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FDA/Food, Drug & Device ADVISORY ■

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Public Health Emergency Set to End May 11, 2023: What It Means for FDA-Regulated Firms and Products

According to a statement released by the Biden Administration on January 30, 2023, the public health emergency (PHE) will be extended one final time from April 11 until May 11, 2023, and then the PHE will terminate. But what does it mean for FDA-regulated clients?

End of PHE ≠ End of FDA Emergency Authorities

What FDA Clients Should Know

COVID-19 / PHE related legal authorities

It is important to remember that there are several types of declarations and determinations related to the current COVID-19 public health emergency, which serve different purposes. These are derived from different laws:

Section 319 of the Public Health Service Act	Section 564 of the Federal Food, Drug, and Cosmetic Act
Public Readiness and Emergency Preparedness Act of 2005	Pandemic and All-Hazards Preparedness Reauthorization Act

January 30, 2023 Biden announcement (Termination of PHE)

Under Section 319 of the Public Health Service (PHS) Act, the PHE was first declared on January 31, 2020, and has been renewed every 90 days since. The current version is set to expire on April 11, 2023. The PHE will be extended one final time until May 11, 2023, and then the PHE will terminate.

January 31, 2023 FDA announcement

On the heels of the announcement by the Biden Administration, the FDA updated its website to explain what happens – at the FDA – once the PHE ends, with a specific focus on emergency use authorizations (EUAs) and COVID-19-related guidances.

Impact on FDA authority

The FDA's authorities and emergency powers **are distinct from, and not directly tied to**, the PHE declaration. The Department of Health and Human Services (HHS) made a separate Determination of Public Health Emergency pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) on February 4, 2020, under which EUAs could be granted for products such as in vitro diagnostics, personal respiratory protective devices, medical devices, and drugs and biological products, among others.

Emergency use authorizations

The Section 319 PHE declaration did not enable the FDA to issue EUAs. Similarly, the termination of the PHE does not have a direct effect on EUAs. Not all EUAs will terminate on May 11, 2023. Rather, an EUA will remain in effect for the duration of the EUA declaration under which it was issued. The FDA must provide advance notice of a termination of an EUA declaration in the *Federal Register*. Only when an EUA declaration is terminated will all EUAs issued pursuant to that EUA declaration cease to be in effect. However, individual EUAs can be revoked by the FDA at any time if the circumstances that initially justified issuance cease to exist.

FDA COVID guidances

The FDA first published a *Federal Register* notice on March 25, 2020, to announce the process for making COVID-19-related FDA guidances, and since that time, the FDA has issued, amended, and rescinded dozens of COVID-19-related guidances (over 75 total). Many guidance documents read, "The policies in this guidance are intended to remain in effect only for the duration of the declaration under Section 564 of the Federal Food, Drug, and Cosmetic Act." This means that FDA guidances will not be immediately and directly impacted by the May 11, 2023 date but will link to the end of the PHE under Section 564.

FDA enforcement discretion

The FDA uses certain guidances to establish the agency's "current thinking" and enforcement strategies for specific products or regulatory issues without needing to go through the notice and comment rulemaking process. During the COVID-19 PHE, the FDA published about 20 guidance documents in which the agency announced its intent to exercise enforcement discretion by allowing certain medical devices to be marketed and sold without meeting full FDA requirements (e.g., premarket review).

FDA's transition plan

In anticipation of the end of the PHE, and subsequent revocation of hundreds of EUAs, and withdrawal of enforcement discretion policy guidances, the FDA published two guidance documents in December 2021 outlining the agency's plans for a phased transition plan back to full regulatory requirements for medical devices:

- Transition Plan for Medical Devices Issued Emergency Use Authorizations
- Transition Plan for Medical Devices That Fall Within Enforcement Policies

EUA transition plan

The FDA's transition plan includes a 180-day, three-phase transition from the announcement to withdrawing EUAs. Depending on the device type, the FDA may require the EUA holder to provide the FDA with its intent to submit a submission for full marketing authorization and approval or a plan to address potential authorization and approval of the full submission. Note, however, that individual EUAs, by their nature, can be withdrawn at any time if the

circumstances justifying their issuance no longer exist, the criteria for their issuance are no longer met, or other circumstances make revocation appropriate to protect the public health or safety.

COVID-19-related guidances

Since a different FDA guidance process was followed (in which most COVID-19-related guidance documents skipped the draft guidance stage and were implemented as-is), the fate of guidance documents largely depends on whether the guidance is in "draft" or "final" form before the end of the PHE. The outcomes for guidance documents in different stages of implementation will be different.

Enforcement policy guidance (devices)

The FDA will also ensure an orderly transition from the PHE with its plan to modify each of the medical device enforcement policies to continue until at least 180 days after the end of the PHE in a three-phase transition. The FDA intends to issue a *Federal Register* notice on how HHS's determination to end the COVID-19 public health emergency declared under the PHS Act will impact the agency's COVID-19-related guidances and which of those guidances it is temporarily extending or letting expire.

Diagnostic tests

The Enforcement Policy Transition Plan does not include diagnostic tests commercialized pursuant to the FDA's Policy for Diagnostic Tests for COVID-19.

COVID-19 FDA Enforcement Policies (That May Change Soon)

- Enforcement Policy for Remote Digital Pathology Devices
- Enforcement Policy for Imaging Systems
- Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring
- Enforcement Policy for Telethermographic Systems
- Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders
- Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices
- Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices
- Enforcement Policy for Infusion Pumps and Accessories
- Enforcement Policy for Clinical Electronic Thermometers
- Enforcement Policy for Face Masks, Barrier Face Coverings, Face Shields, Surgical Masks, and Respirators
- Enforcement Policy for Gowns, Other Apparel, and Gloves
- Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers
- Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices
- Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring
- Enforcement Policy for Modifications to FDA Cleared Molecular Influenza and RSV Tests
- Enforcement Policy for the Quality Standards of the Mammography Quality Standards Act
- Coagulation Systems for Measurement of Viscoelastic Properties: Enforcement Policy

What about the PREP Act?

A Section 319 PHE determination is different from a PREP Act declaration because the declarations are made on different public health determinations and have different legal effects. The PREP Act provides liability immunity for activities **both before and after** a declared public health emergency. A separate declaration under Section 319 or other statutes is not needed for immunity under the PREP Act to take effect. Under the PREP Act, the HHS Secretary determines the period in which liability is limited for each "covered countermeasure." It should be noted that different covered countermeasures have different periods in which PREP Act immunity applies. At the ending of the prespecified period, the Secretary may consult with the manufacturer as appropriate and designate a "reasonable period" to allow for disposition of the covered countermeasure and for covered persons to "take such other actions as may be appropriate."

FDA inspections

The end of the PHE announcement is not expected to impact FDA inspections; both domestic and foreign inspections have resumed after a series of inspectional pauses during 2020–2022. FDA investigators are back in full force and conducting in-person inspections all over the world. Please reach out to Alston & Bird's FDA Compliance & Enforcement Team for inspection questions and assistance in responding to Form FDA-483s, warning letters, untitled letters, requests for information, and other inspection-related correspondence.

In-person FDA meetings

In other news, the FDA also announced that CDER and CBER will resume in-person, face-to-face industry meetings beginning February 13, 2023. The agency is shifting meeting formats in phases and will begin with Type A, BPD Type 1, and Type X meeting requests (i.e., Phase 1). Requests, if granted, for other types of meetings will be conducted virtually. Any meeting requests received or scheduled before February 13, 2023, will not be converted to the in-person format.

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If you have any questions or would like additional information, please contact one of the attorneys with our FDA/Food, Drug & Device Team.

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