of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

PHENAPHEN WITH CODEINE NO. 3 (acetaminophen; codeine phosphate) oral capsules, 325 mg and 30 mg, and PHENAPHEN WITH CODEINE NO. 4 (acetaminophen; codeine phosphate) oral capsules, 325 mg and 60 mg, are the subject of ANDAs 084445 and 084446, held by Wyeth-Ayerst Laboratories, and both initially approved on July 22, 1975. PHENAPHEN WITH CODEINE NO. 3 and PHENAPHEN WITH CODEINE NO. 4 are indicated for the relief of mild to moderately severe pain.

In separate letters dated March 7, 2003, Wyeth-Ayerst requested withdrawal of ANDAs 084445 and 084446 for PHENAPHEN WITH CODEINE NO. 3 (acetaminophen; codeine phosphate) and PHENAPHEN WITH CODEINE NO. 4 (acetaminophen; codeine phosphate) in accordance with 21 CFR 314.150(c). In the **Federal Register** of May 5, 2004 (69 FR 25124), FDA announced that it was withdrawing approval of ANDAs 084445 and 084446, effective June 4, 2004.

LGM Pharma Solutions, LLC, submitted a citizen petition dated May 16, 2025 (Docket No. FDA–2025–P–1372), under 21 CFR 10.30, requesting that the Agency determine whether PHENAPHEN WITH CODEINE NO. 3 (acetaminophen; codeine phosphate) oral capsules, 325 mg and 30 mg, and PHENAPHEN W CODEINE NO. 4 (acetaminophen; codeine phosphate) oral capsules, 325 mg and 60 mg, were voluntarily withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that PHENAPHEN WITH CODEINE NO. 3 (acetaminophen; codeine phosphate) oral capsules, 325 mg and 30 mg, and PHENAPHEN W CODEINE NO. 4 (acetaminophen; codeine phosphate) oral capsules, 325 mg and 60 mg, were not withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that PHENAPHEN WITH CODEINE NO. 3 (acetaminophen; codeine phosphate) oral capsules, 325 mg and 30 mg, and PHENAPHEN W CODEINE NO. 4 (acetaminophen; codeine phosphate) oral capsules, 325 mg and 60 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of PHENAPHEN WITH CODEINE NO. 3 (acetaminophen; codeine phosphate) oral capsules, 325 mg and 30 mg, and PHENAPHEN W CODEINE NO. 4 (acetaminophen; codeine phosphate) oral capsules, 325 mg and 60 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that these drug products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PHENAPHEN WITH CODEINE NO. 3 (acetaminophen; codeine phosphate) oral capsules, 325 mg and 30 mg, and PHENAPHEN W CODEINE NO. 4 (acetaminophen; codeine phosphate) oral capsules, 325 mg and 60 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs for these drug products may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–18023 Filed 9–2–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Emergency Use Authorization Declaration

AGENCY: U.S. Department of Health and Human Services (HHS).

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 (FD&C) Act.* On July 15, 2026, the Secretary of War determined under the FD&C that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of an attack with a chemical, biological, radiological, or nuclear agent or agents; or an attack by an agent or agents that may cause, or are otherwise associated with an imminently life-threatening and specific risk to those forces. Injuries arising from these attacks may cause those forces to experience moderate to severe acute pain and place them at risk of developing life-threatening hemodynamic instability, including shock or respiratory distress. On the basis of this determination, the Secretary of HHS declared on August 31, 2026, pursuant to the FD&C Act, that circumstances exist justifying the authorization of emergency use of drugs identified and supported by the Department of War (DOW) as addressing an unmet military operations-related medical need for use to manage moderate to severe acute pain in casualties caused by, or associated with, an emergency involving biological, chemical, radiological, or nuclear agent or agents, or agents of military combat, including firearms, projectiles, and explosive devices, that may cause, or may otherwise be associated with, an imminently life-threatening and specific risk to U.S. military forces, subject to the terms of any authorization issued under that section.

DATES: The determination was effective July 15, 2026, and the declaration was effective August 31, 2026.

FOR FURTHER INFORMATION CONTACT: L. Paige Ezernack, telephone at (202) 260–

0365 or via email at *paige.ezernack@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under section 564 of the FD&C Act, HHS has the ability to take certain steps to help facilitate the availability of medical countermeasures based on one of four determinations under section 564(b): (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, chemical, biological, radiological, or nuclear (''CBRN'') agent or agents; (2) the identification of a material threat by the Secretary of the 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 [War] 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 CBRN 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 [of HHS] 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 declare that circumstances exist that justify the issuance of emergency use authorizations (EUAs), at which point the Commissioner of the U.S. Food and Drug Administration (FDA), acting under delegated authority from the Secretary of HHS, may issue an EUA or EUAs authorizing the emergency use of an unapproved medical product or an unapproved use of an approved medical product in certain emergency circumstances, if the criteria for issuance of an authorization under section 564 of the FD&C Act are met.

II. Determination by the Secretary of War

On July 15, 2026 the Secretary of War determined, pursuant to sec. 564(b)(1)(B) of the FD&C Act, that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of an attack with a chemical, biological, radiological, or nuclear agent or agents; or an attack by an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces (including agents of military combat such as firearms, projectiles, and explosive devices). Injuries arising from these attacks may cause U.S. military forces to experience moderate to severe acute pain and place them at risk of developing life-threatening hemodynamic instability, including shock or respiratory distress.

III. Declaration of the Secretary of HHS

On August 31, 2026, on the basis of the Secretary of War's determination that there is a military emergency or significant potential for a military emergency involving a heightened risk to U.S. military forces of an attack with an agent or agents that may cause, or are otherwise associated with an imminently life-threatening and specific risk to those forces, I declared that circumstances exist justifying the authorization of emergency use of drugs identified and supported by the DOW as addressing an unmet military operations-related medical need for use to manage moderate to severe acute pain in casualties caused by, or associated with, an emergency involving biological, chemical, radiological, or nuclear agent or agents, or agents of military combat, including firearms, projectiles, and explosive devices, that may cause, or may otherwise be associated with, an imminently life-threatening and specific risk to U.S. military forces, subject to the terms of any authorization issued under that section.

Notice of any EUAs issued by the FDA Commissioner pursuant to this determination and declaration will be provided promptly in the **Federal Register** as required under section 564 of the FD&C Act.

Robert F. Kennedy, Jr.,

Secretary, Health and Human Services.

[FR Doc. 2026–18008 Filed 9–2–26; 8:45 am]

BILLING CODE 4150–37–P

[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.''

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0955–0019]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the National Coordinator for Health IT, 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 collection for public comment.

DATES: Comments on the ICR must be received on or before October 5, 2026.

ADDRESSES: When commenting, please reference the document identifier/OMB control number OS–0955–0019 and title of collection, ''National Survey of Health Information Exchange Organizations (HIO)''. You may send your comments electronically to Wesley Barker, *wesley.barker@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: To obtain copies of supporting material for the proposed collection(s) summarized in this notice, please include the document identifier OS–0955–0019 and title of collection ''National Survey of Health Information Exchange Organizations (HIO)'' for reference, and address inquiries to Wesley Barker, *wesley.barker@hhs.gov.*

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 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: National Survey of Health Information Exchange Organizations (HIO).

Type of Collection: Revision of a previously approved collection.

OMB No. 0955–0019

Abstract: Electronic health information exchange (HIE) was one of three goals specified by Congress in the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act to ensure that the $30 billion federal