

Atlanta, Georgia 30309. Comments can also be sent electronically to Applications.Comments@atl.frb.org:

1. *Washington State Bancshares, Inc. Employee Stock Ownership Trust, Karen Rowe trustee*; to become a bank holding company by acquiring additional voting shares of Washington State Bancshares, Inc., and thereby indirectly acquiring additional voting shares of Washington State Bank, all of Washington, Louisiana.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2026–20741 Filed 10–8–26; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

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 paragraph 7 of the Act.

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 26, 2026.

A. *Federal Reserve Bank of Kansas City* (Jeffrey Imgarten, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001. Comments can also be sent electronically to KCApplicationComments@kc.frb.org:

1. *David E. Rainbolt GST Trust, dated September 15, 1997, BancFirst as trustee, and Dana Kim Rainbolt, Adam Duston Rainbolt, Samuel Johnson Rainbolt, and Jacob Patrick Rainbolt as trust supervisors of the aforementioned trust, all of Oklahoma City, Oklahoma; and David and Kim Rainbolt Foundation and David E. Rainbolt, Dana Kim Rainbolt, Adam Duston Rainbolt, Samuel Johnson Rainbolt, and Jacob Patrick Rainbolt as directors of the aforementioned foundation, all of Oklahoma City, Oklahoma*; to join the Rainbolt Family Control Group, a group acting in concert, to retain voting shares of BancFirst Corporation, Oklahoma City, Oklahoma, and thereby indirectly retain voting shares of BancFirst, and Pegasus Bank, both of Dallas, Texas, and Worthington Bank, Arlington, Texas. David E. Rainbolt has previously been permitted by the Federal Reserve System to acquire voting shares of BancFirst Corporation and is a member of the Rainbolt Family Control Group. Dana Kim Rainbolt, Adam Duston Rainbolt, Samuel Johnson Rainbolt, and Jacob Patrick Rainbolt have been previously permitted by the Federal Reserve System to be members of the Rainbolt Family Control Group.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2026–20740 Filed 10–8–26; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–5816]

Elite Laboratories, Inc. et al.; Withdrawal of Approval of 16 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on June 3, 2026. The document announced the withdrawal of approval

of 16 abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of July 6, 2026. The document indicated that FDA was withdrawing approval of ANDA 207366 for ribavirin solution, 6 grams/vial, held by Navinta LLC, 1499 Lower Ferry Rd., Ewing, NJ 08618; ANDA 212957 for fosaprepitant dimeglumine powder, Equivalent to (EQ) 150 milligrams (mg) base/vial, held by Navinta LLC; and ANDA 218638 for nicardipine hydrochloride (HCl) capsule, 20 mg and 30 mg, held by Navinta LLC. Before FDA withdrew the approval of these ANDAs, Navinta LLC informed FDA that they did not want the approval of the ANDAs withdrawn. Because Navinta LLC timely requested that approval of the ANDAs not be withdrawn, the approval is still in effect. This notice removes the entries for ANDA 207366, ANDA 212957, and ANDA 218638.

FOR FURTHER INFORMATION CONTACT:

Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 301–796–3471, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Wednesday, June 3, 2026 (91 FR 33185), appearing on page 33185 in FR Doc. 2026–11062, the following correction is made:

On page 33185, in the table, the entries for ANDA 207366, ANDA 212957, and ANDA 218638 are removed.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–20730 Filed 10–8–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–10835]

Par Health USA LLC, U.S. Agent for PH Health Limited, et al.; Withdrawal of Approval of 37 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 37 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the

drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of November 9, 2026.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and

Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 301-796-3471, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in table 1 have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval

of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

TABLE 1—ANDAS FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Drug	Applicant
ANDA 071230	Ibuprofen tablet, 300 milligrams (mg)	Par Health USA LLC, U.S. Agent for PH Health Ltd., 300 Tice Blvd., Suite 230, Woodcliff Lake, NJ 07677.
ANDA 071229	Ibuprofen tablet, 200 mg	Do.
ANDA 071231	Ibuprofen tablet, 400 mg	Do.
ANDA 071232	Ibuprofen tablet, 600 mg	Do.
ANDA 071639	Ibuprofen tablet, 200 mg	Do.
ANDA 071644	Ibuprofen tablet, 400 mg	Do.
ANDA 072004	Ibuprofen tablet, 800 mg	Do.
ANDA 075659	AFEDITAB CR (nifedipine) extended-release tablet, 60 mg.	Watson Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.) 400 Interpace Parkway, Parsippany, NJ 07054.
ANDA 076024	Fluoxetine hydrochloride (HCl) tablet, equivalent to (EQ) 10 mg base.	Fosun Pharma USA Inc., 104 Carnegie Center, Suite 204, Princeton, NJ 08540.
ANDA 076191	Fexofenadine HCl tablet, 30 mg, 60 mg, and 180 mg.	Barr Laboratories, LLC. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals, USA, Inc.) 400 Interpace Parkway, Parsippany, NJ 07054.
ANDA 076236	FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE (Fexofenadine HCl; pseudoephedrine HCl) extended-release tablet, 60 mg; 120 mg.	Do.
ANDA 076334	PREVIFEM (ethinyl estradiol; norgestimate) tablet, 0.035 mg; 0.25 mg.	Par Health USA LLC, U.S. Agent for PH Health Ltd.
ANDA 076335	TRI-PREVIFEM (ethinyl estradiol; norgestimate) tablet, 0.035 mg, 0.035 mg, 0.035 mg; 0.18 mg, 0.215 mg, 0.25 mg.	Do.
ANDA 076337	CYCLAFEM 1/35 (ethinyl estradiol; norethindrone) tablet, 0.035 mg; 1 mg.	Do.
ANDA 076338	CYCLAFEM 7/7/7 (ethinyl estradiol; norethindrone) tablet, 0.035 mg, 0.035 mg, 0.035 mg; 0.5 mg, 0.75 mg, 1 mg.	Do.
ANDA 076675	EMOQUETTE (desogestrel; ethinyl estradiol) tablet, 0.15 mg; 0.03 mg.	Do.
ANDA 076681	KIMIDESS (desogestrel; ethinyl estradiol) tablet, 0.15 mg, N/A; 0.02 mg, 0.01 mg.	Do.
ANDA 077075	GILDESS 1.5/30 and GILDESS FE 1.5/30 (ethinyl estradiol; norethindrone acetate) tablet, 0.03 mg; 1.5 mg.	Do.
ANDA 077077	GILDESS 1/20 and GILDESS FE 1/20 (ethinyl estradiol; norethindrone acetate) tablet, 0.02 mg; 1 mg.	Do.
ANDA 077099	ORSYTHIA (ethinyl estradiol; levonorgestrel) tablet, 0.02 mg; 0.1 mg.	Do.
ANDA 077324	Levetiracetam tablet, 250 mg, 500 mg, 750 mg, and 1 gm.	Fosun Pharma USA Inc.
ANDA 077502	MYZILRA (ethinyl estradiol; levonorgestrel) tablet, 0.03 mg, 0.04 mg, 0.03 mg; 0.05 mg, 0.075 mg, 0.125 mg.	Par Health USA LLC, U.S. Agent for PH Health Ltd.
ANDA 078376	GILDAGIA (ethinyl estradiol; norethindrone) tablet, 0.035 mg; 0.4 mg.	Do.
ANDA 078712	CIPROFLOXACIN EXTENDED RELEASE (ciprofloxacin; ciprofloxacin HCl) extended-release tablet, 212.6 mg; EQ 287.5 mg base.	Fosun Pharma USA Inc.
ANDA 080326	Prednisolone tablet, 5 mg	Lachman Consultant Services, Inc., U.S. Agent for Heather Drug Company, 1600 Stewart Ave., Westbury, NY 11590
ANDA 080339	Prednisolone tablet, 5 mg	Fosun Pharma USA Inc.
ANDA 080832	Diphenhydramine HCl capsule, 25 mg and 50 mg.	Do.
ANDA 081249	ACETAMINOPHEN AND CODEINE PHOSPHATE (acetaminophen; codeine phosphate) tablet, 300 mg; 60 mg.	Do.

TABLE 1—ANDAS FOR WHICH APPROVAL IS WITHDRAWN—Continued

Application No.	Drug	Applicant
ANDA 081250	ACETAMINOPHEN AND CODEINE PHOSPHATE (acetaminophen; codeine phosphate) tablet, 300 mg; 30 mg.	Do.
ANDA 086398	BUTALBITAL, ASPIRIN AND CAFFEINE (aspirin; butalbital; caffeine) tablet, 325 mg; 50 mg; 40 mg.	Do.
ANDA 090293	GILDESS 24 FE (ethinyl estradiol; norethindrone acetate) tablet, 0.02 mg; 1 mg.	Par Health USA LLC, U.S. Agent for PH Health Ltd.
ANDA 091520	Bupropion HCl extended-release tablet, 150 mg	Do.
ANDA 203413	CYCLAFEM 0.5/35 (ethinyl estradiol; norethindrone) tablet, 0.035 mg; 0.5 mg.	Do.
ANDA 203911	FLUDEOXYGLUCOSE F18 (Fludeoxyglucose F-18) injectable, 4–500 millicurie/milliliter (mCi/mL).	Nukemed, Inc. dba SpectronRx, 17490 Dugdale Dr., South Bend, IN 46635.
ANDA 203912	Sodium fluoride F-18 injectable, 10–200 mCi/mL.	Do.
ANDA 204455	AMMONIA N 13 (ammonia N-13) injectable, 30 mCi-300 mCi/8 mL (3.75–37.5 mCi/mL).	Do.
ANDA 205699	Bosentan tablet, 62.5 mg and 125 mg	Par Health USA LLC, U.S. Agent for PH Health Limited, 9 Great Valley Parkway, Malvern, PA 19355.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of November 9, 2026. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved abbreviated new drug application violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in table 1 that are in inventory on November 9, 2026 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–20762 Filed 10–8–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–6667]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Biologics License Applications, Procedures and Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by November 9, 2026.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0338. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Biologics License Applications (BLAs), Procedures and Requirements

OMB Control Number 0910–0338—Extension

This information collection helps support implementation of statutory and regulatory requirements under the Public Health Service Act (PHS) and the Federal Food, Drug, and Cosmetic Act (FD&C Act) that govern biologics product licensing. The Food and Drug Administration (FDA) has promulgated regulations in 21 CFR parts 600–680 setting forth applicable standards and procedures that include associated reporting, recordkeeping, and -disclosure requirements. Respondents to the information collection are persons or entities who engage in manufacture of biologics. Respondents to this collection of information are licensed manufacturers of biological products. Based on existing data, we estimate there are 371 such respondents. We provide relevant information and resources on our website at <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber> regarding biologics license applications (BLAs).

Regulations in 21 CFR part 600, subparts A through C (21 CFR 600–600.21), and regulations in 21 CFR 601, subpart A (21 CFR 601.2–21 CFR 601.9) cover general provisions and prescribe requisite content and format elements for applications. Regulations in 21 CFR part 601, subpart C (21 CFR 601.12–21 CFR 601.29) pertain to BLA changes; the electronic submission of information; the suspension, revocation, and reissuance of BLAs; and also provide for