

# 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](http://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](http://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- Not for implementation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

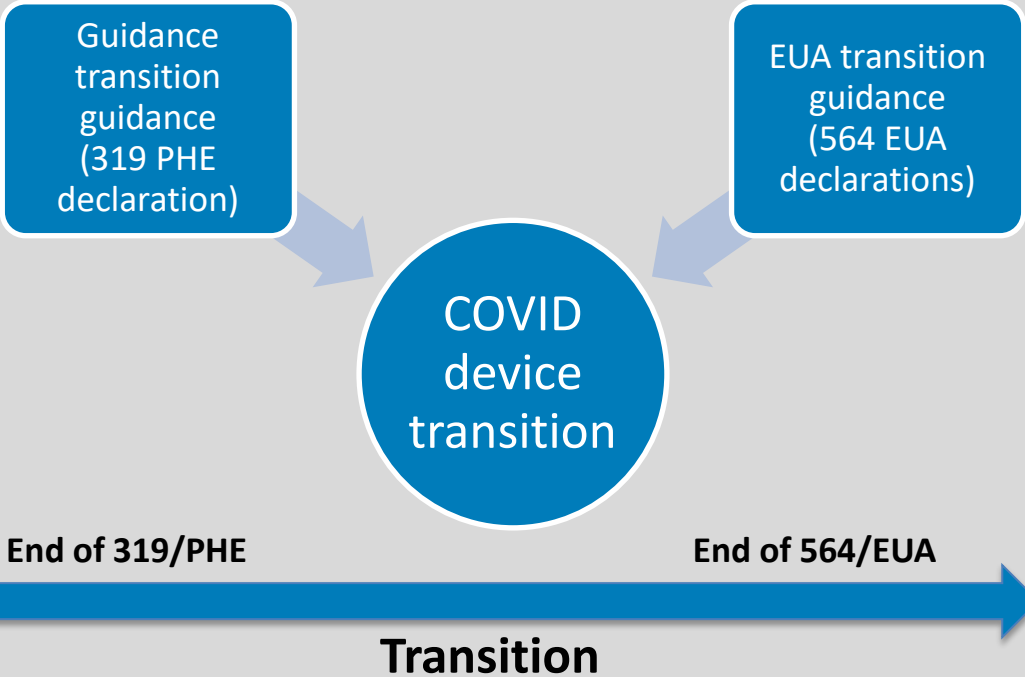
The FDA developed two guidances to describe transition plan to help avoid disruption in device supply and ensure that devices meet applicable requirements after a transition period

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



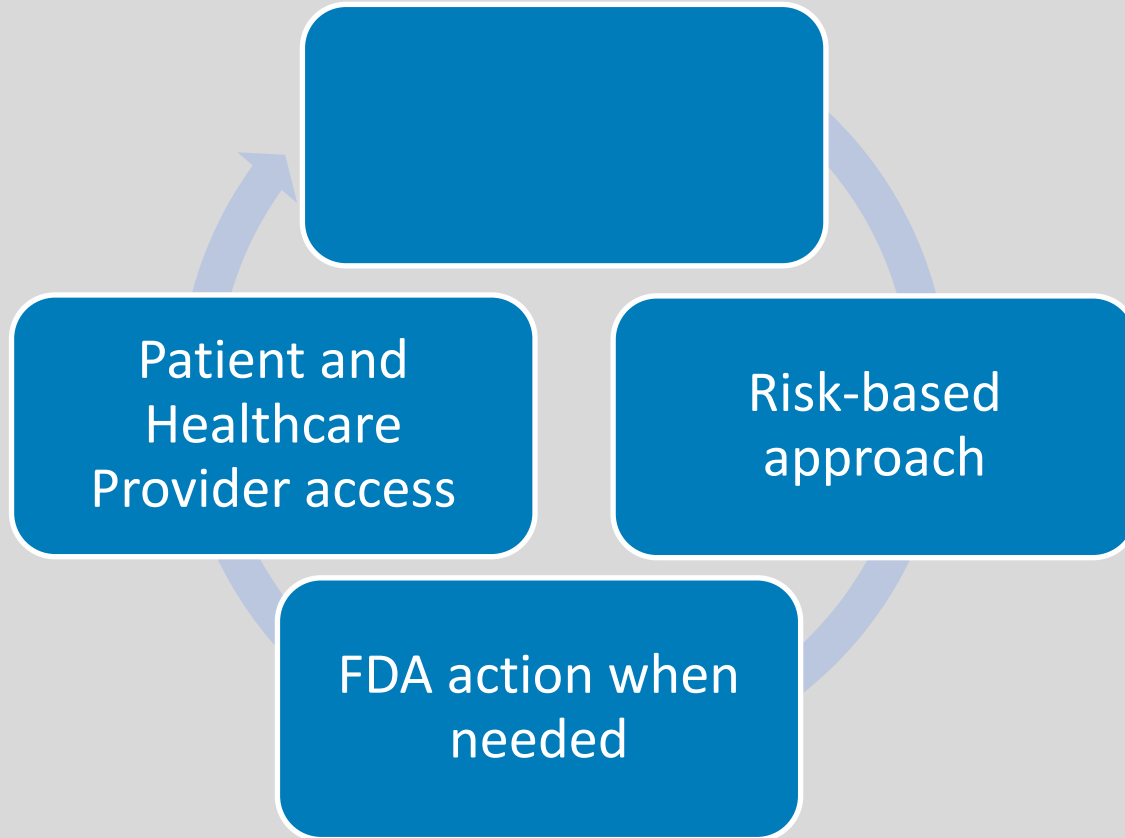
## EUA transition guidance

- 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

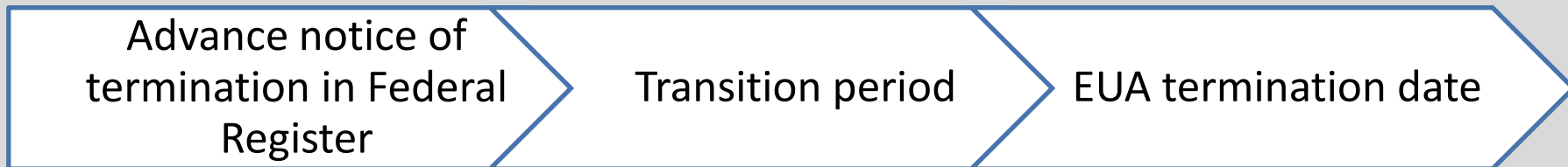
# Guiding Principles



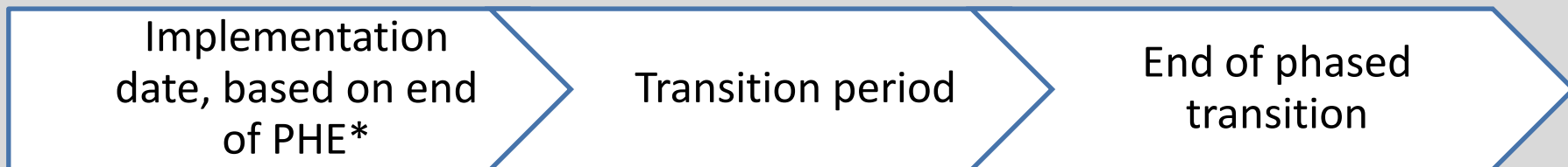
# Transition is generally aligned across both guidances



## Devices with issued EUAs



## Devices that fall within enforcement policies



\*

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



Beginning of 180-day transition



+ 90 Days: Notification of intent for certain life supporting/life sustaining devices



+ 180 Days: FDA expects manufacturers to comply with statutory and regulatory requirements applicable to their devices



Final FDA action

# 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

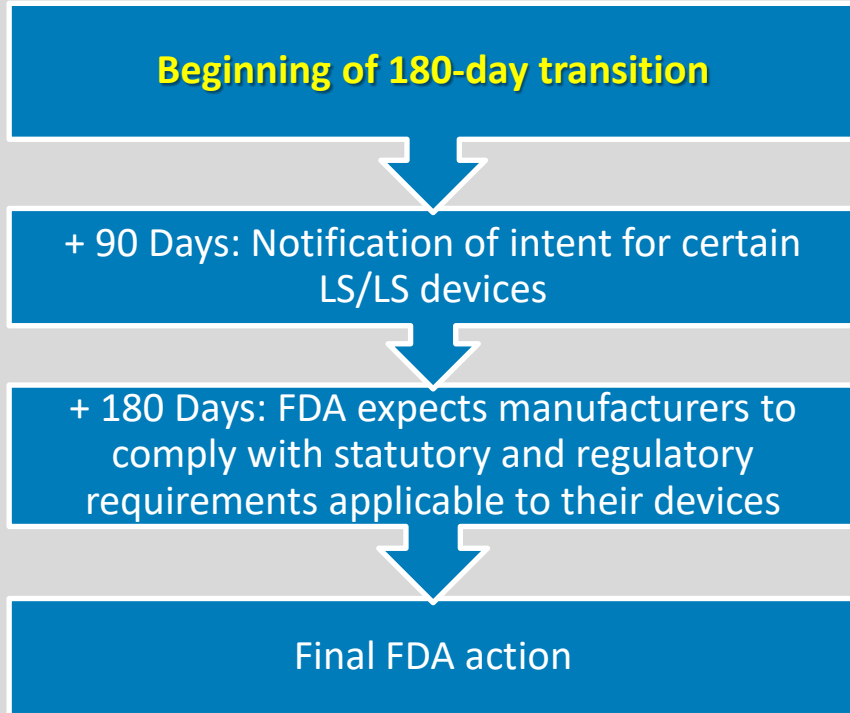
- Remain distributed and used if they are:
  - Restored to cleared/approved version, **OR**
  - Have both publicly available and a physical copy of labeling that describes features and that device lacks FDA clearance or approval

## 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

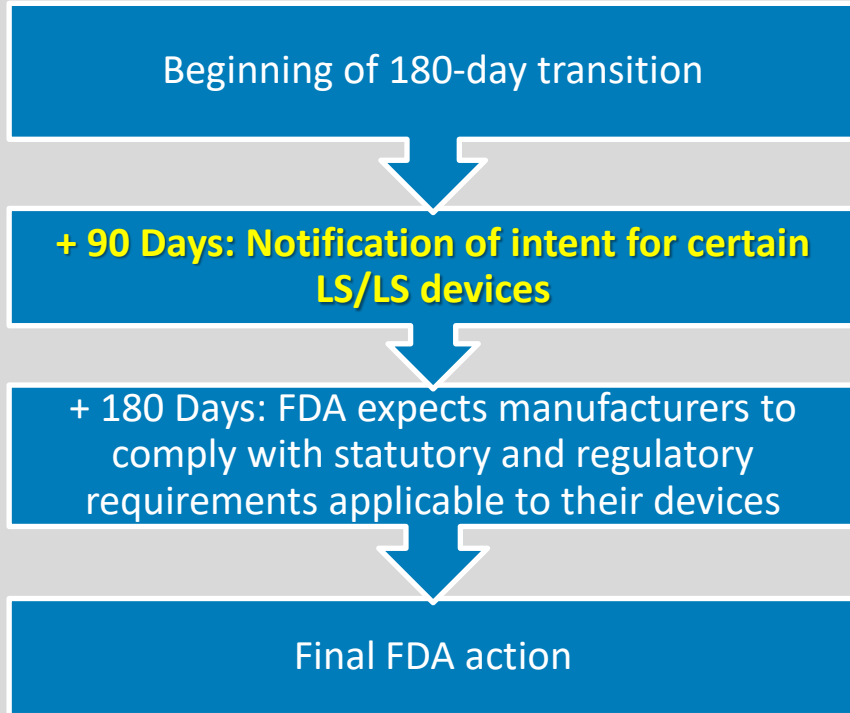


Transition begins on the implementation date or date of advance notice of termination

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

# 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

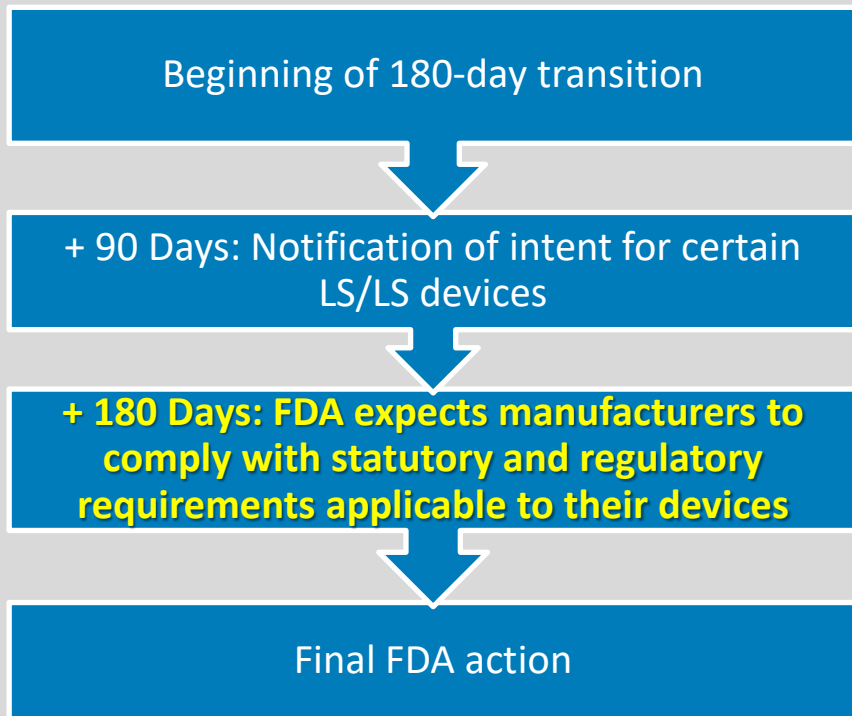
- By 90 days after transition period begins
- Send to Document Control Center
- Cover letter should reference any FDA submission numbers

## 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

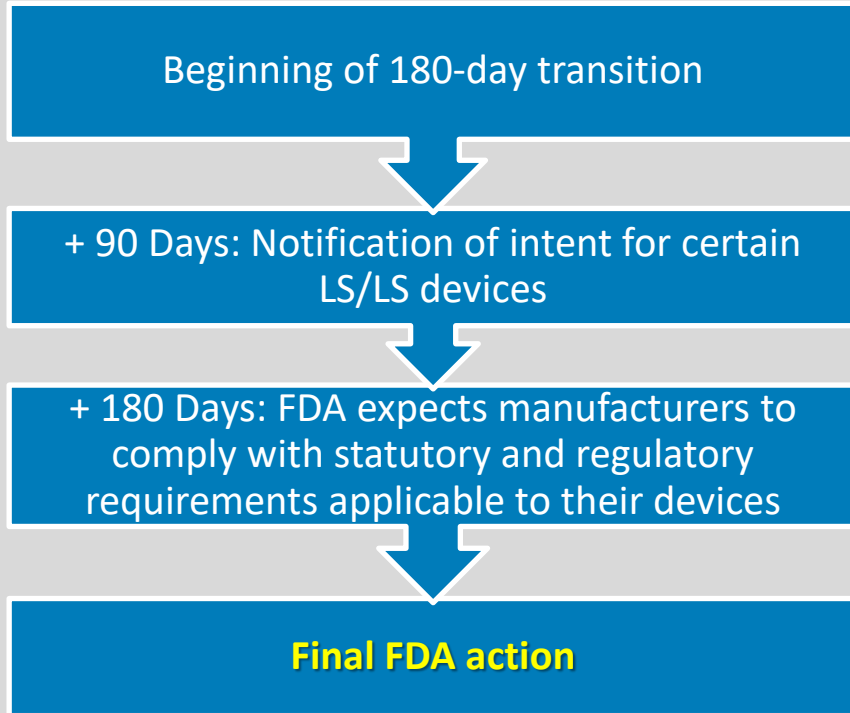
Benefit-risk based plan, in event of negative decision

- 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: 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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