

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**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is

withdrawing approval of 16 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of July 6, 2026.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TABLE 1—ANDAS FOR WHICH APPROVAL IS WITHDRAWN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 040227	Phentermine hydrochloride (HCl) capsule, 30 milligrams (mg)	Elite Laboratories, Inc., 165/144/135 Ludlow Ave., Northvale, NJ 07647. Do.
ANDA 040460	Phentermine HCl capsule, 15 mg	AbbVie Inc., 1 N Waukegan Rd., North Chicago, IL 60064.
ANDA 065025	Cyclosporine solution, 100 mg/milliliters (mL)	Par Health USA LLC, U.S. Agent for PH Health Limited, 300 Tice Blvd., Suite 230, Woodcliff Lake, NJ 07677.
ANDA 075180	Ranitidine HCl tablet, Equivalent to (EQ) 150 mg and EQ 300 mg.	Sunstar Americas, Inc., 301 E Central Rd., Schaumburg, IL 60195.
ANDA 076434	PAROEX (chlorhexidine gluconate) solution, 0.12%	Par Health USA LLC, U.S. Agent for PH Health Limited, 9 Great Valley Parkway, Malvern, PA 19355.
ANDA 090734	OXYCODONE AND ACETAMINOPHEN (acetaminophen; oxycodone HCl) tablet, 325 mg; 7.5 mg and 325 mg; 10 mg.	eVenus Pharmaceutical Lab Inc., U.S. Agent for Jiangsu Hengrui Pharmaceuticals Co., Ltd., 506 Carnegie Center, Suite 102, Princeton, NJ 08540.
ANDA 204960	Cisatracurium besylate injectable, EQ 2 mg base/mL, CISATRACURIUM BESYLATE PRESERVATIVE FREE (cisatracurium besylate) injectable EQ 2 mg base/mL and EQ 10 mg base/mL.	Par Health USA LLC, U.S. Agent for PH Health Limited.
ANDA 206159	DEXTROAMP SACCHARATE, AMP ASPARTATE, DEXTROAMP SULFATE AND AMP SULFATE (amphetamine aspartate; amphetamine sulfate; dextroamphetamine saccharate; dextroamphetamine sulfate) (extended-release capsule, 1.25 mg; 1.25 mg; 1.25 mg; 1.25 mg, 2.25 mg; 2.25 mg; 2.25 mg; 2.25 mg, 3.75 mg; 3.75 mg; 3.75 mg; 3.75 mg, 5 mg; 5 mg; 5 mg, 6.25 mg; 6.25 mg; 6.25 mg; 6.25 mg, and 7.5 mg; 7.5 mg; 7.5 mg; 7.5 mg.	Navinta LLC, 1499 Lower Ferry Rd., Ewing, NJ 08618.
ANDA 207366	Ribavirin solution, 6 grams/vial	PTS Consulting, LLC, U.S. Agent for TP ANDA HOLDINGS, LLC., 6739 Valhalla Ct., Shawnee, KS 66217.
ANDA 210653	Clomipramine HCl capsule, 25 mg, 50 mg, and 75 mg	Makro Technologies Inc., (Makrocare) U.S. Agent for Aizant Drug Research Solutions Private Limited, 116 Village Blvd., Suite # 200, Princeton, NJ 08540.
ANDA 210948	Albuterol sulfate tablet, EQ 2 mg base and EQ 4 mg base	Eagle Pharmaceuticals, Inc., 50 Tice Blvd., Suite 315, Woodcliff Lake, NJ 07677.
ANDA 211538	Vasopressin solution, 20 units/mL	CMC GMP LLC, U.S. Agent for Pharmadax Inc., 9805 NE 116th St. PMB #A255, Kirkland, WA 98034.
ANDA 212106	Entecavir tablet, 0.5 mg and 1 mg	Navinta LLC.
ANDA 212957	Fosaprepitant dimeglumine powder, EQ 150 mg base/vial	CMC GMP LLC, U.S. Agent for Pharmadax Inc.
ANDA 214423	Venlafaxine HCl extended-release tablet, EQ 75 mg base and EQ 150 mg base.	Navinta LLC.
ANDA 218638	Nicardipine HCl capsule, 20 mg and 30 mg	Navinta LLC.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of July 6, 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 July 6, 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request Regular Clearance for the National Institute of Mental Health Data Archive (NDA), (NIMH)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and