COVID-19 Transition Policy Draft Guidances for Devices

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Draft Guidances

- **Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID - 19) Public Health Emergency** www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-issued-emergency-use-authorizations-euas-during-coronavirus-disease.

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

- Referred to as “Transition Guidances” in this presentation

Learning Objectives

- ✓ Describe background of COVID - 19 public health emergency (PHE) that relates to these draft guidances.
- ✓ Review scope of draft guidances, including proposed timeframes for FDA and stakeholder actions
- ✓ Identify resources for additional information and engagement with FDA

Background

Questions addressed by the guidances:

- Why is the FDA issuing this guidance now, while the COVID-19 pandemic is ongoing?
- What are the actions I should take if I do or do not plan to distribute my devices after the relevant EUA declaration is terminated or the PHE expires?
- What are the important milestones that I should know about during the transition process?

The draft guidances are:

- Not for implementation
- Undergoing public comment review and resolution, prior to publishing the final guidances

Background

PHE and EUA declarations

- Declaration of a public health emergency by Secretary of HHS first on January 31, 2020, most recently renewed April 12, 2022
- Three EUA declarations in 2020 for in vitro diagnostics, respiratory protective devices, and for devices, including alternative products used as devices, under section 564 of Federal Food, Drug, and Cosmetic Act (FD&C Act)

EUAs

- FDA continues to review requests for and issue EUAs for devices
- An EUA remains in effect for the duration of the relevant EUA declaration, unless FDA chooses to revoke the EUA, applying the statutory criteria for revocation (section 564 of the FD&C Act)
- Over 900 EUAs have been issued

Enforcement policies

- The FDA issued multiple guidance documents describing enforcement policies to support the COVID-19 response
- These guidances state that they are intended to remain in effect only for the duration of the COVID-19 PHE

Background

Given the magnitude of the COVID-19 PHE, the FDA recognizes continued flexibility, while still providing necessary oversight, will be appropriate to facilitate an orderly and transparent transition back to normal operations

There are unique considerations presented by the COVID-19 PHE, including the manufacturing of devices by non-traditional manufacturers and use of capital or reusable equipment under an EUA

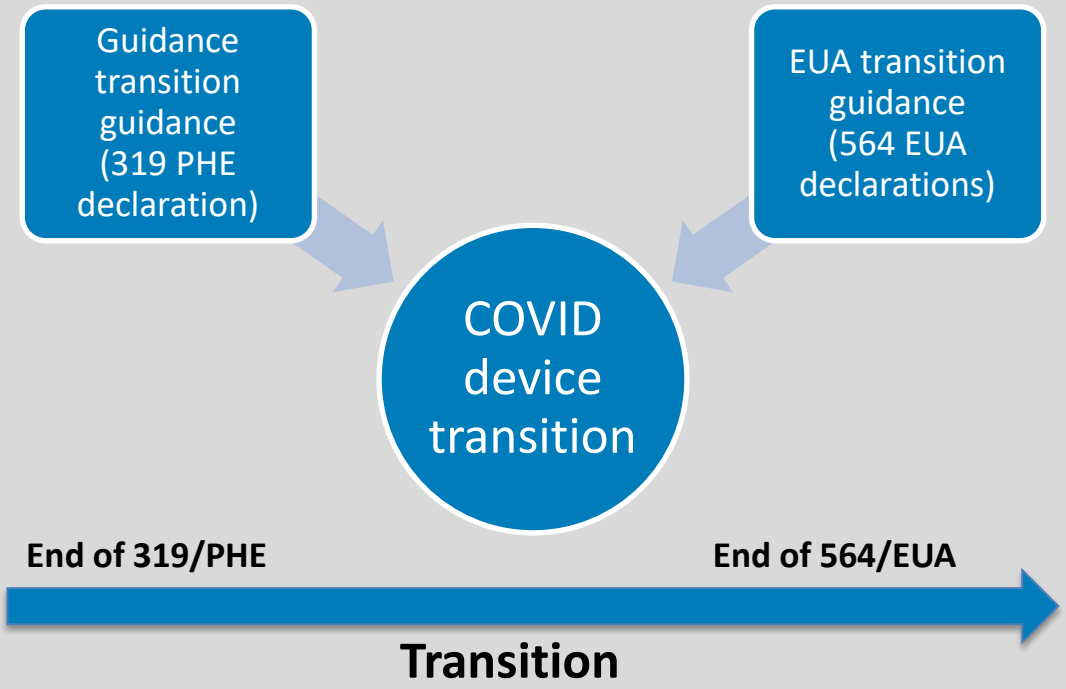
The FDA developed two guidances to describe transition plan to help avoid disruption in device supply and ensure that devices meet applicable requirements after a transition period

The FDA issued these draft guidances to obtain feedback from all interested stakeholders before we finalize these policies

Transition Guidances:
Scope and Timeframes

Transition is proposed in two companion guidance documents

- Introduction
- Background
- Scope
- Guiding principles
- Transition plan
- Examples



Scope

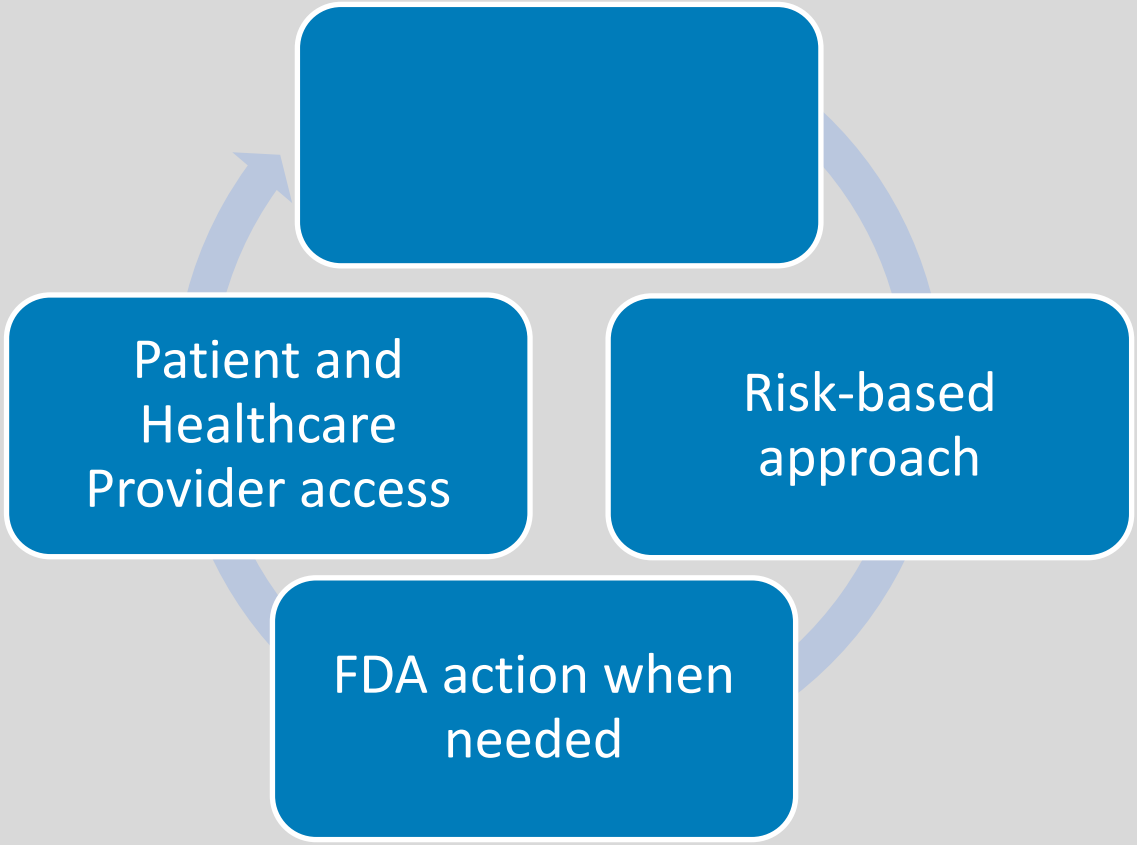
EUA transition guidance

- Devices with EUAs issued on the basis of a COVID-19 EUA declaration
- Does not apply to
  - Devices with EUAs that FDA chooses to revoke because the section 564(c) criteria are no longer met or because other circumstances make such revocation appropriate to protect the public health or safety
  - 564A current good manufacturing practice deviations

Guidance transition guidance

- Devices that fall within enforcement policies listed in guidance
- FDA may add or remove guidances from this list, as appropriate
- FDA intends to remove guidances from the list if they are withdrawn
- “Policy for Diagnostic Tests for COVID-19” guidance is outside scope

Guiding Principles



Transition is generally aligned across both guidances

Devices with issued EUAs

Devices that fall within enforcement policies

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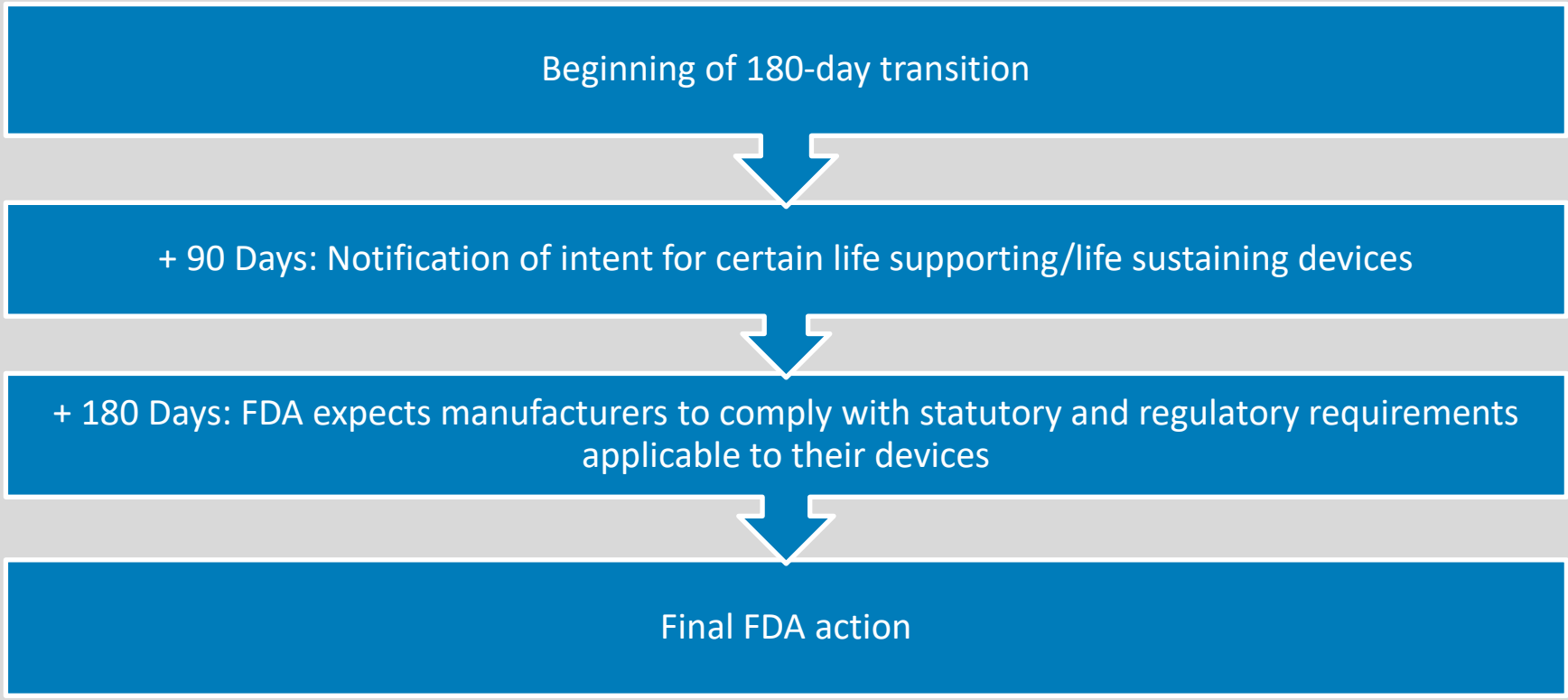
If guidance is finalized before PHE expiration, upon PHE expiration
If guidance is finalized after PHE expiration, announce a date in the guidance that is at least 45 days after the finalization of the guidance

Transition is generally aligned across both guidances



When distribution is not intended to continue beyond transition

SUDs, non LS/LS	• Remain distributed and consumed

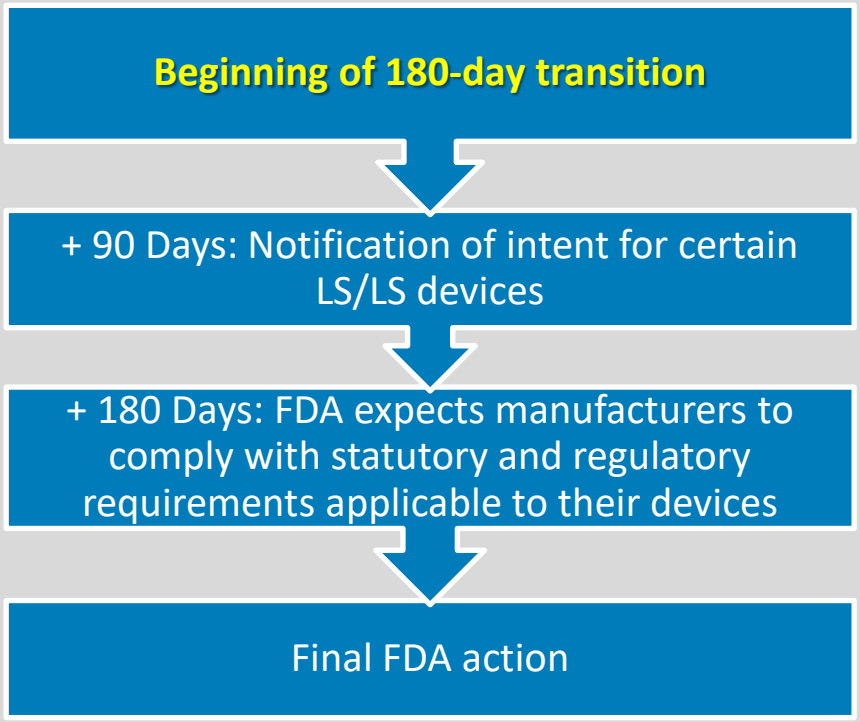
Reusable, non LS/LS	• Remain distributed and used if they are:
	  • Restored to cleared/approved version, **OR**
	  • Have labeling publicly available that describes features and that device lacks FDA clearance or approval

Reusable, LS/LS	• Remain distributed and used if they are:
	  • Restored to cleared/approved version, **OR**
	  • Have both publicly available and a physical copy of labeling that describes features and that device lacks FDA clearance or approval

IVDs under EUA	• Remain distributed for 2 years or until the expiration date, whichever is less

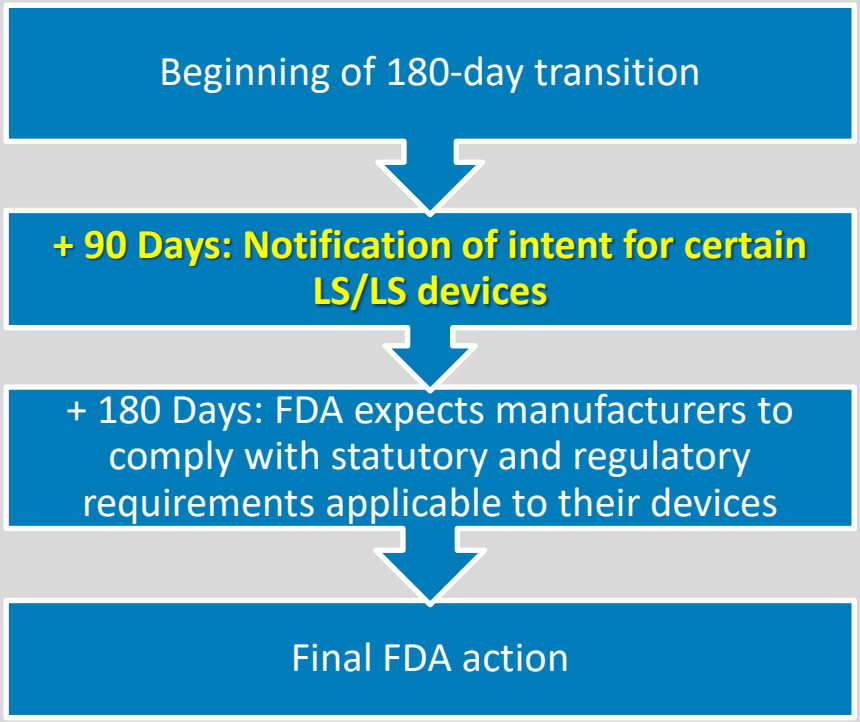
SUD = single-use device; LS/LS = life supporting/life sustaining; IVD = In Vitro Diagnostics

Actions recommended when transition begins



- Transition begins on the implementation date or date of advance notice of termination
- Manufacturers should submit any adverse event reports that were stored
- Manufacturers should begin to prepare marketing submissions if they intend to continue distribution after transition

Actions recommended within 90 days after transition begins



For devices that fall within applicable enforcement policies: Follow 21 CFR part 806 (reports of corrections and removals) and 807 Subparts B-D (registration and listing)

Notification of intent for certain life supporting and life sustaining devices

CFR = Code of Federal Regulations

FDA resource planning through notification of intent for certain devices

Device types

- List of product codes in guidances
- Ventilator and ventilator accessories, anesthesia gas machines, other respiratory devices
- Ultimately, final guidance will identify the product codes for which FDA is requesting this information

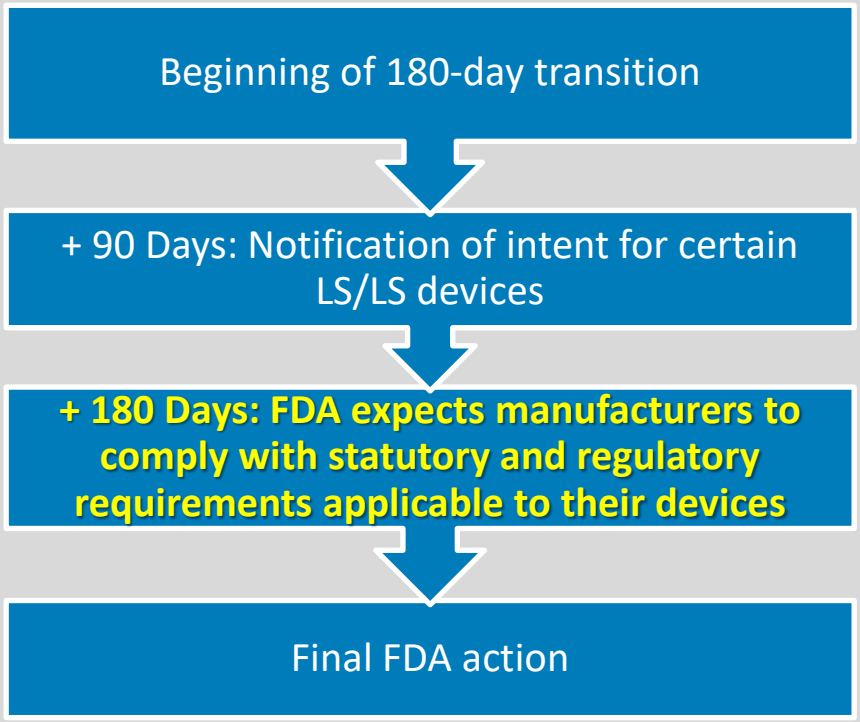
How and when to submit

- By 90 days after transition period begins
- Send to Document Control Center
- Cover letter should reference any FDA submission numbers

Information requested

- General info
- EUA and other submission numbers
- Model number(s)
- Future plans to submit marketing submission
- Future plans to discontinue distribution, restore or relabel, and other efforts to address or mitigate risk of distributed devices

Actions recommended within 180 days after transition begins



- EUA declarations are terminated and FDA withdraws enforcement policies
- Manufacturers must comply with all applicable requirements
- Marketing submissions should have already been submitted to and accepted by FDA, including a Transition Implementation Plan
  - Enforcement policy for marketing submissions during FDA review before final FDA action

Transition Implementation Plan will help guide consistent FDA-manufacturer interactions

Estimated number of devices in distribution

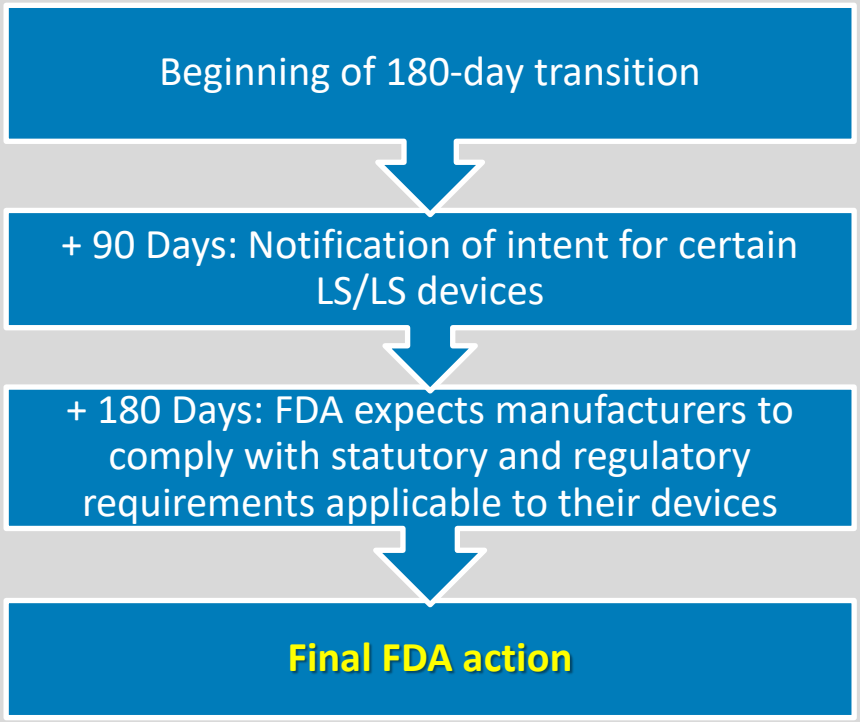
Benefit-risk based plan, in event of negative decision

- Estimated number of devices in distribution
- Benefit-risk based plan for disposition if negative decision
- Notification to stakeholders of regulatory status
- Process and timeline for restoring device or relabeling
- Maintenance plan

Explanation of plans for addressing already distributed product in event of positive decision

- Notification to stakeholders of regulatory status
- Process and timeline for relabeling or updates

FDA expects compliance with applicable requirements upon final FDA actions



FDA expects distribution to cease when:

- Marketing submission not accepted by +180 days
- Negative decision on marketing submission
- Marketing submission withdrawn or fails to provide complete response to a request for additional information

FDA may take regulatory action as appropriate to protect public health

Scenarios not addressed in the guidances: Please reach out to FDA to discuss

- Timeframes and actions described in guidance generally apply
- Manufacturers may wish to initiate discussions with FDA through the Q - Submission Program
- Manufacturers are expected to work toward submission of a marketing application on specific timeline
  - Note that FDA intends to help facilitate this

Example: Telethermographic system

A new telethermographic system that was not 510(k)-cleared and falls within the Enforcement Policy for Telethermographic Systems

Phase 1 (July 1)

- All manufacturers continue to comply with the requirements that were not addressed in the enforcement policy, regardless of whether they intend to distribute their devices beyond the COVID-19 PHE

Phase 2 (September 29)

- **Manufacturer who intends to distribute beyond PHE:**
  - Registers and lists and submits a marketing submission, which is accepted by the Agency
- **Manufacturer who does not intend to distribute beyond PHE:**
  - Ceases distribution during Phase 2 and notifies users of regulatory status
  - Continues to report adverse events

Phase 3 (December 28)

- Guidance document is withdrawn
- **Manufacturer who intends to distribute beyond PHE:** FDA does not intend to object to continued distribution until FDA takes a final action. Manufacturer receives an NSE decision after review and ceases distribution. FDA and manufacturer engage to address already-distributed devices
- **Manufacturer who does not intend to distribute beyond PHE:** Manufacturer leaves previously distributed devices in field and makes revised labeling publicly available, sends notices to users, and continues to report adverse events

Example: Continuous ventilator

A continuous ventilator was authorized under the umbrella EUA for ventilators

July 1

- Advance notice of termination of the relevant EUA declaration is published in the Federal Register

August 1

- Manufacturer submits a Notification of Intent to inform FDA that it does not intend to pursue a marketing authorization

January 1

- Relevant EUA declaration is terminated and the umbrella EUA is no longer in effect
- Manufacturer ceases distribution of the device
- FDA does not intend to object if the manufacturer develops a plan for the already distributed product to remain distributed

Resources

COVID-19 and Medical Devices: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/coronavirus-covid-19-and-medical-devices

COVID-19 EUAs for Medical Devices: https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices

Contacts for Medical Devices During the COVID-19 Pandemic: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/contacts-medical-devices-during-covid-19-pandemic

CDRH Division of Industry and Consumer Education (DICE): https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice

Summary

- FDA has proposed a transition plan for devices with issued EUAs or that fall within enforcement policies during the COVID-19 PHE
- FDA issued these guidances to obtain feedback from stakeholders while the COVID-19 PHE is ongoing
- The transition guidances identify actions and milestones to support FDA and stakeholders through a transparent and orderly transition
- FDA received feedback on the draft guidances from stakeholders to two public dockets, collected on March 23, 2022, and are reviewing the feedback prior to finalizing the guidances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