4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-0020]

SpecGX LLC, et al.; Withdrawal of Approval of 30 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is withdrawing approval of 30 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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, 240-402-6980, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described 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.

Application No.	Drug	Applicant
ANDA 040163	Meperidine Hydrochloride (HCl) Preservative Free Injectable, 10 milligrams (mg)/milliliters (mL)	SpecGx LLC, 385 Marshall Ave., Webster Groves, MO 63119
ANDA 040352	Meperidine HCl Tablets, 50 mg and 100 mg	Do.
ANDA 040680	Oxycodone and Acetaminophen Solution, 325 mg/5 mL; 5 mg/5 mL	Do.

Application No.	Drug	Applicant
ANDA 040773	Benzphetamine HCl Tablets, 50 mg	Do.
ANDA 063002	Ancef in Plastic Container (cefazolin sodium) Injectable, Equivalent to (EQ) 10 mg base/mL and EQ 20 mg base/mL	Baxter Healthcare Corp., 1 Baxter Pkwy., Deerfield, IL 60015
ANDA 076280	Tizanidine HCl Tablets, EQ 2 mg base and EQ 4 mg base	Target Health LLC, U.S. Agent for CASI Pharmaceuticals, Inc., 450 Commerce Boulevard, Carlstadt, NJ 07072
ANDA 077021	Cilostazol Tablets, 100 mg	Do.
ANDA 077310	Cilostazol Tablets, 50 mg	Do.
ANDA 077517	Ondansetron HCl Tablets, EQ 4 mg base, EQ 8 mg base, and EQ 24 mg base	Do.
ANDA 078319	Sumatriptan Succinate Injectable, EQ 4 mg base/0.5 mL (EQ 8 mg base/mL) and EQ 6 mg base/0.5 mL (EQ 12 mg base/mL)	Antares Pharma, Inc., 100 Princeton South Corporate Center, Suite 300, Ewing, NJ 08628
ANDA 087748	Blephamide S.O.P (Prednisolone Acetate; Sulfacetamide Sodium) Ointment, 0.2%; 10%	Allergan Sales, LLC, 2525 Dupont Dr., Irvine, CA 92612
ANDA 087804	Butalbital, Acetaminophen, and Caffeine Tablets, 325 mg; 50 mg; 40 mg	SpecGx LLC
ANDA 087846	Imipramine HCl Tablets, 10 mg, 25 mg, and 50 mg	Do.
ANDA 090623	Ranitidine HCl Syrup, EQ 15 mg base/mL	Aurobindo Pharma USA, Inc., U.S. Agent for Aurobindo Pharma Ltd., 279 Princeton-Hightstown Rd., East Windsor, NJ 08520
ANDA 202321	Oxymorphone HCl Tablets, 5 mg, and 10 mg	SpecGx LLC
ANDA 202946	Oxymorphone HCl Extended-Release Tablets, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg	Do.
ANDA 204823	Cyproheptadine HCl Syrup, 2 mg/5 mL	Patrin Pharma, Inc., P.O. Box 1481, Skokie, IL 60076
ANDA 206672	Entecavir Tablets, 0.5 mg and 1 mg	Target Health LLC
ANDA 206710	Paricalcitol Capsules, 1 microgram (mcg), 2 mcg, and 4 mcg	Alvogen PB Research and Development LLC, U.S. Agent for Lotus Pharmaceutical Co., Ltd., Nantou Plant, 44 Whippany Rd, Suite 300, Morristown, NJ 07960
ANDA 207578	Ranitidine HCl Tablets, EQ 150 mg base	Aurobindo Pharma USA, Inc.
ANDA 207579	Ranitidine HCl Tablets, EQ 75 mg base	Do.
ANDA 209550	Tenofovir Disoproxil Fumarate Tablets, 300 mg	Target Health LLC
ANDA 209787	Methotrexate Sodium Tablets, EQ 2.5 mg base	Alvogen PB Research and Development LLC
ANDA 210228	Ranitidine HCl Tablets, EQ 150 mg base	PTS Consulting, LLC, U.S. Agent for THINQ Pharma-CRO Private Ltd., 6739 Vahalla Ct., Shawnee, KS 66217
ANDA 210250	Ranitidine HCl Tablets, EQ 75 mg	Do.

Application No.	Drug	Applicant
	base	
ANDA 211058	Ranitidine HCl Capsules, EQ 150 mg base and EQ 300 mg base	Aurobindo Pharma USA, Inc.
ANDA 212312	Sildenafil Citrate for Suspension, EQ 10 mg base/mL	Tris Pharma, Inc., 2033 Route 130, Suite D, Monmouth Junction, NJ 08852
ANDA 212626	Vigabatrin for Solution, 500 mg/packet	SpecGx LLC
ANDA 213456	Colesevelam HCl Tablets, 625 mg	SPH Phililab Inc., 5207 Militia Hill Rd., Suite 100, Plymouth Meeting, PA 19462
ANDA 215343	Fluticasone Propionate Ointment, 0.005%	BF Suma Pharmaceuticals Inc., U.S. Agent for Bright Future Pharmaceutical Laboratories Ltd., 5001 Earle Ave., Rosemead, CA 91770

Therefore, approval of the applications listed in the table, 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 the table. Introduction or delivery for introduction into interstate commerce of products listed in the table 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 the table 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.

Dated: March 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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