

NOTICE OF INTENT TO TERMINATE RECEIVERSHIPS—Continued

Fund	Receivership name	City	State	Date of appointment of receiver
10216	Riverside National Bank of Florida	Fort Pierce	FL	04/16/2010
10534	City National Bank New Jersey	Newark	NJ	11/01/2019

The liquidation of the assets for each receivership has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors. Based upon the foregoing, the Receiver has determined that the continued existence of the receiverships will serve no useful purpose. Consequently, notice is given that the receiverships shall be terminated, to be effective no sooner than thirty days after the date of this notice. If any person wishes to comment concerning the termination of any of the receiverships, such comment must be made in writing, identify the receivership to which the comment pertains, and be sent within thirty days of the date of this notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Section, 600 North Pearl, Suite 700, Dallas, TX 75201. No comments concerning the termination of the above-mentioned receiverships will be considered which are not sent within this timeframe.

(Authority: 12 U.S.C. 1819.)

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on September 1, 2026.

Jennifer M. Jones,

Deputy Executive Secretary.

[FR Doc. 2026-18050 Filed 9-2-26; 8:45 am]

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FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Benjamin W. McDonough, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than October 5, 2026.

A. Federal Reserve Bank of Richmond (Brent B. Hassell, Assistant Vice President) P.O. Box 27622, Richmond, Virginia 23261. Comments can also be sent electronically to Comments.applications@rich.frb.org:

1. *First Bancorp, Southern Pines, North Carolina*; to acquire First Carolina Bancshares Corporation, Florence, South Carolina, and thereby indirectly acquire Carolina Bank & Trust Company, Lamar, South Carolina.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2026-18058 Filed 9-2-26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-P-1372]

Determination That PHENAPHEN WITH CODEINE NO. 3 (Acetaminophen; Codeine Phosphate) Oral Capsules, 325 Milligrams and 30 Milligrams, and PHENAPHEN WITH CODEINE NO. 4 (Acetaminophen; Codeine Phosphate) Oral Capsules, 325 Milligrams and 60 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that PHENAPHEN WITH CODEINE NO. 3 (acetaminophen; codeine phosphate) oral capsules, 325 milligrams (mg) and 30 mg, and PHENAPHEN WITH CODEINE NO. 4 (acetaminophen; codeine phosphate) oral capsules, 325 mg and 60 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for 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, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993-0002, 301-796-8363, Stacy.Kane@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route

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]

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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-