacturers that the transition is beginning followed by a specific period in which manufacturers will need to prepare and submit applications for appropriate marketing authorization. Predictably, both Transition Plan Guidances state that distribution of an EUA or Enforcement Policy Device must be discontinued if the manufacturer does not submit, and FDA has not accepted, a marketing submission by the time the designated transition period ends. Of course, manufacturers must also comply with all applicable device regulations, including registration and listing, quality system requirements, unique device identifier (UDI), and other labeling requirements, once the transition period ends. EUA and Enforcement Policy Devices that are class I or otherwise exempt from premarket notification requirements do not need to comply with the marketing submission requirements of the Transition Plan Guidances.

Importantly, the enforcement policy Transition Plan Guidance specifically excludes in vitro diagnostic

tests for COVID-19, so any manufacturer of a COVID-19 test must follow the EUA Transition Plan Guidance.

In both guidances, FDA states that the agency will announce the start of the transition period for EUA and Enforcement Policy Devices in the Federal Register, and the EUAs and enforcement policies will terminate 180 days later. Even though the transition periods for both types of devices are equivalent in terms of duration, there are some differences—in particular, it is not clear that FDA will initiate the transition periods simultaneously. In addition, while the EUA Transition Plan Guidance does not provide any specific structure to the transition period, the enforcement policy Transition Plan Guidance divides the transition period into three phases:

- Phase 1 begins on the day of FDA's announcement. The agency expects manufacturers to begin complying with adverse event reporting requirements (21 C.F.R. Part 807) if not already doing so.

- Phase 2 begins 90 days after the start date. Before Phase 2 starts, the agency expects manufacturers to begin complying with correction and removal reporting requirements (21 C.F.R. Part 806). If a manufacturer plans to distribute an Enforcement Policy Device after the transition period, the manufacturer should register and list with FDA before the start of Phase 2.

- Phase 3 begins 180 days after the start date. FDA will withdraw the enforcement policies and manufacturers are expected to comply with all applicable device regulations at the start of Phase 3.

If FDA receives and accepts a marketing application for an Enforcement Policy Device prior to the start of Phase 3, the manufacturer may continue to market and distribute the device. However, if FDA does not receive a marketing submission for the Enforcement Policy Device before Phase 3 begins, or if the agency issues a negative decision on a marketing submission for the device, the manufacture must discontinue distribution of such device.

For EUA Devices, a manufacturer that wishes to distribute such a device after the transition period must submit, and FDA must accept, a marketing submission for the EUA Device before the 180-day period ends. FDA will terminate all EUAs once the transition period ends, so any manufacturers that elect not to distribute an EUA Device after the transition period, as well as manufacturers that have not submitted marketing submissions or have received a negative decision from FDA on a marketing submission for an EUA Device, must discontinue distribution as of the termination date.

FDA recommends that manufacturers of certain reusable life-supporting or life-sustaining EUA or Enforcement Policy Devices submit a "notification of intent" informing FDA whether or not they will submit a marketing submission to support the continued distribution of such devices. If a manufacturer does not intend to submit a marketing submission, the notification should describe plans to discontinue distribution, restore the EUA or Enforcement Policy Device to a legally marketed version, provide updated labeling, and other measures to address or mitigate potential risks relating to modifications made with respect to the EUA or enforcement policy. In addition, FDA requests that each manufacturer include a "transition implementation plan" as part of each marketing submission for an EUA or Enforcement Policy Device. The transition implementation plan should provide the following information:

- Estimated number of devices distributed;
- Benefit-risk based plan for disposition of distributed devices in the event FDA issues a negative decision on the marketing submission; and
- Plans for addressing distributed devices in the event FDA issues a positive decision on the marketing submission.

In particular, if changes or modifications to already-distributed EUA or Enforcement Policy Devices will be necessary to comply with the specifications described in the marketing submission, the manufacturer should discuss plans for the correction or removal of such devices from the marketplace. Additionally, FDA may request that a manufacturer initiate a recall of already-distributed devices where necessary.

Finally, for EUA or Enforcement Policy Devices that are discontinued after the implementation period ends, FDA does not intend to request market removal of such devices distributed before the end date if they fall within one of the following categories:

- Single use, non-life-supporting/non-life-sustaining devices that are consumed by the end user.
- Reusable, non-life-supporting/non-life-sustaining devices that are restored to their legally marketed versions or for which updated labeling accurately describing the product features and regulator status (i.e., that the device is not FDA-cleared or approved) is made publicly available.
- Reusable, life-supporting/life-sustaining devices that are restored to their legally marketed versions or that have physical copies of and publicly available updated labeling accurately describing the product features and regulatory status (i.e., that the device is not FDA-cleared or approved).
- In vitro diagnostic devices that are used for no more than the earlier of 2 years after the EUA termination date or the expiration date.

Although 180 days for the transition period before the termination of COVID-19 EUAs and FDA enforcement policies seems like a considerable amount of time, manufacturers will need to prepare substantial marketing submissions, including new information requested by FDA in the Transition Plan Guidances, and in some cases implement appropriate systems and controls to ensure compliance with applicable device regulations by the end of such period. On December 21, 2021, CDRH reported that it has issued more than 1,900 EUAs for devices during the pandemic and that it continues to receive over 100 EUA requests per month, so there will likely be a significant resourcing issues if all marketing submissions for EUA and Enforcement Policy Devices are submitted towards the end of the transition period, rather than on a rolling basis. The release of the Transition Plan Guidances marks the beginning of FDA's preparations for the transition, so manufacturers of EUA and Enforcement Policy Devices should likewise start their own preparations by becoming familiar with the guidances, considering whether to continue distribution of such devices after the transition period, and beginning to develop plans for compliance with the conventional device regulations.

FDA is currently accepting public comments on the Transition Plan Guidances, and it has scheduled a webinar for stakeholders on the plans for February 22, 2022. Anyone interested in commenting to either or both draft guidances should submit their comments to docket FDA-2021-D-1118 for the enforcement policy Transition Plan Guidance and to docket FDA-2021-D-1149 for the EUA Transition Plan Guidance.

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