4164-01-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

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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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Table 1.-- ANDAs for Which Approval Is Withdrawn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
ANDA 040460	Phentermine HCl capsule, 15 mg	Do.
ANDA 065025	Cyclosporine solution, 100	AbbVie Inc., 1 N. Waukegan Rd., North

Application No.	Drug	Applicant
	mg/milliliters (mL)	Chicago, IL 60064
ANDA 075180	Ranitidine HCl tablet, Equivalent to (EQ) 150 mg and EQ 300 mg	Par Health USA LLC, U.S. Agent for PH Health Limited, 300 Tice Blvd., Suite 230, Woodcliff Lake, NJ 07677
ANDA 076434	PAROEX (chlorhexidine gluconate) solution, 0.12%	Sunstar Americas, Inc., 301 E. Central Rd., Schaumburg, IL 60195
ANDA 090734	OXYCODONE AND ACETAMINOPHEN (acetaminophen; oxycodone HCl) tablet, 325 mg; 7.5 mg and 325 mg; 10 mg	Par Health USA LLC, U.S. Agent for PH Health Limited, 9 Great Valley Parkway, Malvern, PA 19355
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	eVenus Pharmaceutical Lab Inc., U.S. Agent for Jiangsu Hengrui Pharmaceuticals Co., Ltd., 506 Carnegie Center, Suite 102, Princeton, NJ 08540
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; 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	Par Health USA LLC, U.S. Agent for PH Health Limited
ANDA 207366	Ribavirin solution, 6 grams/vial	Navinta LLC, 1499 Lower Ferry Rd., Ewing, NJ 08618
ANDA 210653	Clomipramine HCl capsule, 25 mg, 50 mg, and 75 mg	PTS Consulting, LLC, U.S. Agent for TP ANDA HOLDINGS, LLC., 6739 Valhalla Ct., Shawnee, KS 66217
ANDA 210948	Albuterol sulfate tablet, EQ 2 mg base and EQ 4 mg base	Makro Technologies Inc., (Makrocare) U.S. Agent for Aizant Drug Research Solutions Private Limited, 116 Village Blvd., Suite # 200, Princeton, NJ 08540
ANDA 211538	Vasopressin solution, 20 units/mL	Eagle Pharmaceuticals, Inc., 50 Tice Blvd., Suite 315, Woodcliff Lake, NJ 07677
ANDA 212106	Entecavir tablet, 0.5 mg and 1 mg	CMC GMP LLC, U.S. Agent for Pharmadax Inc., 9805 NE 116th St. PMB #A255, Kirkland, WA 98034
ANDA 212957	Fosaprepitant dimeglumine powder, EQ 150 mg base/vial	Navinta LLC
ANDA 214423	Venlafaxine HCl extended-release tablet, EQ 75 mg base and EQ	CMC GMP LLC, U.S. Agent for Pharmadax Inc.

Application No.	Drug	Applicant
	150 mg base	
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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] 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. 2026-11062 Filed: 6/2/2026 8:45 am; Publication Date: 6/3/2026]