DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. HHS–ASPR–2026–0200]

Termination of Three Declarations Authorizing Emergency Use of Medical Devices During the COVID–19 Pandemic

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C) Act. On February 4, 2020, as amended on March 15, 2023, HHS determined that there is a public health emergency, or significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves the virus (later referred to as SARS–CoV–2) that causes COVID–19. On the basis of this determination, the HHS Secretary declared that circumstances exist justifying the authorization of emergency use of (1) in vitro diagnostics for detection and/or diagnosis of SARS–CoV–2 (February 4, 2020); (2) personal respiratory protective devices during the COVID–19 outbreak (March 2, 2020); and (3) medical devices, including alternative products used as medical devices (March 24, 2020). On June 29, 2026, the HHS Secretary determined that circumstances no longer exist justifying the authorization of emergency use of these medical devices. On the basis of this determination, the HHS Secretary is terminating these declarations (''EUA declarations''), effective on December 26, 2026.

DATES: Termination of the EUA declarations for: (1) in vitro diagnostics for detection and/or diagnosis of the SARS–CoV–2 virus; (2) personal respiratory protective devices; and (3) medical devices, including alternative products used as medical devices is effective December 26, 2026.

FOR FURTHER INFORMATION CONTACT: L. Paige Ezernack, telephone at (202) 260–0365 or via email at *aspr.dpa@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. EUA Background

Under section 564 of the FD&C Act, the Commissioner of the Food and Drug Administration (FDA or the Agency), acting under delegated authority from the Secretary of HHS, may issue an EUA authorizing (1) the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or (2) an unapproved use of an approved drug, approved or cleared device, or licensed biological product.

Before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of four determinations: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear (''CBRN'') agent or agents; (2) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act [1] sufficient to affect national security or the health and security of United States citizens living abroad; (3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with (i) a biological, chemical, radiological, or nuclear agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces; or (4) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents. Based on any of these four determinations, the Secretary of HHS may then declare that circumstances exist that justify emergency use authorization of medical product(s), at which point FDA may issue an EUA if the criteria for issuance of an authorization under section 564 of the FD&C Act are met.

A declaration justifying an authorization under section 564 of the FD&C Act terminates upon the earlier of: (1) a determination by the Secretary of HHS, in consultation as appropriate with the Secretary of Homeland Security or the Secretary of Defense, that the circumstances justifying emergency authorization based on the determination have ceased to exist; or (2) a change in the approval status of the product under emergency authorization such that the product is no longer unapproved, unlicensed, or uncleared, or is no longer intended for an unapproved use.

II. Determination and Declarations That Emergency Use Is Justified by the Secretary of Health and Human Services

On February 4, 2020, the HHS Secretary determined that there is a public health emergency that has significant potential to affect national security or the health and security of U.S. citizens living abroad, and that involves the SARS–CoV–2 virus that causes COVID–19. On the basis of such determination, the HHS Secretary declared on that same day, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the SARS–CoV–2 virus that causes COVID–19. Based on the February 4, 2020 determination, the HHS Secretary issued two more declarations justifying emergency uses related to devices: on March 2, 2020, for personal respiratory protective devices during the COVID–19 outbreak, and on March 24, 2020, for medical devices, including alternative products used as medical devices. On March 15, 2023, the HHS Secretary amended the February 4, 2020 determination to recognize the fact that there is ''a public health emergency, or *a significant potential for a public health emergency,* that affects, or has a significant potential to affect, national security or the health and security of [U.S.] citizens living abroad . . .'' and that involves the SARS–CoV–2 virus that causes COVID–19 (emphasis added). The February 4, 2020 determination, as amended on March 15, 2023, continued to support previously-issued EUA declarations, including the three declarations justifying emergency use of COVID–19 medical devices.

III. Termination of the Three Declarations That Circumstances Exist Justifying the Emergency Use of Medical Devices During the COVID–19 Pandemic

The Secretary of HHS has determined circumstances no longer exist to justify emergency use of medical devices as set forth in the EUA declarations. There has been significantly less demand for in

[1] 42 U.S.C. 247d–6b, which states: ''[t]he Homeland Security Secretary, in consultation with the Secretary and the heads of other agencies as appropriate, shall on an ongoing basis—(i) assess current and emerging threats of chemical, biological, radiological, and nuclear agents; and (ii) determine which of such agents present a material threat against the United States population sufficient to affect national security.''

vitro diagnostics for detection and/or diagnosis of SARS–CoV–2, respiratory protective devices, and other medical devices, including those that have been issued EUAs, as the COVID–19 emergency progressed over time. There are now over fifty COVID–19 tests that have been granted traditional marketing authorization and demand for COVID–19 tests has significantly reduced. Adequate numbers of personal respiratory protective devices and other medical devices of the types that were authorized under the EUA declaration for ''medical devices, including alternative products used as medical devices'' (*e.g.,* blood purification devices, continuous renal replacement and hemodialysis devices, remote or wearable patient monitoring devices, respiratory assist devices, ventilators and ventilator accessories, screening tools) have been authorized through traditional marketing pathways. FDA continues to encourage manufacturers of in vitro diagnostics for detection and/or diagnosis of SARS–CoV–2, certain personal respiratory protective devices, and other medical devices to obtain authorization through traditional premarket pathways as appropriate. As such, the Secretary of HHS is terminating the three EUA declarations for medical devices on December 26, 2026.

IV. Advance Notice of Termination for Appropriate Disposition

The Secretary must provide advance notice of any termination of a declaration under section 564 of the FD&C Act. The period of advance notice must be a period reasonably determined to provide: in the case of an unapproved product, a sufficient period for disposition of the product, including the return of such product (except such quantities of product as are necessary to provide for continued use consistent with section 564(f)(2) of the FD&C Act) to the manufacturer (in the case of a manufacturer that chooses to have such product returned); and, in the case of an unapproved use of an approved product, a sufficient period for the disposition of any labeling, or any information under section 564(e)(2)(B)(ii) of the FD&C Act, as the case may be, that was provided with respect to the emergency use involved. If an EUA for an unapproved product issued by FDA ceases to be effective due to the termination of the Secretary of HHS's declaration justifying emergency use, the Secretary of HHS shall consult with the manufacturer of such product with respect to the appropriate disposition of the product.

FDA issued a final guidance document, *Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID–19)* in March 2023, to describe its general recommendations for this transition process with respect to devices issued EUAs related to COVID–19, recognizing that it would take time for device manufacturers, device distributors, healthcare facilities, healthcare providers, patients, consumers, and FDA to adjust from policies adopted and operations implemented during the COVID–19 pandemic to ''normal operations.'' A notice of availability for the guidance appeared in the **Federal Register** of March 27, 2023 (88 FR 18144). In December 2021, FDA issued a draft guidance with the title *Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.* The draft contemplated a 180-day period for advance notice of termination of each EUA declaration pertaining to devices. A notice of availability for the draft guidance appeared in the **Federal Register** of December 23, 2021 (86 FR 72978). In the draft guidance's notice of availability, FDA solicited comments on whether the contemplated 180-day period for advance notice of termination of each EUA declaration pertaining to devices would sufficiently allow for an appropriate transition period that avoids exacerbating product shortages and supply chain disruptions. After considering the comments received and revising the guidance as appropriate in response to the comments, FDA issued the final guidance in March 2023.

In the March 2023 guidance, FDA stated that HHS intends to publish the advance notice of termination of each EUA declaration pertaining to devices 180 days before the day on which the EUA declaration is terminated and recommended that manufacturers of devices authorized under EUAs begin planning their post-EUA regulatory and disposition strategies. FDA also stated its belief that issuance of the guidance in draft (in December 2021) with a contemplated transition policy and request for public comment (including from manufacturers of EUA-authorized devices) satisfied the requirement to consult with manufacturers. To address any unique considerations or other issues related to disposition of product that were not otherwise discussed in the guidance, FDA also recommended engagement with the Agency as soon as possible. Consistent with the guidance, which FDA issued over three years ago, HHS has determined that 180 days is a sufficient period for disposition of the products authorized under these declarations.

This **Federal Register** notice serves as advance notice that the medical device-related declarations will terminate, effective December 26, 2026, as required under section 564 of the FD&C Act. Notice of termination of EUAs issued by FDA pursuant to each one of the three declarations will be provided by FDA in the **Federal Register**, as required under section 564 of the FD&C Act.

Robert F. Kennedy, Jr.

Secretary, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0490]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health (OASH), Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed Information Collection Request (ICR) for public comment.

DATES: Comments on the ICR must be received on or before August 31, 2026.

ADDRESSES: Submit your comments to *Natalie.Klein@hhs.gov* or by calling (240) 453–6900.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier ''0990–0490–60D'' and project title, ''Office for Human Research Protections Research Complaint Form'' for reference, to Natalie Klein, Acting Director, Office for Human Research Protections, email: *Natalie.Klein@hhs.gov,* or call (240) 453–6900.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of