U.S. FOOD & DRUG ADMINISTRATION

Welcome To Today's Webinar

Thanks for joining us!
We'll get started in a few minutes

Today's Topic:

Final Guidances on COVID-19 Transition Plans for:

(1) Medical Devices That Fall within Enforcement Policies Issued During the COVID-19 Public Health Emergency and
(2) Medical Devices Issued Emergency Use Authorizations Related to COVID-19

April 18, 2023

COVID-19 Transition Plans for Devices

Kathryn Drzewiecki, PhD
Policy Advisor
Office of Policy

Melissa View, JD
Regulatory Policy Analyst
Office of Policy

Center for Devices and Radiological Health
U.S. Food and Drug Administration

Kathryn Drzewiecki, PhD
Policy Advisor
Office of Policy

Final Guidances

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

- **Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19)**
  - **Referred to as "EUA Transition Guidance"**
  - **www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-issued-emergency-use-authorizations-euas-related-coronavirus-disease**

- Collectively referred to as "COVID-19 Transition Guidances" in this presentation

Learning Objectives

- Describe background of COVID-19 public health emergency declarations that relate to these final guidances
- Provide a summary of comments received and changes made to draft guidances
- Review scope of final guidances, including timeframes for FDA and stakeholder actions

Background

Background

PHE and EUA declarations

- Declaration of PHE under section 319 of the PHS Act by HHS on January 31, 2020; most recently renewed February 11, 2023; PHE expires on May 11, 2023
- Determination and declarations under section 564 of the FD&C Act remain in effect
- Three EUA declarations in 2020: certain in vitro diagnostics; respiratory protective devices; and devices, including alternative products used as devices

EUAs

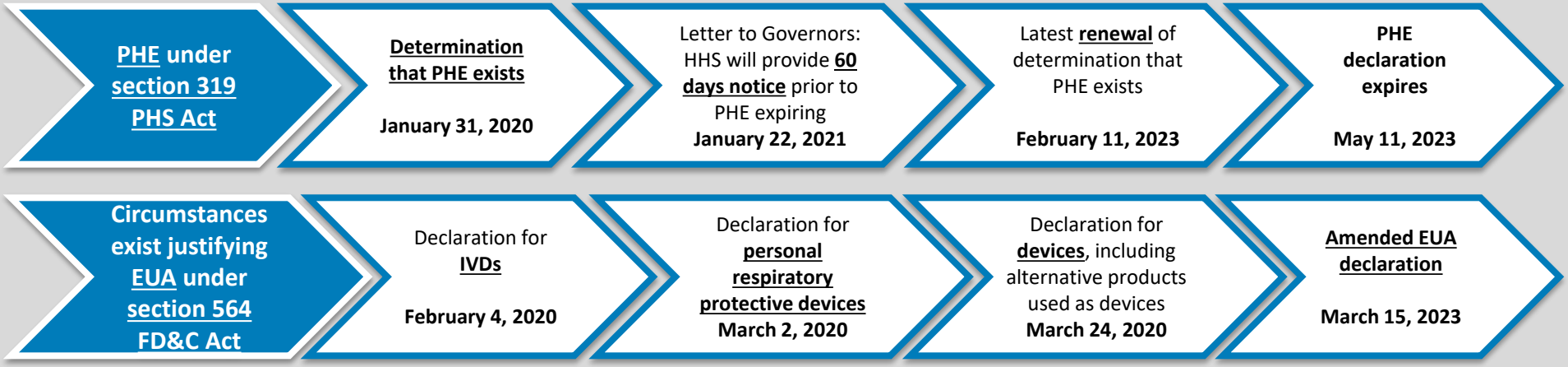
- Over 950 EUAs have been issued for COVID-19-related medical devices
- An EUA remains in effect for the duration of the relevant EUA declaration, unless revoked by FDA

Enforcement policies

- FDA issued 28 guidance documents describing enforcement policies to support the COVID-19 response
- Guidances within the scope of the Enforcement Policies Transition Guidance (“List 1”, 15/28) originally stated that were intended to remain in effect only for the duration of the COVID-19 PHE; now, the guidances in List 1 state that they are intended to continue in effect for 180 days after the section 319 PHE declaration expires

Public Health Emergency (PHE)
Public Health Service Act (PHS Act)
Federal Food, Drug, and Cosmetic Act (FD&C Act)
Emergency Use Authorization (EUA)

Background



- Determination under section 319 of the PHS Act does not enable FDA to issue EUAs
- EUA declaration under section 564 of the FD&C Act is distinct from and not dependent on PHE declaration under section 319 of the PHS Act
- An EUA may remain in effect beyond duration of the declared PHE
- An EUA remains in effect for the duration of the relevant EUA declaration, unless FDA revokes the EUA, applying the statutory criteria for revocation (section 564 of the FD&C Act)

EUA termination:
HHS intends to publish the advance notice of termination of each EUA declaration pertaining to devices in the Federal Register 180 days before the day on which the EUA declaration is terminated

Background

Questions addressed by the COVID-19 Transition Guidances:

- Why is FDA issuing these guidances now?
- What actions should I take if I do or don't plan to distribute my device after the transition period and the relevant enforcement policy is no longer in effect or the relevant EUA declaration terminates?
- What important milestones should I know about during the transition process?

Background

Given the magnitude of the COVID-19 pandemic, FDA recognizes it will take time for stakeholders to adjust from policies adopted and operations implemented during the COVID-19 pandemic to normal operations

There were many unique considerations presented by the COVID-19 pandemic, including manufacturing of devices by non-traditional manufacturers and distribution and use of capital or reusable equipment

FDA developed the COVID-19 Transition Guidances to provide stakeholders with recommendations and an appropriate transition period to ensure an orderly and transparent transition to normal operations

The approach described in the COVID-19 Transition Guidances is expected to help ensure that devices meet applicable requirements after the transition period and help avoid disruptions in device supply

Summary of Comments Received and Changes to COVID-19 Transition Guidances

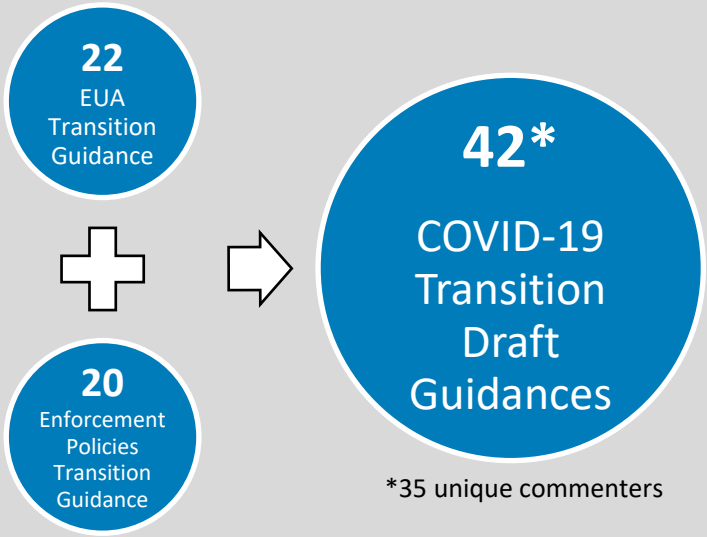
Summary of Comments Received

Comments on both COVID-19 Transition Guidances:

- Requested clarifications regarding "publicly available" labeling and devices considered "already distributed"
- Suggested inclusion of reference to the use of real-world evidence in marketing submissions
- Feedback regarding unique device identification implementation
- Requested that stakeholders are made aware of manufacturers' plans for the transition

Comments on Enforcement Policies Transition Guidance:

- Transition timeline extension



*35 unique commenters

Comments on EUA Transition Guidance:

- Suggested removal of the recommendations for interim labeling
- Requested clarification regarding policies for IVDs, including application of CLIA, dual submissions, and LDTs

In vitro diagnostics (IVDs)
Clinical Laboratory Improvement Amendments (CLIA)
Laboratory developed tests (LDTs)

Summary of Changes from Draft to Final

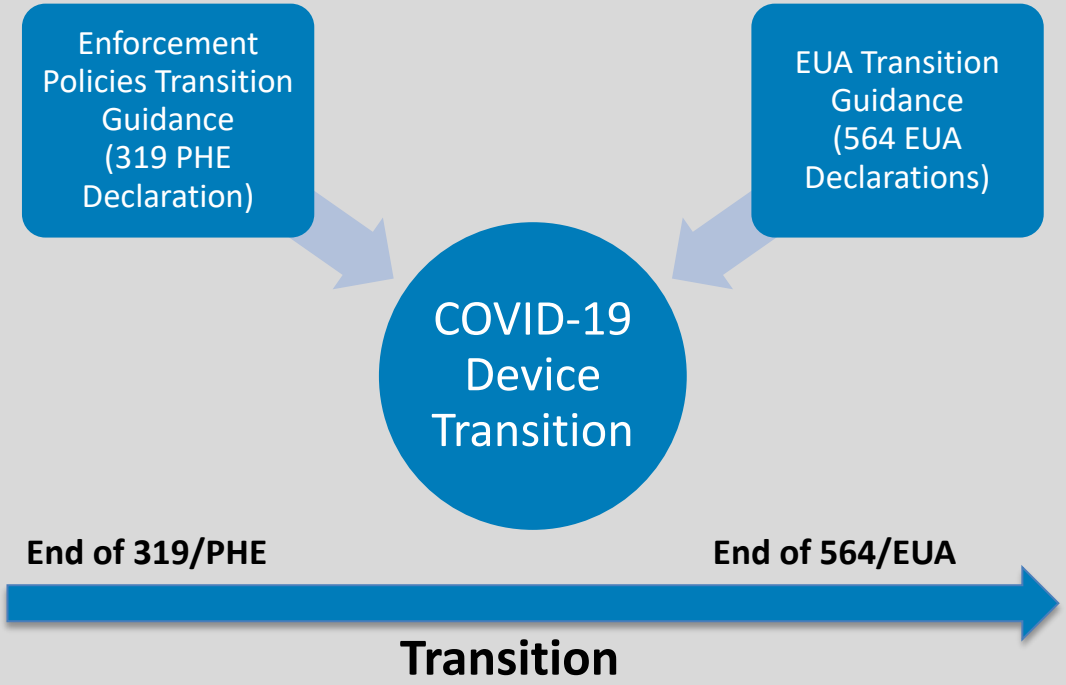
- **Revised labeling recommendations:**
  - Updated labeling can be provided as ***either a physical copy or an electronic copy*** (stakeholders may request a physical copy of updated labeling for reusable, life-supporting/life-sustaining devices)
  - ***Removed recommendation for interim labeling*** (EUA Transition Guidance)
  - Provides ***enforcement policy*** that while the device marketing submission is under FDA review, FDA does not intend to object if devices continue to be labeled as previously authorized under the EUA or as described in the relevant List 1 guidance
- **Additional clarity on many topics, including:**
  - ***Devices considered to be "already distributed"***
  - ***Real-world data,*** which may have been obtained as a result of device use during the COVID-19 pandemic, may be submitted in support of a marketing submission
  - ***IVDs, including CLIA and LDTs***
- **Recommendations for stakeholder collaboration regarding transition planning**
- **Additional explanation and examples to clarify these policies**

COVID-19 Transition Guidances: Scope and Timeframes

Melissa View, JD
Regulatory Policy Analyst
Office of Policy

Transition period in the COVID-19 Transition Guidances

- Introduction
- Background
- Scope
- Guiding Principles
- Transition Plan
- Examples



Scope

Enforcement Policies Transition Guidance

- Devices that fall within enforcement policies within scope of guidance identified in “List 1” (See Appendix)
- Does not apply to:

Guidance	URL
Policy for COVID-19 Tests (Revised)	www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-revised
Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests (Revised)	www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-evaluating-impact-viral-mutations-covid-19-tests-revised
Enforcement Policy for the Quality Standards of the Mammography Quality Standards Act During the COVID-19 PHE	www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-quality-standards-mammography-quality-standards-act-during-covid-19-public-health
Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the COVID-19 PHE (Revised)	www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during
Enforcement Policy for Clinical Electronic Thermometers During the COVID-19 PHE	www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-clinical-electronic-thermometers-during-coronavirus-disease-2019-covid-19-public
Enforcement Policy for Face Masks and Barrier Face Coverings During the COVID-19 PHE	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-barrier-face-coverings-during-coronavirus-disease-covid-19-public

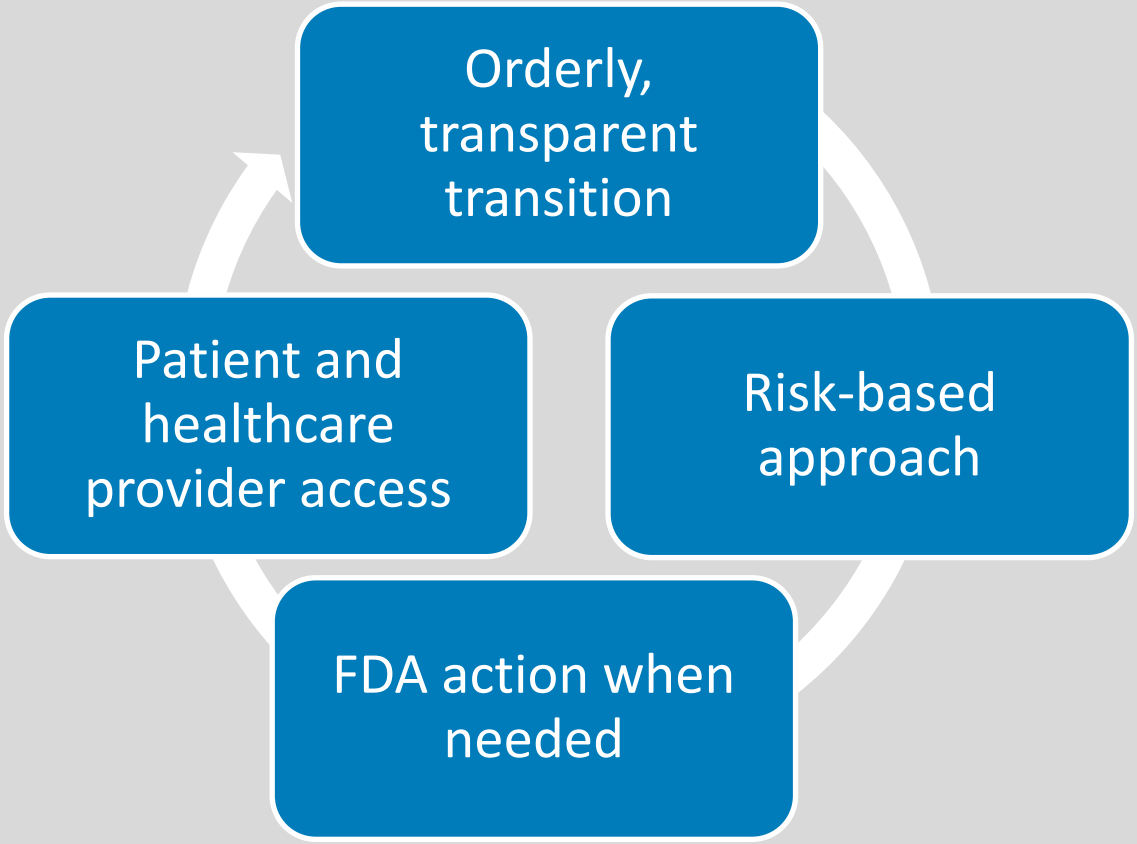
Scope

EUA Transition Guidance

- Devices issued an EUA under section 564 of the FD&C Act on the basis of a device EUA declaration related to COVID-19

- Does not apply to:
  - Devices with EUAs that FDA chooses to revoke because the criteria in section 564(c) of the FD&C Act are no longer met or because other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(B)-(C) of the FD&C Act)
  - Current good manufacturing practice deviations (section 564A(c) of the FD&C Act)

Guiding Principles



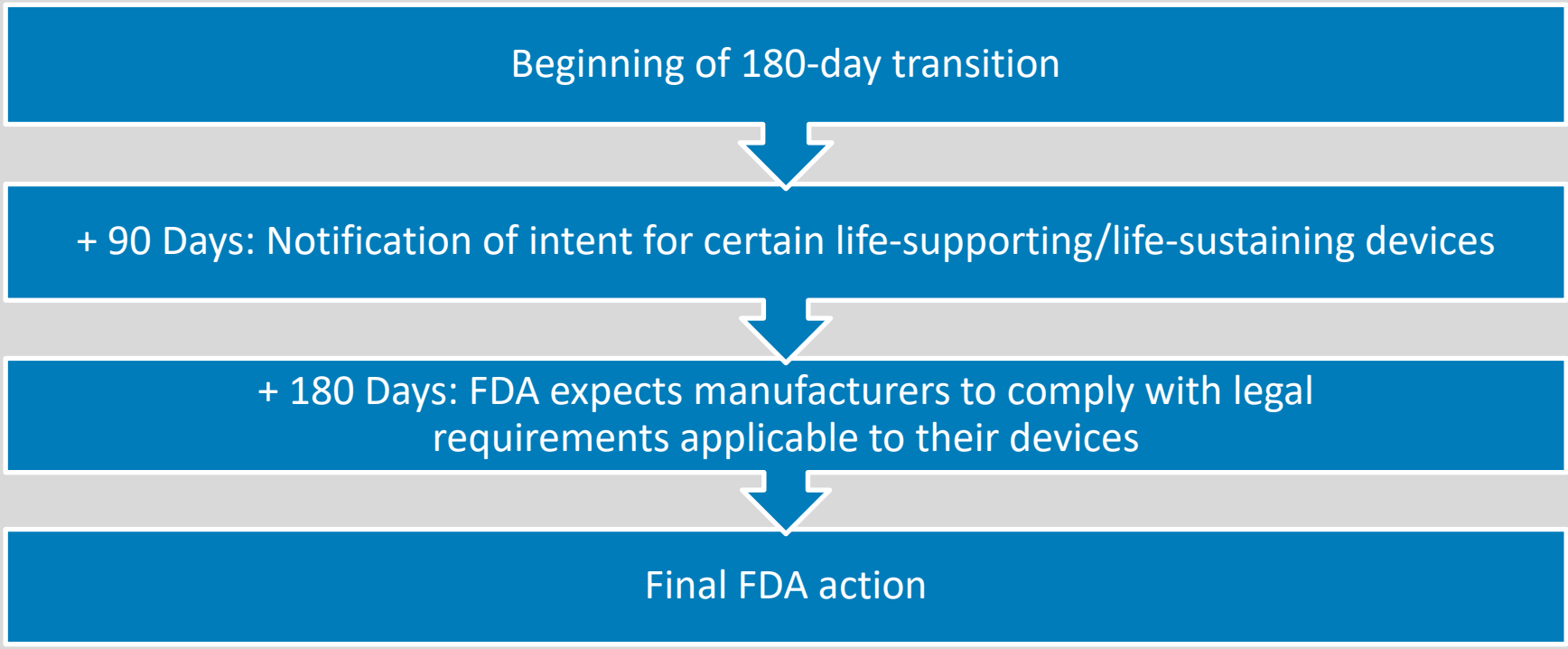
Transition is generally aligned across both guidances

Devices with issued EUAs

Devices that fall within enforcement policies

* The implementation date is the date the COVID-19 section 319 PHE declaration expires, which is **May 11, 2023**

Transition is generally aligned across both guidances



When distribution is not intended to continue beyond transition

For devices that were already distributed before the end of the transition (EUA termination date or end of Phase 2)

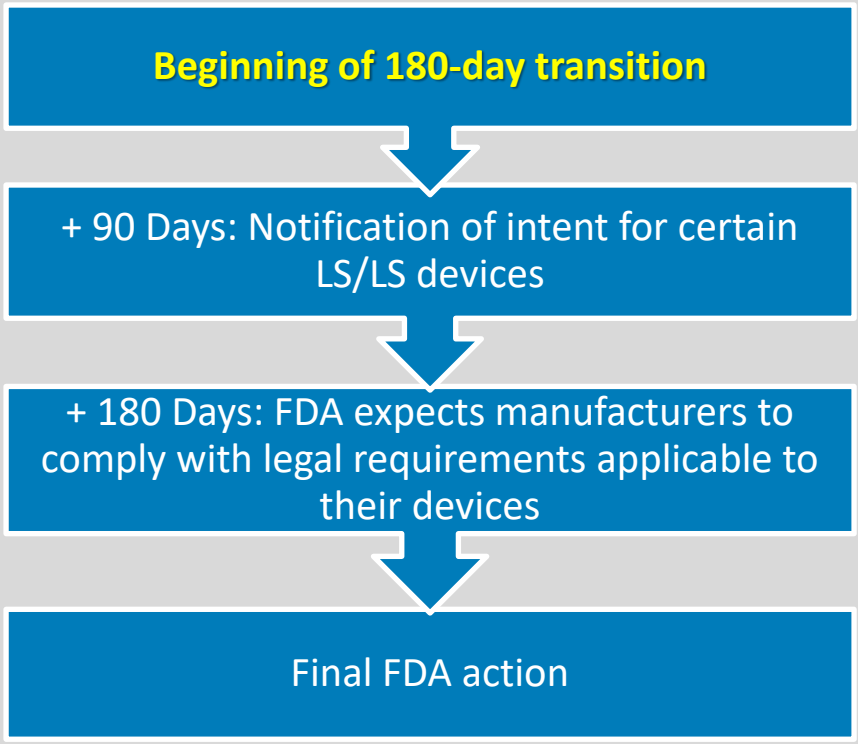
Single-use devices, non-LS/LS	• May be used by the end user prior to the product expiration date

Reusable, non-LS/LS	• May be used if they are:
	  • Restored to FDA-cleared/approved version, **OR**
	  • Have a physical and/or electronic copy of updated labeling that accurately describes the product features and states that device lacks FDA clearance, approval, or authorization

Reusable, LS/LS	• May be used if they are restored to FDA-cleared/approved version, **OR** • **If not restored**, a physical and/or electronic copy of updated labeling that accurately describes the product features and that device lacks FDA clearance, approval, or authorization should be provided, and **such devices are not used**

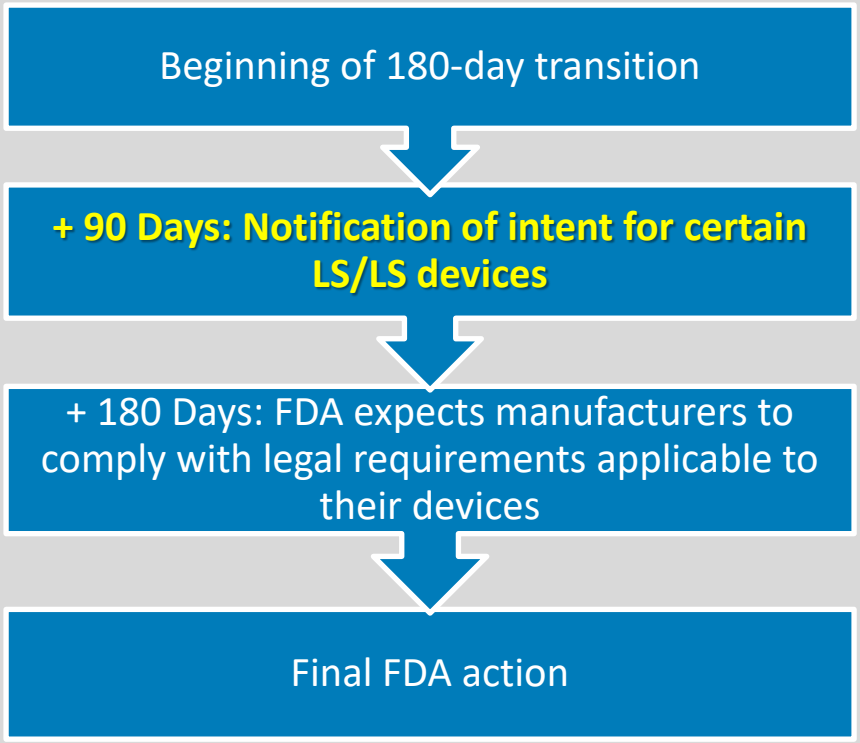
Life-supporting/life-sustaining (LS/LS)

Actions recommended when transition begins



- Transition begins on date of advance notice of termination / implementation date
- Manufacturers should **submit any adverse event reports (21 CFR 803)**
- Manufacturers should be **preparing 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 806** (reports of corrections and removals), **21 CFR 820** (Quality System requirements), and **21 CFR 807 Subparts B-D** (registration and listing)

Notification of intent for certain life-supporting/life-sustaining devices

Code of Federal Regulations (CFR)

FDA resource planning through Notification of Intent for certain devices

Device types

- List of procodes in guidances
- Ventilator and ventilator accessories, anesthesia gas machines, other respiratory devices
- Guidances identify product codes for which FDA is requesting this information

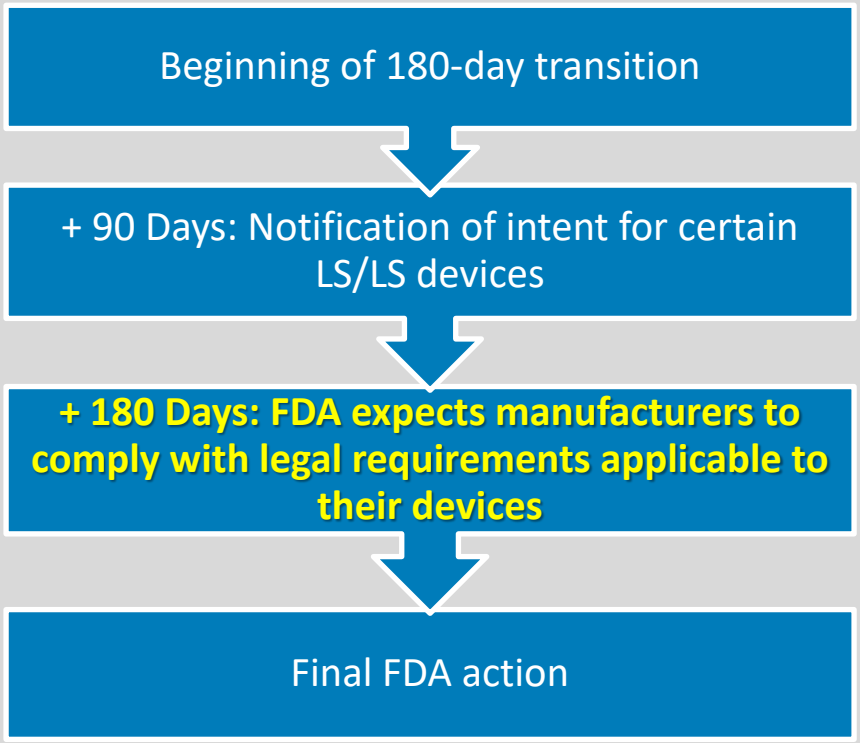
How and when to submit

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

Information requested

- General information
- EUA and related FDA submission numbers
- Model numbers
- Future plans to submit marketing submission
- Future plans to discontinue distribution, restore or relabel, and other efforts to address or mitigate risk of already distributed devices

Actions recommended within 180 days after transition begins



- EUA declarations are terminated / COVID-19 enforcement policies are no longer in effect
- **Manufacturers must comply with all legal requirements**
- **Marketing submissions, including Transition Implementation Plan,** should have **already been submitted to and accepted by FDA**
- **Enforcement policy for FDA marketing authorization and certain labeling and UDI requirements** during FDA review before final FDA action

Transition Implementation Plan will help guide consistent FDA-manufacturer interactions

Transition Implementation Plan

Include the **Transition Implementation Plan in the cover letter** for your marketing submission

Also, as applicable, include in the cover letter that the device:

- Is/was **previously authorized under an EUA and the EUA request number**
- Is/was **distributed as described in a policy in a guidance in List 1**
- **Submission number(s) for related premarket submissions**

Estimated number of devices in distribution

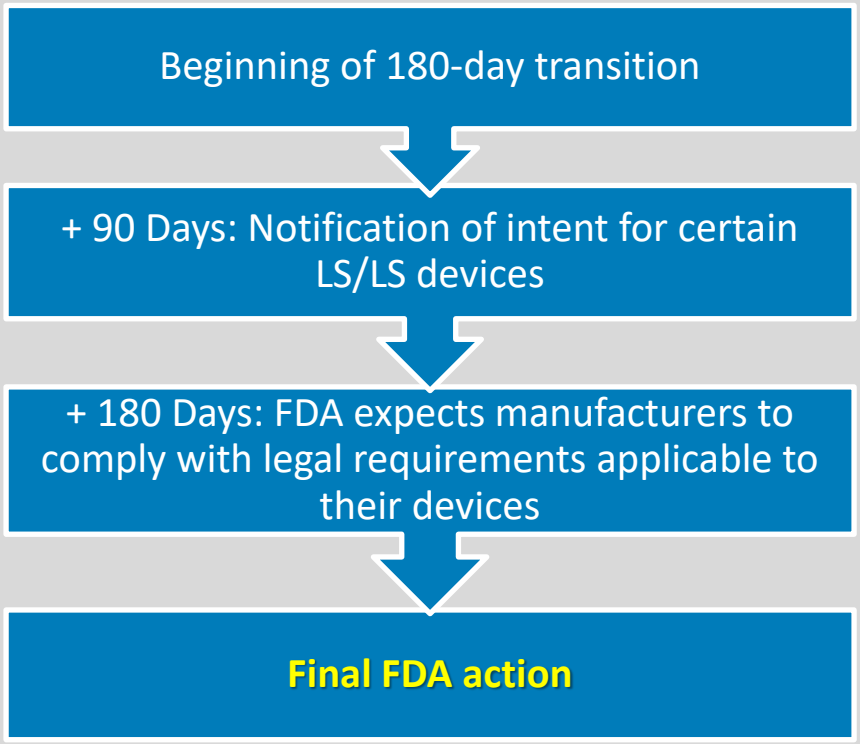
Benefit-risk based plan for already distributed devices in event of negative decision

- Explanation of the benefit-risk based plan for disposition of already distributed devices
- Notification to stakeholders of regulatory status
- Process and timeline for restoring device to FDA-cleared/approved version or providing a physical and/or electronic copy of updated labeling that accurately describes the product features and that device lacks FDA clearance, approval, or authorization
- Maintenance plan

Plans for already distributed devices in event of positive decision

- Explanation of plan for addressing already distributed devices
- Notification to stakeholders of regulatory status
- Process and timeline for providing updated labeling or components for the FDA-cleared/approved version of the device

FDA expects compliance with legal requirements upon final FDA action



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 request for additional information**

FDA may take regulatory action as appropriate to protect public health

Kathryn Drzewiecki, PhD
Policy Advisor
Office of Policy

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

- Recommendations, actions, and timeframes described in the COVID-19 Transition Guidances 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 falls within the Enforcement Policy for Telethermographic Systems

Phase 1 (Begins May 11)	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 transition period and the enforcement policies are no longer in effect
Phase 2 (Begins August 9)	**Manufacturer who intends to distribute beyond transition period:** • Registers and lists (21 CFR Part 807 Subparts B-D) • By the end of Phase 2, submits a marketing submission, including a Transition Implementation Plan, which is accepted by FDA **Manufacturer who does not intend to distribute beyond transition period:** • Ceases distribution during Phase 2 • Continues to report adverse events consistent with 21 CFR Part 803

Phase 3 (Begins November 7)
 	
COVID-19 enforcement policy is no longer in effect after the 180-day transition period ends
	Manufacturer who intends to distribute beyond transition period:
	• Continues to distribute until FDA takes a final action
	• Complies with all other legal requirements applicable to the device (such as registration and listing, quality system, and reports of corrections and removals requirements under 21 CFR Parts 807, 820, and 806)
	• In a scenario where the manufacturer receives an NSE decision after FDA's review:
	  • Manufacturer ceases distribution
	  • FDA and manufacturer engage on the Transition Implementation Plan to address already distributed devices
	Manufacturer who does not intend to distribute beyond transition period:
	• Previously distributed devices remain distributed
	• Provides an electronic copy of updated labeling (noting product features and regulatory status)
	• Continues to report adverse events consistent with 21 CFR Part 803

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

All manufacturers continue to comply with the requirements in the EUA conditions of authorization

August 1*

Manufacturer who <u>intends to distribute</u> beyond EUA termination date:
- Submits a Notification of Intent to inform FDA that it intends to pursue marketing authorization
- By the EUA termination date, submits a marketing submission, including a Transition Implementation Plan, which is accepted by FDA

Manufacturer who <u>does not intend to distribute</u> beyond EUA termination date:
- Submits a Notification of Intent, including manufacturer's plans for already distributed devices, to inform FDA that it does not intend to pursue marketing authorization

All manufacturers continue to comply with the requirements in the EUA conditions of authorization

January 1*

Relevant EUA declaration is terminated, and the umbrella EUA is no longer in effect

Manufacturer who <u>intends to distribute</u> beyond EUA termination date:
- Continues to distribute until FDA takes a final action
- Complies with all other legal requirements applicable to the device (such as registration and listing, quality system, and reports of corrections and removals requirements under 21 CFR Parts 807, 820, and 806).
- In a scenario where the manufacturer receives a positive decision after FDA's review:
    - FDA and manufacturer engage on the Transition Implementation Plan to address already distributed devices

Manufacturer who <u>does not intend to distribute</u> beyond EUA termination date:
- Ceases distribution and leaves already distributed devices with stakeholders that have expressed interest in keeping the devices; however, already distributed devices are not used
- Provides an electronic copy of updated labeling (noting product features and regulatory status)

***Dates are hypothetical**

Appendix

Guidances within List 1 of the Enforcement Policies Transition Guidance

- Enforcement Policy for Remote Digital Pathology Devices During the COVID-19 PHE; www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-remote-digital-pathology-devices-during-coronavirus-disease-2019-covid-19-public
- Enforcement Policy for Imaging Systems During the COVID-19 PHE; www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-imaging-systems-during-coronavirus-disease-2019-covid-19-public-health-emergency
- Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the COVID-19 PHE; www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-fetal-and-maternal-monitoring-devices-used-support-patient
- Enforcement Policy for Telethermographic Systems During the COVID-19 PHE; www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-telethermographic-systems-during-coronavirus-disease-2019-covid-19-public-health
- Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders During the COVID-19 PHE; www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-digital-health-devices-treating-psychiatric-disorders-during-coronavirus-disease
- Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices During the COVID-19 PHE; www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-extracorporeal-membrane-oxygenation-and-cardiopulmonary-bypass-devices-during
- Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the COVID-19 PHE; www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-remote-ophthalmic-assessment-and-monitoring-devices-during-coronavirus-disease
- Enforcement Policy for Infusion Pumps and Accessories During the COVID-19 PHE; www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-infusion-pumps-and-accessories-during-coronavirus-disease-2019-covid-19-public

Guidances within List 1 of the Enforcement Policies Transition Guidance (continued)

- Enforcement Policy for Face Shields, Surgical Masks, and Respirators During the COVID-19 PHE; www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-shields-surgical-masks-and-respirators-during-coronavirus-disease-covid-19
- Enforcement Policy for Gowns, Other Apparel, and Gloves During the COVID-19 PHE; www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-gowns-other-apparel-and-gloves-during-coronavirus-disease-covid-19-public-health
- Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the COVID-19 PHE; www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-sterilizers-disinfectant-devices-and-air-purifiers-during-coronavirus-disease
- Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the COVID-19 PHE; www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-ventilators-and-accessories-and-other-respiratory-devices-during-coronavirus
- Enforcement Policy for Modifications to FDA Cleared Molecular Influenza and RSV Tests During the COVID-19 PHE; www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-modifications-fda-cleared-molecular-influenza-and-rsv-tests-during-coronavirus
- Coagulation Systems for Measurement of Viscoelastic Properties: Enforcement Policy During the COVID-19 PHE (Revised); www.fda.gov/regulatory-information/search-fda-guidance-documents/coagulation-systems-measurement-viscoelastic-properties-enforcement-policy-during-coronavirus
- Enforcement Policy for Viral Transport Media During the COVID-19 PHE (Revised); www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-viral-transport-media-during-coronavirus-disease-2019-covid-19-public-health

Summary

- FDA finalized the COVID-19 Transition Guidances to provide recommendations for a return to normal operations for devices that fall within certain enforcement policies issued during the COVID-19 PHE or devices issued EUAs
  - FDA considered public comments received in finalizing the two guidances

- The COVID-19 Transition Guidances identify actions and milestones to support FDA and stakeholders through a transparent and orderly transition
  - **Phase 1 begins on May 11, 2023**

- For manufacturers intending to continue to distribute their devices after the relevant enforcement policy is no longer in effect, or termination of the relevant EUA declaration, **FDA recommends preparing your marketing submission as soon as possible**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