DECEMBER 30, 2021

For more information, contact:

Amanda Klingler
+1 202 626 9255
aklingler@kslaw.com

Jessica Ringel
+1 202 626 9259
jringel@kslaw.com

Kyle Sampson
+1 202 626 9226
ksampson@kslaw.com

Steven Niedelman
+1 202 626 2942
sniedelman@kslaw.com

King & Spalding

Washington, D.C.
1700 Pennsylvania Avenue, NW
Washington, D.C. 20006-4707
Tel: +1 202 737 0500

FDA Issues Draft Guidances on Transitioning Devices from EUAs and Agency Enforcement Policies

During the ongoing COVID-19 pandemic, the Center for Devices and Radiological Health (CDRH) in the U.S. Food and Drug Administration (FDA or the Agency) issued a series of Emergency Use Authorizations (EUAs) and guidance documents regarding Agency Enforcement Policies to ease regulatory requirements for medical devices needed to diagnose, treat, or prevent COVID-19 and mitigate exposure to the SARS-CoV-2 virus. FDA never intended for these EUAs and Enforcement Policies to be permanent, and the Agency has signaled for several months that manufacturers of devices brought to market under these exemptions should prepare to transition their devices to full compliance with FDA requirements. On December 23, 2021, FDA issued two companion draft guidance documents outlining the Agency's proposed process for these transitions:

- *Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency* (the EUA Transition Draft Guidance); and
- *Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency* (the Enforcement Policy Transition Draft Guidance).

FDA is accepting comments on both draft guidance documents until March 23, 2022 through *Regulations.gov* (docket FDA-2021-D-1149 for the EUA Transition Draft Guidance and docket FDA-2021-D-1118 for the Enforcement Policy Transition Draft Guidance).

The draft guidance documents set forth similar processes and recommendations for manufacturers who have determined either to continue to distribute or to cease the marketing of their devices after the end of an applicable EUA or FDA Enforcement Policy. In both cases, FDA proposes a transition period of not less than 180 days, though with

different starting points, as described below. FDA intends to exercise its enforcement discretion and permit the continued distribution of devices originally brought to market under an EUA or FDA Enforcement Policy if, prior to the end of the 180-day transition period, a marketing submission has been submitted to the Agency and has passed the initial Refuse to Accept (RTA) phase. Further, for those devices that a manufacturer chooses to discontinue distributing, at the end of the 180-day transition phase FDA does not intend to require removal of devices remaining in the field, provided that certain labeling changes or device modifications are made.

PROPOSED TIMING

Both the EUA Transition Draft Guidance and Enforcement Policy Transition Draft Guidance would provide manufacturers transition periods of at least 180 days either (1) to discontinue distribution of devices brought to market under an EUA—including an umbrella EUA—or an FDA Enforcement Policy, or (2) to seek permanent marking authorization for the device by submitting a 510(k), De Novo classification request, or premarket approval (PMA) application.

For EUAs, FDA intends to issue an advance notice of termination in the Federal Register, as required by the Federal Food, Drug, and Cosmetic Act's statutory provisions for EUAs. FDA proposes to issue the advance notice of termination 180 days before the planned EUA termination date, giving manufacturers roughly six months to transition their devices to full regulatory compliance or, alternatively, to discontinue distribution.

For FDA Enforcement Policies, FDA similarly plans a 180-day transition period. The transition period will commence either (1) at the end of the COVID-19 Public Health Emergency (PHE), as declared by the Secretary of the Department of Health and Human Services (HHS), if the draft guidance is finalized before the end of the COVID-19 PHE, or (2) on an "implementation date" announced in the final guidance, if the draft is not finalized until after the end of the COVID-19 PHE. In either case, FDA proposes a period of not less than 180 days.

DEVICES TO BE MARKETED AFTER WITHDRAWAL OF A RELEVANT EUA OR ENFORCEMENT POLICY

For devices currently marketed under an EUA—including an umbrella EUA—or an Enforcement Policy, including modified versions of previously cleared or approved devices, the two draft guidances outline FDA's recommendations and expectations for submissions for permanent marketing authorization. In both cases, if a submission is accepted by FDA, that is, if it passes the RTA phase, prior to the end of the 180-day transition period and before the effective date of the withdrawal of the applicable EUA or FDA Enforcement Policy, then FDA intends to exercise enforcement discretion and permit the continued distribution of the device while the marketing submission is pending before the Agency. This enforcement discretion applies only to the premarket clearance/approval requirements. At the end of the 180-day transition period and while the marketing submission is pending, FDA expects manufacturers to comply with all other regulatory requirements, including Medical Device Reporting (21 C.F.R. Part 803), Reports of Corrections and Removals (21 C.F.R. Part 806), Registration and Listing (21 C.F.R. Part 807), and the Quality System Regulation (21 C.F.R. Part 820).

In both draft guidances, FDA recommends that any marketing submission include the manufacturer's "transition implementation plan" for the disposition of devices distributed prior to FDA's final decision on the pending submission, for both a potential positive FDA decision (e.g., 510(k) clearance, De Novo grant, or PMA approval) and a potential negative FDA decision (e.g., not substantially equivalent determination (NSE) or De Novo or PMA denial). FDA notes that the Agency may request a product recall (a correction or removal, as relevant) of distributed devices if the version of the device that is cleared or approved differs from the distributed versions. Additionally, in the hypothetical examples provided in the Enforcement Policy Transition Draft Guidance, FDA states that the Agency may request a product recall of distributed devices if the manufacturer's marketing submission is not approved or cleared. We note that this request would differ from FDA's stated policy for devices for which the manufacturer voluntarily discontinues distribution, in which no removal would be required if the recommended device correction or labeling changes are made.

The draft guidances do not provide information about FDA's review of marketing submissions submitted under the transition guidances. It is an open question whether and how FDA will consider the marketing history of a device under an EUA or Enforcement Policy in the Agency's benefit-risk determination when deciding whether to clear or approve a device. Manufacturers may wish to submit Pre-Submissions to FDA prior to filing a marketing submission to obtain feedback on the use of such real-world data. Of course, FDA's current Pre-Submission response times for review groups that have been most heavily impacted by pandemic operations, including those responsible for in vitro diagnostics (IVDs) and personal protective equipment (PPE), are currently extended beyond the standard timeframes (and an influx of marketing submissions for EUA and FDA Enforcement Policy devices may add to the backlog). On December 21, 2021, Jeff Shuren, the Director of CDRH, and William Maisel, the Director of CDRH's Office of Product Evaluation and Quality, released a statement on CDRH's workload lamenting that in 2021 Pre-Submission reviews in the "heaviest hit divisions" have generally been completed "within 120 days—approximately 7 weeks longer than the pre-pandemic average."[1] In practical effect, this means that a Pre-Submission may consume a considerable portion of the 180-day transition period and result in a failure to submit and pass the RTA phase prior to the end of the 180 days. Accordingly, if manufacturers want FDA feedback on use of real-world data to support a marketing submission, or any other aspect of their submission, then we recommend initiating the Pre-Submission process before FDA finalizes the draft guidances and before FDA's announcements of its planned discontinuation of EUAs or FDA Enforcement Policies.

DEVICES TO BE DISCONTINUED AFTER WITHDRAWAL OF A RELEVANT EUA OR ENFORCEMENT POLICY

For devices that the manufacturer does not intend to continue distributing after the end of the relevant EUA or Enforcement Policy, both the EUA Transition Draft Guidance and the Enforcement Policy Transition Draft Guidance provide guidelines for the continued use of such devices in the field. Specifically, FDA "does not intend to object to the disposition of already distributed devices," meaning that FDA will not request or require a removal of the devices from the field, if the devices were (i) distributed prior to the withdrawal of the relevant EUA or FDA Enforcement Policy and (ii) the following limited requirements are met:

1. **Single-use, non-life-supporting/non-life sustaining devices:** no additional requirements; the devices can be consumed by end users.
2. **Reusable, non-life-supporting/non-life sustaining devices:** the manufacturer should either (a) restore the device to the previously cleared or approved version (assuming the device marketed under an EUA or Enforcement Policy is a modification of a cleared or approved device), or (b) maintain publicly available labeling (e.g., on the company website) that describes the product features and a statement of the fact that the device lacks FDA clearance or approval.
3. **Reusable, life-supporting/life-sustaining devices:** the manufacturer should either (a) restore the device to the previously cleared or approved version (assuming the device marketed under an EUA or Enforcement Policy is a modification of a cleared or approved device), or (b) maintain publicly available labeling (e.g., on the company website) and also distribute physical copies of labeling to users that describes the product features and a statement of the fact that the device lacks FDA clearance or approval.
4. **In vitro diagnostic devices:** no additional requirements; the tests can be used by end users until two years after the EUA withdrawal or the test's expiration date, whichever comes first.

Although FDA will not require the removal of any EUA or FDA Enforcement Policy device from the field if these recommendations are followed, FDA does remind manufacturers in both draft guidances that the devices remain subject to Medical Device Reporting (MDR) obligations under 21 C.F.R. Part 803 for as long as the devices remain in the field. The draft guidances do not explicitly reference compliance with corrections and removals reporting under 21 C.F.R. Part 806 for devices that remain in the field, but to the extent that Part 806 compliance was not waived in the applicable EUA

or FDA Enforcement Policy, FDA is likely to require compliance with those reporting obligations in the event of a problem with the devices remaining in the field.

NOTIFICATIONS OF INTENT FOR LIFE-SUPPORTING/LIFE-SUSTAINING DEVICES

Finally, for manufacturers of certain life-supporting or life-sustaining devices, FDA requests the submission of information regarding the manufacturer's plans for the device after the end of the relevant EUA or Enforcement Policy. Section V.A of the EUA Transition Draft Guidance and Section V.C.1 of the Enforcement Policy Transition Draft Guidance each contain a table listing the product codes that fall within the scope of this request. For devices in those product codes that are marketed under an EUA—including an umbrella EUA—or an FDA Enforcement Policy, FDA requests that manufacturers inform FDA whether they plan (i) to submit a marketing submission or (ii) to discontinue distribution of the device. If a manufacturer plans to discontinue distribution of a device, FDA requests information about the manufacturer's plan to comply with the requirements listed above regarding modification of devices in the field and their labeling. These notifications should be sent to FDA soon after the draft guidances are finalized and the transition periods start.

KEY TAKEAWAYS

Although the new guidances are still in draft form, both documents help to reduce the uncertainty surrounding the continued use and distribution of new and modified devices intended to diagnose, treat, or prevent COVID-19 that came to market under CDRH-issued EUAs and FDA Enforcement Policies. We expect that the final guidance documents will largely preserve the key policy points of the EUA Transition Draft Guidance and Enforcement Policy Transition Draft Guidance. The key takeaways—and remaining uncertainties—include:

- FDA is likely to provide at least 180 days' notice before ending the EUAs and FDA Enforcement Policies that are currently in effect (though, we note, public health demands may result in earlier terminations, as occurred in the June and July 2021 revocations of EUAs for non-NIOSH-approved respirators and decontamination systems for respirators).
- If manufacturers elect to discontinue the distribution of an EUA or FDA Enforcement Policy device, then FDA will not require removal of the devices from the field provided that certain relabeling or reconditioning steps are taken.
- If manufacturers seek to continue distribution of EUA or FDA Enforcement Policy devices and submit a marketing submission that FDA accepts prior to the end of the 180-day transition period, then FDA will exercise enforcement discretion to permit continued distribution of the devices while the submission is pending with the Agency. To the extent that other regulatory requirements (e.g., MDR reporting, reports of corrections and removals, registration and listing, or the Quality System Regulation) were waived under the EUA or FDA Enforcement Policy, those requirements will apply in full while the marketing submission is pending.
- Whether and how FDA might apply lessened data requirements for the clearance or approval of devices that have strong real-world data from use during the pandemic remains to be seen.
- If FDA denies a marketing submission, or if the cleared or approved device differs from the devices distributed pursuant to an EUA or Enforcement Discretion Policy, the Agency may request a recall of previously distributed devices.
- Manufacturers may want to begin their transition planning now to ensure that there is enough time—including time to potentially receive Pre-Submission feedback from FDA—to submit a 510(k), De Novo, or PMA, and pass the RTA phase, within the deadline to receive enforcement discretion for uninterrupted distribution.

As noted, FDA is accepting comments on the draft guidance documents until March 23, 2022. Please let us know if we can be of help in assisting your firm in commenting on the draft guidance documents or preparing to transition your EUA or FDA Enforcement Policy devices.

[1] Jeff Shuren & William Maisel, *Looking Ahead to 2022 as FDA's Center for Devices and Radiological Health Manages a Sustained Increase in Workload* (Dec. 21, 2021), https://www.fda.gov/news-events/fda-voices/looking-ahead-2022-fdas-center-devices-and-radiological-health-manages-sustained-increase-workload.