DEPARTM

Food and Drug Administration

[FDA-2025-N-3346]

Elite Laboratories, Inc., et al.; Withdrawal of Approval of 72 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 72 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of October 23, 2025.

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Table 1.-- ANDAs for Which Approval Is Withdrawn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 040228	Phentermine Hydrochloride (HCl) capsule, 37.5 milligrams (mg)	Elite Laboratories, Inc., 165/144/135 Ludlow Ave., Northvale, NJ 07647
ANDA 040538	Prednisone tablet, 2.5 mg	Hikma Pharmaceuticals USA Inc., U.S. Agent for Hikma Pharmaceuticals LLC, 1809 Wilson Rd., Columbus, OH 43228
ANDA 040890	Prednisone tablet, 1 mg	Do.
ANDA 063000	Polymyxin B Sulfate injectable, Equivalent to (EQ) 500,000 units base/vial	Adrastea Pharma LLC, 1008 S. Main St., Suite 225, Georgetown, TX 78626
ANDA 065175	Nystatin powder, 100,000 units/gram (gm)	Do.
ANDA 065177	Colistimethate Sodium injectable, EQ 150 mg base/vial	Nexus Pharmaceuticals, LLC, 400 Knightsbridge Parkway, Lincolnshire, IL 60069
ANDA 065455	Vancomycin HCl injectable, EQ 10 gm base/vial	Hospira, Inc., 275 North Field Dr., Building H1-3S, Lake Forest, IL 60045
ANDA 065511	Azithromycin injectable, EQ 500 mg base/vial	Do.
ANDA 070631	Valproic Acid capsule, 250 mg	Upsher-Smith Laboratories, LLC, 6701 Evenstad Dr., Maple Grove, MN 55369
ANDA 071425	DESOWEN (desonide) ointment, 0.05%	Galderma Laboratories, L.P., 2001 Ross Ave., Suite 1600, Dallas, TX 75201
ANDA 072354	DESOWEN (desonide) ointment, 0.05%	Do.
ANDA 072786	Fentanyl Citrate injectable, EQ 0.05 mg base/milliliter (mL)	Hospira, Inc.
ANDA 073045	Albuterol aerosol, metered, 0.9 mg/inhalation	Mylan Pharmaceuticals ULC (formerly Genpharm Inc.), 781 Chestnut Ridge Rd., Morgantown, WV 26505
ANDA 074332	Bumetanide injectable, 0.25 mg/mL	Hospira, Inc.
ANDA 074776	Timolol Maleate solution, EQ 0.5% base	Bausch & Lomb Inc., 400 Somerset Corporate Blvd., Bridgewater, NJ 08807
ANDA 074778	Timolol Maleate solution, EQ 0.25% base	Do.
ANDA 074912	Selegiline HCl tablet, 5 mg	Stason Pharmaceuticals, Inc., U.S. Agent for Kenton Chemicals and Pharmaceuticals Corp., 11 Morgan, Irvine, CA 92618
ANDA 074941	Diltiazem HCl injectable, 5 mg/mL	Hospira, Inc.
ANDA 074993	Ketorolac Tromethamine injectable, 30 mg/mL, and 15 mg/mL	Do.
ANDA 075505	Loratadine syrup, 1 mg/mL	Teva Pharmaceuticals USA, Inc., 400 Interpace Parkway, Building A, Parsippany, NJ 07054
ANDA 075940	Dacarbazine injectable, 200 mg/vial	Hospira, Inc.

Application No.	Drug	Applicant
ANDA 075962	Tramadol HCl tablet, 50 mg	Watson Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Parkway, Building A, Parsippany, NJ 07054
ANDA 076715	Modafinil tablets, 100 mg, and 200 mg	Do.
ANDA 076774	Haloperidol injectable, EQ 5 mg base/mL	Syneos Health, LLC, U.S. Agent for Gland Pharma Limited, 1030 Sync St., Morrisville, NC 27560
ANDA 078024	Ciprofloxacin in Dextrose, injectable, 5% in plastic container, 200 mg/100 mL, and 400 mg/200 mL	Baxter Healthcare Corp., One Baxter Parkway, Deerfield, IL 60015
ANDA 078030	Stavudine for solution, 1 mg/mL	Cipla USA, Inc., U.S. Agent for Cipla Limited, 10 Independence Blvd., Suite 300, Warren, NJ 07059
ANDA 078062	Ciprofloxacin injectable, 200 mg/20 mL (10 mg/ mL), and 400 mg/40mL (10 mg/mL)	Baxter Healthcare Corp.
ANDA 078084	Metronidazole in plastic container, injectable, 500 mg/100 mL	Do.
ANDA 078095	Zaleplon capsules, 5 mg, and 10 mg	Upsher-Smith Laboratories, LLC
ANDA 078213	Propranolol HCl tablets, 10 mg, 20 mg, 40 mg, 60 mg, and 80 mg	NorthStar Rx LLC, U.S. Agent for NorthStar Healthcare Holdings Limited, 4835 Crumpler Rd., Suite A, Memphis, TN 38141
ANDA 078253	Allopurinol tablets, 100 mg, and 300 mg	Do.
ANDA 079211	Ranitidine HCl syrup, EQ 15 mg base/mL	Morton Grove Pharmaceuticals Inc. / Wockhardt USA LLC, U.S. Agent for Wockhardt Limited, 6451 Main St., Morton Grove, IL 60053
ANDA 079212	Ranitidine HCl syrup, EQ 15 mg base/mL	Do.
ANDA 084399	Phendimetrazine Tartrate tablet, 35 mg	Upsher-Smith Laboratories, LLC
ANDA 088465	Prednisone tablet, 50 mg	Hikma Pharmaceuticals USA Inc., U.S. Agent for Hikma Pharmaceuticals LLC

Application No.	Drug	Applicant
ANDA 089804	Fluphenazine HCl tablets, 1 mg, 2.5 mg, 5 mg, and 10 mg	Prasco, LLC dba Prasco Laboratories, 6125 Commerce Ct., Mason, OH 45040
ANDA 090071	Venlafaxine HCl extended-release capsules, EQ 37.5 mg base, EQ 75 mg base, and EQ 150 mg base	Bausch Health US LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807
ANDA 090075	Epirubicin HCl injectable, 50 mg/25	Hisun Pharmaceuticals USA, Inc., U.S.

Application No.	Drug	Applicant
	mL (2 mg/mL), and 200 mg/100 mL (2 mg/mL)	Agent for Hisun Pharmaceutical (Hangzhou) Co., Ltd., 200 Crossing Blvd., 2nd floor, Bridgewater, NJ 08807
ANDA 090125	Nicardipine HCl injectable, 25 mg/10 mL (2.5 mg/mL)	Navinta LLC, 1499 Lower Ferry Rd., Ewing, NJ 08618
ANDA 090811	Bivalirudin injectable, 250 mg/vial	Hospira, Inc.
ANDA 091095	Nitrofurantoin capsules, 25 mg, 50 mg, and 100 mg	Actavis Laboratories FL, Inc., an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc., 400 Interpace Parkway, Building A, Parsippany, NJ 07054
ANDA 091152	Benztropine Mesylate injectable, 1 mg/mL	Luitpold Pharmaceuticals, Inc., One Luitpold Dr., P.O. Box 9001, Shirley, NY 11967
ANDA 091397	Levofloxacin injectable, EQ 250 mg/50 mL (EQ 5 mg/mL), EQ 750 mg/150 mL (EQ 5 mg/mL), and EQ 500 mg/100 mL (EQ 5 mg/mL)	Baxter Healthcare Corp.
ANDA 091596	Tranexamic Acid injectable, 100 mg/mL	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047
ANDA 091667	Misoprostol tablets, 0.1 mg, and 0.2 mg	Novel Laboratories Inc., 400 Campus Dr., Somerset, NJ 08873
ANDA 091671	Hydrocodone Polistirex and Chlorpheniramine Polistirex extended-release suspension, EQ 8 mg maleate/5 mL; EQ 10 mg bitartrate/5 mL	Neos Therapeutics, LP, 2940 N. Highway 360, Suite 400, Grand Prairie, TX 75050
ANDA 201634	Donepezil HCl tablets, 5 mg, and 10 mg	Indicus Pharma LLC, 2530 Meridian Parkway, Suite 300, Durham, NC 27713
ANDA 203106	Potassium Chloride extended-release capsules, 8 milliequivalent (mEq) and, 10 mEq	Upsher-Smith Laboratories, LLC
ANDA 203110	Hydralazine HCl injectable, 20 mg/mL	Adrastea Pharma LLC
ANDA 203665	Fludeoxyglucose F18 injectable, 20-500 millicurie (mCi)/mL	SOFIE Co. dba SOFIE, 21000 Atlantic Blvd., Suite 730, Dulles, VA 20166
ANDA 204403	Rivastigmine extended-release film, 4.6 mg/24 hours (hr), 9.5 mg/24 hr, and 13.3 mg/24 hr	Alvogen, Inc., 44 Whippany Rd., Suite 300, Morristown, NJ 07960
ANDA 204530	Sodium Fluoride F18 injectable, 10-200 mCi/mL	B&H Consulting Services, Inc., U.S. Agent for Hot Shots NM, LLC, 50 Division St., Suite 206, Somerville, NJ 08876
ANDA 204541	Sodium Fluoride F18 injectable, 10-200 mCi/mL	Essential Isotopes LLC, 1513 Research Park Dr., Columbia, MO 65211
ANDA 204667	Ammonia N 13 injectable, 18.8 mCi-	SOFIE Co. dba SOFIE

Application No.	Drug	Applicant
	188 mCi/5 mL (3.75-37.5 mCi/mL)	
ANDA 204860	Prochlorperazine Edisylate injectable, EQ 5 mg base/mL	Nexus Pharmaceuticals, LLC
ANDA 205901	Telmisartan tablets, 20 mg, 40 mg, and 80 mg	Hetero USA, Inc., U.S. Agent for Hetero Labs Ltd., Unit V, 1035 Centennial Ave., Piscataway, NJ 08854
ANDA 206071	Methocarbamol solution, 1 gram (gm)/10 mL (100 mg/mL)	Navinta LLC
ANDA 206468	Dicyclomine HCI injectable, 10 mg/mL	Nexus Pharmaceuticals, LLC
ANDA 206561	Indomethacin Sodium injectable, EQ 1 mg base/vial	Navinta LLC
ANDA 206681	Oxacillin Sodium injectable, EQ 1 gm base/vial, and EQ 2 gm base/vial	Piramal Critical Care, Inc., 3950 Schelden Circle, Bethlehem, PA 18017
ANDA 206724	Budesonide delayed-release capsule, 3 mg	Syneos Health, LLC, U.S. Agent for Natco Pharma Limited, 1030 Sync St., Morrisville, NC 27560
ANDA 206760	Oxacillin Sodium injectable, EQ 10 gm base/vial	Piramal Critical Care, Inc.
ANDA 208679	Fludeoxyglucose F 18 injectable, 20-300 mCi/mL	Memorial Sloan Kettering Cancer Center, 1275 York Ave., New York, NY 10065
ANDA 208878	Midazolam HCI injectable, EQ 5 mg base/mL	Fresenius Kabi USA, LLC
ANDA 210356	Haloperidol injectable, EQ 5 mg base/mL	Do.
ANDA-210774	Acyclovir ointment, 5%	Apotex Corp., U.S. Agent for Apotex Inc., 2400 North Commerce Pkwy., Suite 400, Weston, FL 33326
ANDA 211794	Acyclovir ointment, 5%	Cipla USA, Inc., U.S. Agent for Cipla Limited
ANDA 212775	Azelastine HCl spray, metered, 0.2055 mg/spray	Aurobindo Pharma USA, Inc., U.S. Agent for Aurobindo Pharma Ltd., 279 Princeton-Hightstown Rd., East Windsor, NJ 08520
ANDA 213247	Metformin HCI extended-release tablets, 500 mg, and 1 gm	Elity, LLC, U.S. Agent for TWi Pharmaceuticals, Inc., 175 SW 166th Ave., Pembroke Pines, FL 33027
ANDA 213394	Metformin HCI extended-release tablets, 500 mg, and 1 gm	PHL US Pharma LLC, U.S. Agent for Utopic Pharmaceuticals Inc., 3396 Kipling St., Palo Alto, CA 94306
ANDA 213823	Bortezomib injectable, 3.5 mg/vial	Baxter Healthcare Corp.
ANDA 214436	Pemetrexed Disodium powder, EQ 100 mg base/vial, and EQ 500 mg base/vial	Do.
ANDA 218354	Edaravone solution, 30 mg/100 mL (0.3 mg/mL)	Long Grove Pharmaceuticals LLC, 9450 W. Bryn Mawr Ave., Suite 200,

Application No.	Drug	Applicant
		Rosemont, IL 60018

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of October 23, 2025. 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 new drug application or ANDA 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 October 23, 2025 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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