MEDCON
CONFERENCE
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Transition Plans for Devices Issued EUAs Related to COVID-19

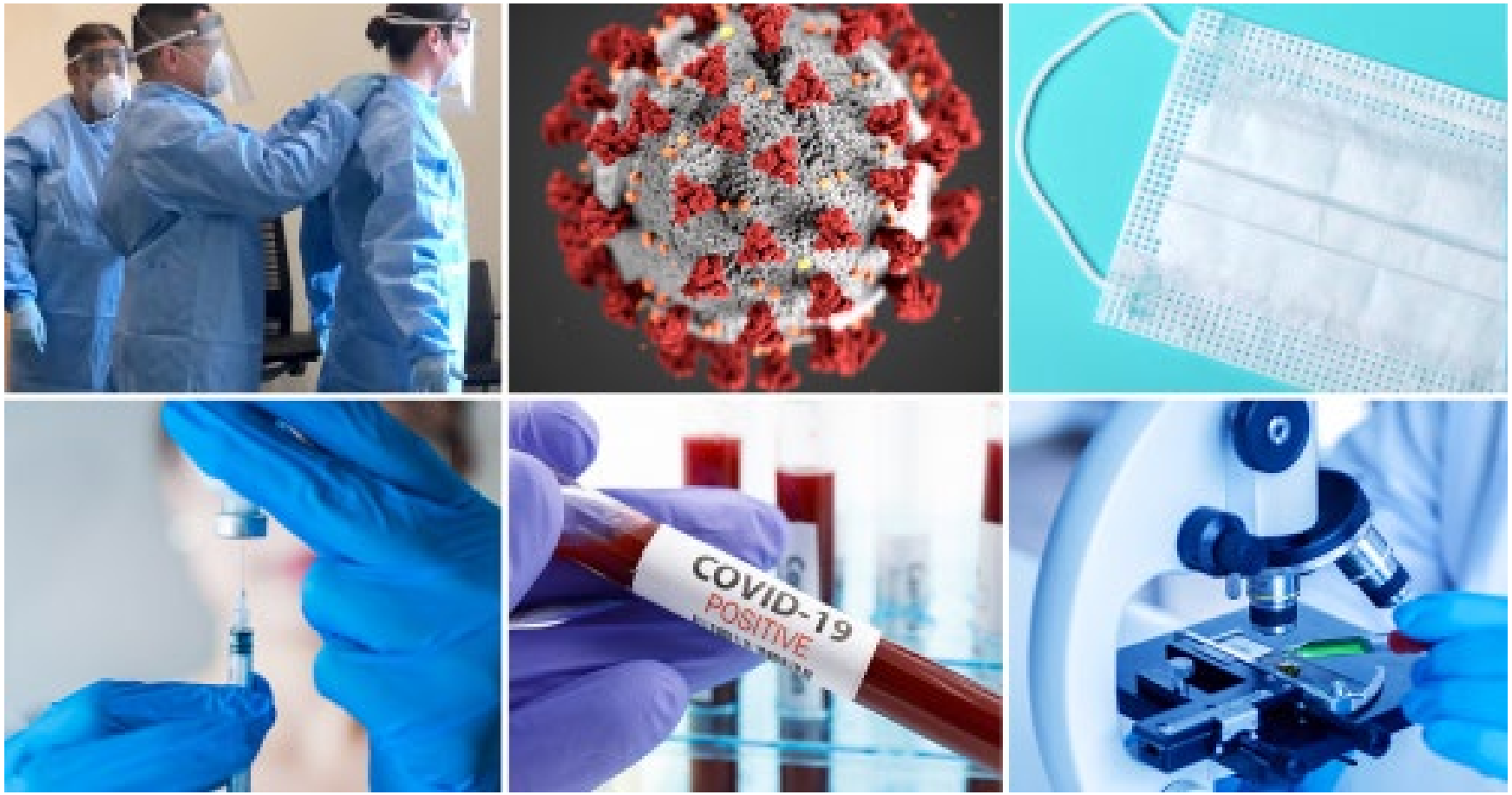
Eli Tomar, JD, MPH

Associate Director, Guidance, Legislation, & Special Projects

Office of Policy, CDRH, FDA

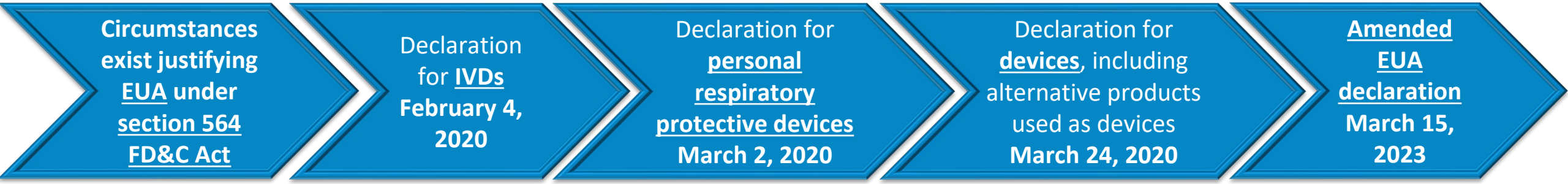
AFDO RAPS HEALTHCARE PRODUCTS COLLABORATIVE

COVID-19 Response



- EUA Authorities & the COVID-19 Timeline
- CDRH Response to COVID-19: By the Numbers
- COVID-19 EUA Transition Guidance
- Practical Experience (RWE, CLIA)
- Lessons Learned & Next Steps

Emergency Use Authorization (EUA) – section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act



- **EUA declaration** under section 564 of the FD&C Act **is distinct from and not dependent** on a **public health emergency (PHE) declaration under section 319 of the Public Health Service Act**
  - When the Secretary of HHS declares that an EUA is appropriate, FDA may authorize **unapproved medical products or unapproved uses of approved medical products** to be used in an emergency
  - **An EUA may remain in effect beyond the 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

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**

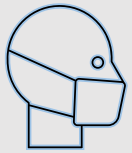
CDRH PANDEMIC RESPONSE

INCLUDES

>4,000

MEDICAL DEVICES AUTHORIZED

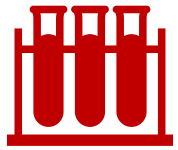
(EUA AND TRADITIONAL MARKETING AUTHORIZATION)

IN VITRO DIAGNOSTICS (IVDs)*	**350** MOLECULAR	**94** ANTIBODY	**64** ANTIGEN	**5** BREATH	**1,340 REVISIONS TO EUA AUTHORIZATIONS**
OTHER MEDICAL DEVICES*		**1,168** PPE	**249** VENTILATORS	**923** OTHER	

* Includes EUA and traditional marketing authorizations through 3/28/23

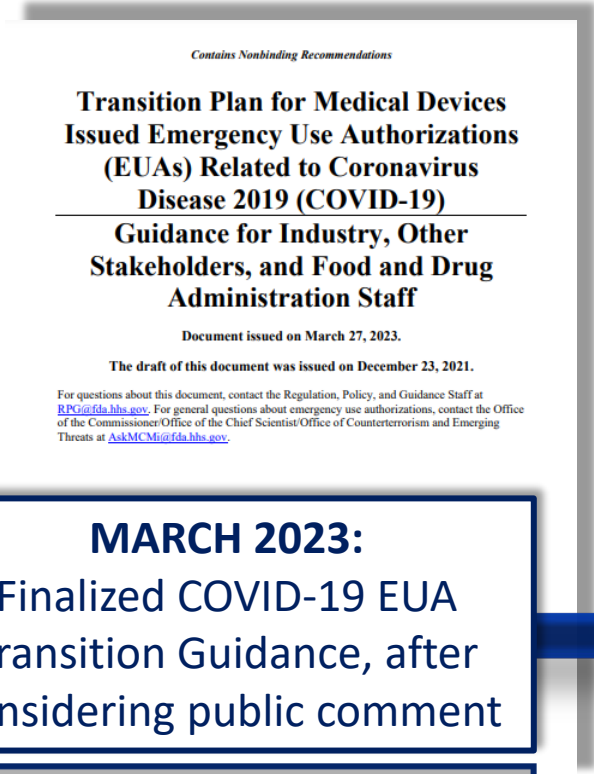
AFDO RAPS HEALTHCARE PRODUCTS COLLABORATIVE

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



DECEMBER 2021:
Issued COVID-19 EUA Transition Guidance in draft

FEBRUARY 2020:
Began issuance of device EUAs related to COVID-19



Contains Nonbinding Recommendations

Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19)

Guidance for Industry, Other Stakeholders, and Food and Drug Administration Staff

Document issued on March 27, 2023.

The draft of this document was issued on December 23, 2021.

For questions about this document, contact the Regulation, Policy, and Guidance Staff at RPG@fda.hhs.gov. For general questions about emergency use authorizations, contact the Office of the Commissioner/Office of the Chief Scientist/Office of Counterterrorism and Emerging Threats at AskMCMi@fda.hhs.gov.

MARCH 2023:
Finalized COVID-19 EUA Transition Guidance, after considering public comment

22 comments

EUA TERMINATION DATE(S) TBD:

- **Advance notice of termination of *each EUA declaration pertaining to devices*** – could occur at different times
- **EUA declaration terminates 180 days after the advance notice of termination**

FDA developed the COVID-19 EUA Transition Guidance to:

- Provide stakeholders with **recommendations and an appropriate transition period** to ensure an orderly and transparent transition
- Help ensure that **devices meet applicable requirements** after the transition period
- Help **avoid disruptions in device supply** and **facilitate continued access to devices** for the healthcare community

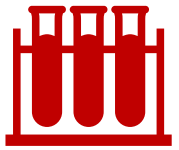
FDA seeks to encourage and facilitate an appropriate transition period to help avoid exacerbating product shortages and supply chain disruptions…

Manufacturers with a **submission accepted by FDA** before the EUA termination date…

- **Continue to distribute their devices** that were issued EUAs
- **Transition to traditional marketing authorization**

Manufacturers that **do not have a marketing submission accepted by FDA** before the EUA termination date…

- **Stop distribution of their devices**
- In most instances, may leave **"already distributed" devices in distribution** to facilitate continued healthcare community access
- Voluntarily withdraw devices from market



TESTS

RESPIRATORS

OTHER DEVICES

Specific recommendations for transition strategies (continue/discontinue distribution) further described in COVID-19 EUA Transition guidance

Transition Timeline for Devices Issued EUAs

Advance notice of termination published in Federal Register:
Beginning of 180-day transition

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

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+ 180 Days when EUA declaration terminates: FDA expects manufacturers to comply with legal requirements applicable to their devices

↓

Final FDA action

Key Comments & 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)
  - 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
- Additional clarity on other 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 remaining distributed until expiration; CLIA & LDT clarifications***
- Recommendations for **stakeholder collaboration** regarding transition planning
- Additional explanation and examples to clarify these policies

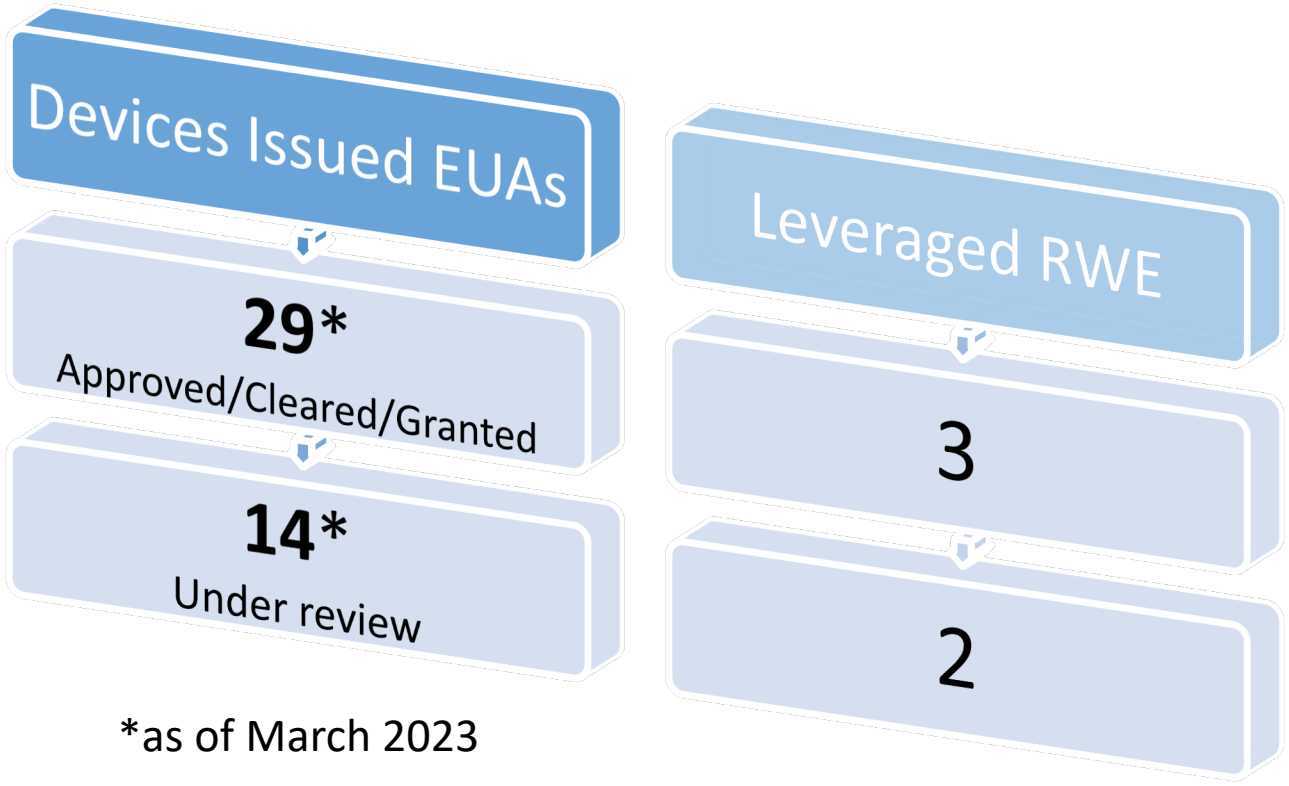
Real-World Evidence (RWE) in Marketing Submissions for Transitioning Devices

- Manufacturers may wish to use real-world data (RWD) from device use during the COVID-19 pandemic:

RWD from IVD use to support a CLIA Waiver by Application

RWD from device use by non-traditional users

RWD from device use to support an expanded indications for use



*as of March 2023

In Vitro Diagnostics (IVDs)

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)

In the COVID-19 EUA Transition Guidance, FDA announced **enforcement policies** for:

- Manufacturers that wish to **continue distribution of COVID-19 tests;** have a **submission accepted by FDA by the EUA termination date**
- Manufacturers that **do not wish to continue distribution** of COVID-19 tests; **COVID-19 tests that are already distributed may remain distributed and used**

FDA and CMS have discussed the COVID-19 EUA Transition guidance:

- For COVID-19 tests that are distributed consistent with FDA's policies, laboratories using such COVID-19 tests should **consider whether CLIA requirements administered by CMS may apply**
- **Questions about CMS' CLIA requirements?**
  - Engage directly with CMS

LABORATORY DEVELOPED TESTS (LDTs)

Following **termination of the EUA declaration for COVID-19 IVDs**, FDA intends to have the **same enforcement approach for COVID-19 LDTs as it does for other LDTs**

Come Talk to FDA for Transition Assistance!

- Recommendations, actions, and timeframes described in the COVID-19 EUA Transition Guidance generally apply
- Manufacturers may wish to initiate discussions with FDA through the **Q-Submission Program**, for example, to discuss:
  - Ongoing clinical trials
  - Longer-term non-clinical studies
  - Planned study designs for comparison and reproducibility studies for a dual submission
  - Product disposition, if not covered in guidance (e.g., restoration to cleared/approved-version of device is not possible)
- FDA recommends that manufacturers of devices authorized under EUAs **plan their post-EUA regulatory and disposition strategies now**

FDA

Lessons Learned from COVID-19 EUAs

Novel EUA mechanisms

Unprecedented EUA volume and need for prioritization

Novel approach to umbrella EUAs

Provision of EUA templates for requestors

Organizational agility and additional support for EUA review

Interaction & communication

Extensive interaction between EUA requestors and CDRH review team (TPLC Advisory Program (TAP) model)

Novel means for sharing timely information (e.g. IVD Town Halls, device specific webinars)

Supply chain stresses prompted multi-party dialogue with key stakeholders (i.e. distributors, purchasers, other USG)

RWD/RWE

Real-world use of unapproved devices and uses provides unique opportunities to leverage RWE

Dx reform

EUA submissions revealed inadequate validation of tests

Modern regulatory framework is necessary to assure tests are accurate, support preparedness, and spur innovation in the U.S.

Summary

- FDA finalized the COVID-19 EUA Transition Guidance to **provide recommendations for a return to normal operations for devices issued EUAs**
  - FDA considered public comments received in finalizing the guidance
- The COVID-19 EUA Transition Guidance **identifies actions and milestones to support FDA and stakeholders** through a transparent and orderly transition
  - The transition will commence with an advance notice of termination 180 days before termination of the relevant EUA declaration(s)
  - FDA does not have information about termination of the device-related EUA declarations
- For manufacturers intending to continue to distribute their devices after termination of the relevant EUA declaration, **FDA recommends preparing your marketing submission as soon as possible**

Questions?