Medical Products Post-Public Health Emergency:
Emergency Use Authorizations and the Transition to a New Normal

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U.S. FOOD & DRUG ADMINISTRATION

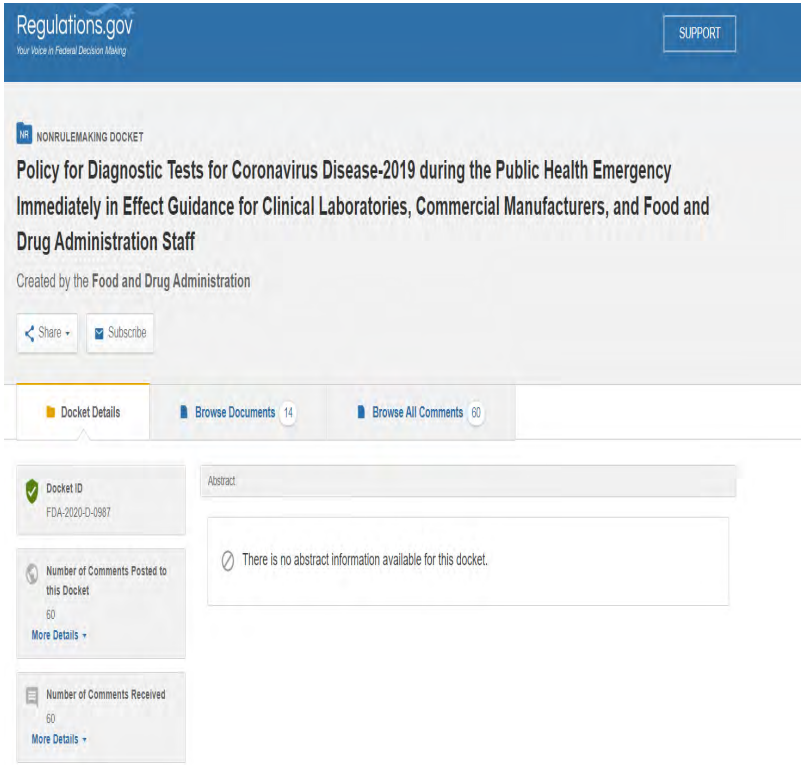
FDLI

FDA COVID-19-Related Guidances

Title	Guidance Type	Product Area	Date Posted
Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	Final Guidance for Industry, Other Stakeholders, and Food and Drug Administration Staff	Medical Devices	March 27, 2023
Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19)	Final Guidance for Industry, Other Stakeholders, and Food and Drug Administration Staff	Medical Devices	March 27, 2023
Enforcement Policy for Face Shields, Surgical Masks, and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency	Final Guidance for Industry and Food and Drug Administration Staff	Medical Devices	March 13, 2023
Enforcement Policy for Face Masks and Barrier Face Coverings During the Coronavirus Disease (COVID-19) Public Health Emergency	Final Guidance for Industry and Food and Drug Administration Staff	Medical Devices	March 13, 2023
Policy for Coronavirus Disease-2019 Tests (Revised)	Final Guidance for Developers and Food and Drug Administration Staff	Medical Devices	January 12, 2023
Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests	Final Guidance for Test Developers and Food and Drug Administration Staff	Medical Devices	January 12, 2023
Emergency Use Authorization for Vaccines to Prevent COVID-19 (Updated)	Final Guidance for Industry	Biologics	March 31, 2022
Investigational COVID-19 Convalescent Plasma	Final Guidance for Industry	Biologics	January 1, 2022
Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised)	Final Guidance for Commercial Manufacturers, Clinical Laboratories, and FDA Staff	Medical Devices	November 15, 2021
FDA Guidance on Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency (Updated August 30, 2021)	Final Guidance for Industry, Investigators, and Institutional Review Boards	Drugs Biologics Medical Devices	August 30, 2021
Development of Monoclonal Antibody Products Targeting SARS-CoV-2, Including Addressing the Impact of Emerging Variants, During the COVID 19 Public Health Emergency	Final Guidance for Industry	Drugs	February 22, 2021

https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders

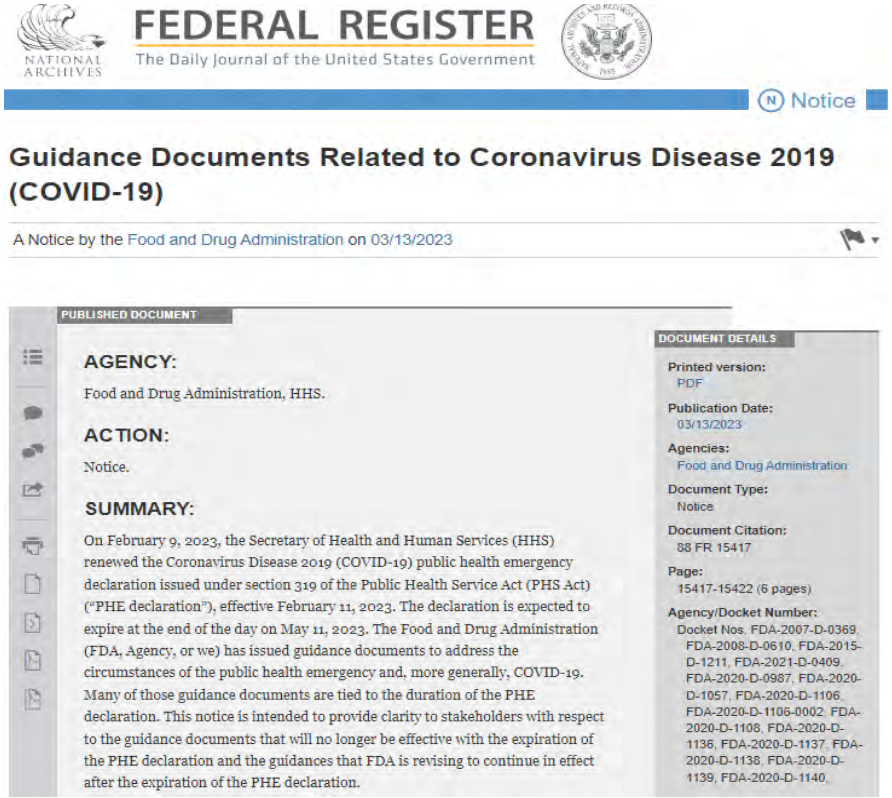
Assessment of COVID-19 Guidances



- Comments submitted to dockets
- Experience with implementation
- Notifications about drug/biologic and medical device supply chain issues (§§506C, 506J FD&C Act)
- Voluntary surveys
- Stakeholder engagement and outreach

Federal Register Notice (FRN)

March 13, 2023: FDA published a notice in the *Federal Register* (88 FR 15417) describing plans for COVID-19-related guidance documents



FEDERAL REGISTER
The Daily Journal of the United States Government

Notice

Guidance Documents Related to Coronavirus Disease 2019 (COVID-19)

A Notice by the Food and Drug Administration on 03/13/2023

PUBLISHED DOCUMENT

AGENCY:

Food and Drug Administration, HHS.

ACTION:

Notice.

SUMMARY:

On February 9, 2023, the Secretary of Health and Human Services (HHS) renewed the Coronavirus Disease 2019 (COVID-19) public health emergency declaration issued under section 319 of the Public Health Service Act (PHS Act) ("PHE declaration"), effective February 11, 2023. The declaration is expected to expire at the end of the day on May 11, 2023. The Food and Drug Administration (FDA, Agency, or we) has issued guidance documents to address the circumstances of the public health emergency and, more generally, COVID-19. Many of those guidance documents are tied to the duration of the PHE declaration. This notice is intended to provide clarity to stakeholders with respect to the guidance documents that will no longer be effective with the expiration of the PHE declaration and the guidances that FDA is revising to continue in effect after the expiration of the PHE declaration.

DOCUMENT DETAILS

Printed version:
PDF

Publication Date:
03/13/2023

Agencies:
Food and Drug Administration

Document Type:
Notice

Document Citation:
88 FR 15417

Page:
15417-15422 (6 pages)

Agency/Docket Number:
Docket Nos. FDA-2007-D-0369, FDA-2008-D-0610, FDA-2015-D-1211, FDA-2021-D-0409, FDA-2020-D-0987, FDA-2020-D-1057, FDA-2020-D-1106, FDA-2020-D-1106-0002, FDA-2020-D-1108, FDA-2020-D-1136, FDA-2020-D-1137, FDA-2020-D-1138, FDA-2020-D-1139, FDA-2020-D-1140,

COVID-19-Related Guidances to Be Revised (1/3)

- March 13th FRN identified 24 guidances FDA intends to retain with appropriate changes. FDA has begun revising those guidances, *e.g.*:

- 5/2023: *Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products* (**Final**)
  - Supersedes the April 2020 COVID-19 guidance *Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products.*
  - Provides recommendations to assess blood donor eligibility using individual risk-based questions to reduce risk of transfusion-transmitted HIV.
  - Questions same for every donor, regardless of sexual orientation, sex, or gender.

- 5/2023: *GFI #271 Reporting and Mitigating Animal Drug Shortages* (**Final**)
  - Replaces the May 2020 guidance *GFI #271 Reporting and Mitigating Animal Drug Shortages During the COVID-19 Public Health Emergency*.
  - The recommendations, which assist sponsors in providing timely notifications to help FDA prevent or mitigate animal drug shortages, remain the same from the May 2020 guidance.
  - Edits clarifying guidance continues to reflect FDA's current thinking.

COVID-19-Related Guidances to Be Revised (2/3)

- 4/2023: *Notifying FDA of a Discontinuance or Interruption in Manufacturing of Finished Products or Active Pharmaceutical Ingredients Under Section 506C of the FD&C Act* (**Draft**)
  - When finalized, will replace the March 2020 guidance *Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act.*
  - Would explain (1) who must notify FDA and for what products, (2) when to notify FDA, and (3) what details to include in notifications.

- 3/2023: *Potency Assay Considerations for Monoclonal Antibodies and Other Therapeutic Proteins Targeting Viral Pathogens* (**Draft**)
  - When finalized, will replace the January 2021 guidance *COVID-19: Potency Assay Considerations for Monoclonal Antibodies and Other Therapeutic Proteins Targeting SARS-CoV-2 Infectivity.*
  - Critical quality control measure is development and implementation of potency assay(s) adequate to ensure each lot produced consistently with potency to achieve clinical efficacy, and potency maintained over product shelf life.
  - Guidance intended to help developers of CDER-regulated mAbs/therapeutic proteins provide adequate information to assess potency at each stage of a product's life cycle.

COVID-19-Related Guidances to Be Revised (3/3)

- 12/2022: *Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria* (**Final**)
  - Supersedes the April 2020 COVID-19 guidance *Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria.* Recommendations unchanged from April 2020 guidance.
  - Recommendations for screening blood donors for malaria risk and implementing pathogen reduction of blood and blood components, except Source Plasma.

- 5/2022: *Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements* (**Draft**)
  - When finalized, will replace the April 2020 guidance *Alternative Procedures for Blood and Blood Components During the COVID-19 Public Health Emergency*.
  - Draft guidance explains conditions under which FDA does not intend to take regulatory action for a blood establishment's failure to comply with certain requirements in biologics regulations regarding donation suitability; donor eligibility; and quarantine hold for Source Plasma.
  - When finalized, expect policy to increase availability of blood/blood components, while maintaining blood donors' health and the safety of blood/blood components.

Medical Device Transition Guidances

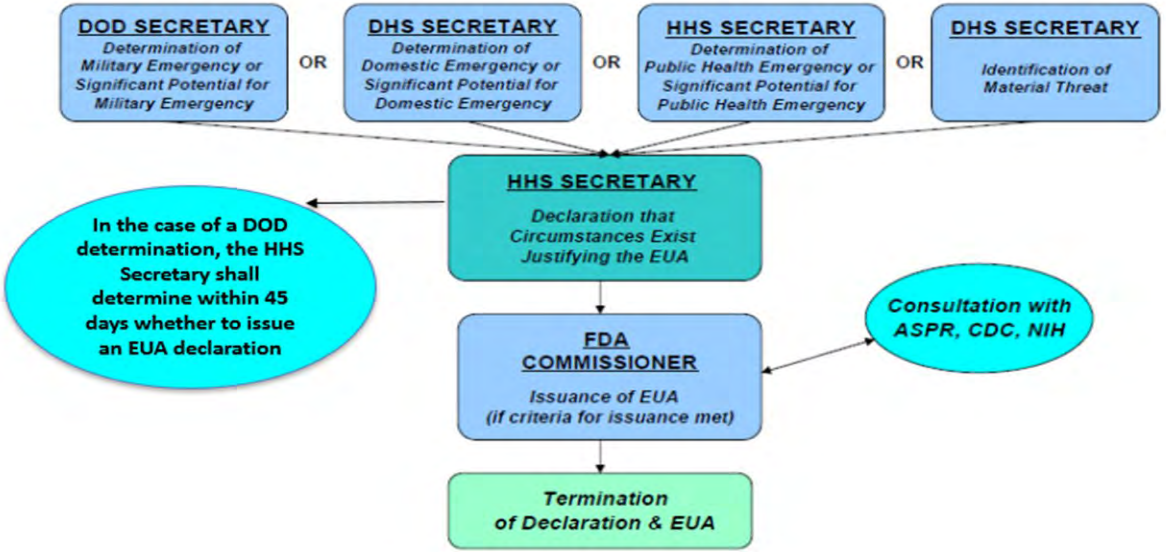
- *Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency* (March 2023)
  - Applies to devices within enforcement policies described in the 15 “List 1” guidances.
  - 180-day transition period; May 11, 2023 implementation date (based on expiration of COVID-19 PHE declared under the Public Health Service Act).
  - Manufacturers who intend to continue distribution after the transition should submit – and have FDA accept – traditional marketing submissions before the 180-day transition period ends.
  - After the transition period, FDA expects manufacturers to comply with legal requirements applicable to their devices.
  - FDA does not intend to object to continued distribution of devices within scope of the enforcement policy transition plan where a required marketing submission is under FDA review.

- *Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19)* (March 2023)
  - 180 days advance notice before termination of an EUA declaration.
  - If manufacturers want to continue distributing devices after the EUA declaration terminates, will have that 180-day period to submit, and FDA accept, a traditional marketing submission.
  - After the relevant EUA declaration is terminated, manufacturers expected to comply with applicable legal requirements (e.g., registration/listing, Quality System, reports of corrections and removals).
  - FDA does not intend to object to continued distribution of a device after the EUA declaration is terminated where the manufacturer’s traditional marketing submission is under FDA review.

EUA Authority: Section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act

- For use in emergencies involving CBRN agent(s) (and for DOD, agents of war) FDA can authorize for use to diagnose, prevent, treat:
  - An unapproved medical product, or
  - Unapproved use of an approved product
- Statutory criteria must be met:
  - Serious or life-threatening disease/condition caused by the CBRN agent referred to in the HHS EUA Declaration
  - Reasonable belief that the product “may be effective”
  - Known/potential benefits outweigh known/potential risks
  - No adequate, approved, available alternative to the product

EUAs and Summary of Issuance Process



Status of COVID-19 Medical Products

- HHS amended the section 564 EUA determination to provide for the “significant potential for a public health emergency” (3/15/2023) [88 FR 16644 (March 20, 2023)]
- The EUAs remain in effect until the relevant EUA determination is terminated or FDA revokes them
  - HHS must provide advanced notice before terminating, providing for a reasonable time period for product disposition
- FDA is supporting broader U.S. government transition efforts related to commercial distribution and continued liability protections

Resources

- FAQs: What happens to EUAs when a public health emergency ends? | FDA
- COVID-19-Related Guidance Documents: COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders | FDA
- HHS PHE webpage: COVID-19 Public Health Emergency (PHE) | HHS.gov
- ASPR PREP Act webpages: https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx and https://aspr.hhs.gov/legal/PREPact/Pages/PREP-Act-Question-and-Answers.aspx#COVID
- Expiration dating extensions webpages:Expiration Dating Extension | FDA and COVID-19 Therapeutic Product Expiration (hhs.gov)