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Transition Plan for Medical Devices that fall within enforcement policies and EUAs issued during the COVID-19 Public Health Emergency

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About MEDIcept

MEDIcept strives to provide our clients with proven, trusted, and cost-effective solutions. We are an international consulting firm specializing in medical device, IVD, combination product, and biotechnology Regulatory, Quality, Clinical, Auditing, and Educational Services. Since 1996, we have worked with thousands of companies to solve their most critical FDA, global regulatory authority, and ISO issues. Our integrated solutions are rooted in our direct experience and span all stages of the product life.

Our staff includes former FDA and Notified Body personnel and industry experts with an in-depth functional knowledge of medical devices, IVDs, combination products, and biotechnology. Compliance requires the navigation of a complex maze of requirements. MEDIcept can provide state-of-the-art interpretation of those regulations, guidance documents, and standards and provides our clients with the information they need to comply safely and cost-effectively.

We use our expertise to quickly identify the root cause, coalesce corrective actions, and provide easy to understand structured solutions or recommended improvements. Since we know corrective action implementation is where many projects fail, we do not just write an action list. We make sure all stakeholders understand why the solutions were chosen and why they are needed. We work hand-in-hand with clients to implement the solutions, so the solutions have been culturally absorbed when the project is done.

MEDIcept is committed to providing our clients with what they need. We are committed to quality deliverables because we value our clients' time and resources. This is why 90% of our clients come back to us repeatedly to solve new issues and recommend us to their colleagues.

Transition Plan for Medical Devices that fall within enforcement policies and EUAs issued during the COVID-19 Public Health Emergency

EXECUTIVE SUMMARY

FDA has provided their thoughts on 180-day transition plans to get back to standard practices (compliance with the Federal Food, Drug, and Cosmetic Act and regulatory requirements) for medical devices issued Emergency Use Authorizations (EUAs) or that fall within Enforcement Policies issued during the Coronavirus Disease 2019 (COVID-19) Public Health Emergency. FDA will tell industry 180 days in advance of the planned termination of Emergency Used Authorizations or withdrawal of the enforcement policies. Manufacturers with devices placed on the market under the COVID-19-related enforcement policies or COVID-19 EUA declarations need to start planning for and working on the relevant submissions to FDA ***now***, especially if they intend to continue distribution of their device(s).

INTRODUCTION

The FDA has proposed a transition plan for medical devices issued Emergency Use Authorizations (EUAs) or that fall within Enforcement Policies issued during the Coronavirus Disease 2019 (COVID-19) Public Health Emergency. The transition plans are described in two draft FDA guidances. The FDA had these guidances open for comment through March 23, 2022, and they are now being finalized.

1. Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, and
2. Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency.

PROBLEM DEFINITION

Manufacturers of EUA devices and/or devices that fall within enforcement policies will be given 180 days' notice of termination of each EUA declaration and withdrawal of the enforcement policies.

Manufacturers who intend to continue to distribute their devices after the EUA termination date or withdrawal of the enforcement policy guidance will need to comply with the applicable sections of the Code of Federal Regulations, such as the Quality System Regulation, good manufacturing practices, and labeling requirements including UDI, and will need to submit the appropriate regulatory submission, such as a 510(k).

HIGH-LEVEL SOLUTION

Per the FDA Guidance on EUAs, FDA recommends "manufacturers submit their marketing submissions to FDA with sufficient time for the submission to be accepted by FDA before the EUA termination date." Per the FDA Guidance on Enforcement Policies, FDA has outlined a three-phase approach over the course of 180 days "to help facilitate a smooth and consistent transition back to normal operations."

SOLUTION DETAILS

For devices with Emergency Use Authorizations, these devices will no longer be authorized for emergency use beginning on the EUA termination date. FDA will provide 180 days' advance notice of each EUA declaration termination. The transition plan for devices that have EUAs is noted in ***Table 1.***

For devices that fall within the Enforcement Policies, medical device manufacturers have 180 days from the date the COVID-19 section 319 Public Health Emergency expires (aka the implementation date) to transition to normal operations. The three phases as outlined in the FDA Guidance for Medical Devices That Fall Within Enforcement Policies are outlined in ***Table 2.***

SUMMARY

FDA has provided their thoughts on transition plans for medical devices issued Emergency Use Authorizations (EUAs) or that fall within Enforcement Policies issued during the Coronavirus Disease 2019 (COVID-19) Public Health Emergency and will provide 180 days' notice for manufacturers to transition. This advance notice and detailed expectations should help avoid disruption in device supply and ensure that devices authorized under the EUA or fall within enforcement policies meet the applicable FD&C Act requirements after termination of the relevant COVID-19 EUA declaration or cessation of the COVID-19-related enforcement policies.

Table 1 - Transition plan for devices with EUAs

Scenario	Actions
"Notifications of Intent" for Certain Reusable Life-Supporting or Life-Sustaining Devices	• FDA recommends that manufacturers of EUA-authorized devices with the product codes listed below submit to FDA information regarding whether or not they intend to submit a marketing submission to continue distributing their product after the EUA termination date: BSZ BTL BTT CAW CBK MNS MNT NOU ONZ QAV QOO • If the manufacturer is not planning to submit a marketing submission, the manufacturer should discuss its plans to discontinue distribution of the device, to restore the device to a previously FDA-cleared or approved version, to provide updated labeling and any other efforts to address or mitigate potential risks of devices that remain distributed after the EUA termination date
Marketing Submission for devices distributed after the EUA termination date	• Submit marketing submission to FDA with sufficient time for it to be accepted by FDA before the EUA termination date • Comply with all applicable regulatory requirements, including but not limited to the applicable marketing submission requirements, Quality System Regulation under 21 CFR Part 820, adverse event reporting requirements under 21 CFR Part 803, registration and listing under 21 CFR Part 807 Subparts B-D, and Unique Device Identification under 21 CFR Part 801 Subpart B and 221 CFR Part 830 • Include a Transition Implementation Plan that addresses the manufacturers' plans for both dealing with devices already distributed in the case of a positive decision or in the case of a negative decision on the marketing submission • FDA does not intend to object to the continued distribution of devices within the scope of the Guidance for EUA devices after the EUA termination date where: o the manufacturer has submitted a marketing submission to FDA and had it accepted by FDA before the EUA termination date; and o FDA has not taken a final action on the marketing submission
No intention to continue to distribute the device after the EUA termination date	FDA generally does not intend to request market removal of already distributed devices as follows: • Single use, non-life supporting/non-life sustaining devices (e.g., face masks) that were distributed before the EUA termination date and are consumed by the end user • Reusable, non-life supporting/non-life sustaining devices (e.g., remote patient monitoring devices) that were distributed before the EUA termination date and are used by their end user. Such devices should either: o Be restored by the manufacturer to the previously FDA-cleared or approved version, or o Have publicly available labeling that accurately describes the product features and that the product lacks FDA clearance or approval • Reusable life-supporting/life-sustaining devices (e.g., ventilators, extracorporeal membrane oxygenation systems, continuous renal replacement therapy systems) that were distributed before the EUA termination date remain distributed. Such devices should either: o Be restored by the manufacturer to the previously FDA-cleared or approved version of the device, or o Have publicly available labeling that accurately describes the product features and that the product lacks FDA clearance or approval • In vitro diagnostic devices that were distributed before the EUA termination date remain distributed and are used for no more than 2 years after the EUA termination date or until the expiration date, whichever is less
Discontinuing distribution	FDA expects manufacturers to discontinue distribution of a device within the scope of the Guidance for EUA devices: • On the EUA termination date, if the manufacturer has not submitted a marketing submission 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 response to an FDA request for additional information

Table 2 - Phases as outlined in the FDA Guidance

Scenario	Actions
Intention to continue to distribute the device after the Public Health Emergency expires	Phase 1: Implementation Date (Day 0) • If not already doing so, follow adverse event reporting requirements under 21 CFR Part 803 • Begin to prepare their marketing submissions, if applicable
	Phase 2: 90 days after the Implementation Date • For manufacturers that intend to continue to distribute their devices, register their establishment and list their device(s) under 21 CFR Part 807 Subparts B-D. Manufacturers should also submit reports of corrections and removals consistent with 21 CFR Part 806 • Manufacturers of devices under the product codes BSZ, BTL, BTT, CAW, CBK, MNS, MNT, NOU, ONZ or QAV should send a Notification of Intent to the CDRH Document Control Center at FDA • Prepare to submit a marketing submission to FDA and have it accepted by FDA before the start of Phase 3
	Phase 3: 180 days after the Implementation Date • Before the start of Phase 3, if manufacturers submit a marketing submission(s), and that submission is accepted by FDA, FDA will allow for continued distribution of the device after the withdrawal of the guidances as long as the submission is still under review. With the marketing submission, the manufacturer should include a "transition implementation plan" that addresses the manufacturer's plans for devices already in distribution in the case of a positive decision or the plan for discontinuing distribution in the case of a negative decision on the marketing submission • FDA does not intend to object to the continued distribution of devices as long as the manufacturer has submitted a marketing submission to FDA and had it accepted by FDA before the start of Phase 3 and FDA has not taken a final action on the marketing submission. However, the manufacturer is expected to comply with all other applicable statutory and regulatory requirements (such as registration and listing, QS requirements, and reports of corrections and removals required under 21 CFR Parts 807, 820, and 806) • FDA expects distribution to cease if the manufacturer does not submit a required marketing submission and had it accepted by FDA before the beginning of Phase 3, 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 response to an FDA request for additional information within the allotted time identified in FDA's letter
No intention to continue to distribute the device after the Public Health Emergency expires	Prior to the start of Phase 3: • Manufacturer ceases distributing devices and notifies users that the product does not have FDA clearance or approval and that they will not be pursuing FDA clearance or approval • Manufacturer continues to report adverse events
	At start of Phase 3 (180 days after the Implementation date): • Manufacturer can leave previously distributed devices in the field but makes revised labeling publicly available that describes all the product features, and that the product is not FDA-cleared or approved for marketing • Manufacturer sends notice to users stating that the product is not FDA-cleared or approved • Manufacturer continues to report adverse events

CALL TO ACTION

Manufacturers with devices placed on the market under the COVID-19-related enforcement policies or COVID-19 EUA declarations need to start planning for and working on the relevant submissions to FDA ***now***, especially if they intend to continue distribution of their device(s). The submissions must be accepted by FDA prior to the EUA termination date or within 180 days of the implementation date.

FDA has 15 calendar days after receipt of the submission to refuse to accept it if the submission is not administratively complete. Manufacturers will need time to address the missing information and FDA then has another 15 calendar days from the receipt of the new information to conduct the acceptance review. Manufacturers need to account for this and submit to FDA early enough to have their submission accepted prior to the EUA termination date or within 180 days of the implementation date.

Guidance Document Links

1. Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency - *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-issued-emergency-use-authorizations-euas-during-coronavirus-disease.*
2. Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency - *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-fall-within-enforcement-policies-issued-during-coronavirus-disease.*