the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Research Complaint Form.

Type of Collection: Revision.

OMB No.: 0990–0490.

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research Protections (OHRP), is requesting a revision of the currently approved collection for the Office of Management and Budget (OMB) No. of 0990–0490, OHRP Research Complaint Form. This form provides a simplified standardized format for submitting to OHRP allegations of noncompliance involving human subject research conducted or supported by HHS. The information collected will help OHRP ensure the rights of human subjects involved in such research and that OHRP-assured institutions are complying with the HHS Protection of Human Subjects regulations.

The revision request involves (1) updates to the form's frontmatter to conform to recent changes to the Federalwide Assurance (FWA) form (OMB No. 0990–0278); (2) addition of two new data collection elements to obtain information on the complainants' prior attempts to resolve the issue and past related submissions to OHRP; (3) clearer wording of instructions; and (4) additional details on the form about how OHRP communicates with complainants and shares information with other regulatory agencies.

ESTIMATED ANNUALIZED BURDEN HOUR TABLE

Form name	Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Research Complaint Form	Members of the general public	600	1	0.5	300

Catherine Howard,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2026–13467 Filed 7–1–26; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. HHS–ASPR–2026–0199]

Termination of Declaration Authorizing Emergency Use of Drug and Biological Products During the COVID–19 Pandemic

AGENCY: Office of the Secretary, U.S. Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services 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, the HHS Secretary 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 United States (U.S.) citizens living abroad, and that involves the virus (later referred to as SARS–CoV–2) that causes COVID–19. Based on this determination, on March 27, 2020, the HHS Secretary declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID–19 pandemic. On June 29, 2026, the HHS Secretary determined that circumstances no longer exist justifying the authorization of emergency use of drugs and biological products during the COVID–19 pandemic. Based on this determination, the HHS Secretary is terminating this declaration, effective on June 29, 2027.

DATES: Termination of the declaration for drugs and biological products during the COVID–19 pandemic is effective June 29, 2027.

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

SUPPLEMENTARY INFORMATION:

I. EUA Background

Under section 564 of the FD&C Act, the Commissioner of the U.S. Food and Drug Administration (FDA or the Agency), acting under delegated authority from the Secretary of HHS, may issue an Emergency Use Authorization (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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 the FDA may issue an EUA if the criteria for issuance of an

[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.''

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 HHS

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. Based on such determination, on March 27, 2020, the HHS Secretary issued a declaration justifying emergency use of drugs and biological products during the COVID–19 pandemic. 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 March 27, 2020 declaration justifying emergency use of COVID–19 drugs and biological products.

III. Determination of the Secretary of HHS and Termination of the Declaration That Circumstances Exist Justifying the Emergency Use of Drugs and Biological Products During the COVID–19 Pandemic

The Secretary of HHS has determined circumstances no longer exist to justify emergency use of drugs and biological products during the COVID–19 pandemic. There has been decreasing reliance on the use of authorized drugs and biological products as the COVID–19 emergency progressed over time. The EUAs for COVID–19 vaccines and convalescent plasma have been revoked and there are COVID–19 vaccines and convalescent plasma products that are licensed through traditional pathways (*i.e.,* approval of a Biologics License Application (BLA)). There are now FDA-approved therapeutic options for all ages and across all spectrum of disease (*e.g.,* mild to requiring hospitalization). The FDA continues to encourage sponsors of EUA authorized products to obtain approval as appropriate through traditional pathways (*i.e.,* approval of a New Drug Application (NDA) or BLA). If there is a gap between termination of an EUA authorization for a product and FDA approval, sponsors can work with the FDA to facilitate access to these investigational drugs through clinical trials and expanded access protocols, as appropriate. As such, the Secretary of HHS is terminating the declaration for drugs and biological products during the COVID–19 pandemic, effective on June 29, 2027.

IV. Advance Notice of Termination

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 the 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. The FDA has determined that 12 months is a sufficient period for disposition of the products authorized under these declarations.

We also note that FDA has worked with the manufacturer of each currently EUA-authorized drug product about seeking marketing approval or licensure, as appropriate. Considering the currently approved and available drug products, we believe that 12 months is also a reasonable period for sponsors to complete generation of data that can support the potential submission of an NDA or BLA for review. During this 12-month transition period, FDA intends to decline to review and process any new EUA requests for COVID–19 drugs or biological products. For EUA products currently authorized under the COVID–19 declaration for drugs and biological products, FDA intends to review amendments to EUAs that are necessary or appropriate for the protection of public health (*e.g.,* amendments that are necessary to facilitate appropriate use of the product as authorized, such as labeling changes to account for drug interactions or updating variant susceptibility data); the Agency does not intend to review any other requested EUA amendments, such as amendments to change an authorized product's formulation that are not necessary to facilitate appropriate use of the product as authorized.[2]

This **Federal Register** notice serves as advance notice that the drugs and biological products declaration will terminate, effective June 29, 2027, as required under section 564 of the FD&C Act. Notice of termination of EUAs issued by the FDA will be provided by the 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.

[FR Doc. 2026–13374 Filed 6–30–26; 11:15 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Invention Available for License: Chimeric VLP Vaccines To Prevent HTLV–1 Infection

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) seeks research co-development partners and/or licensees for Chimeric VLP Vaccines to Prevent HTLV–1 Infection.

[2] The issuance of an EUA is discretionary. It is an authorization that the government ''may'' issue when necessary to protect the public health in an emergency. FDA is not required to review and process EUA requests or to issue EUAs and must in each case determine whether utilizing limited resources to review EUA requests is appropriate, balanced against other public health needs.