4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-4590]

Morton Grove Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 21 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 21 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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) (21CFR 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 040759	Phenytoin Sodium Capsules, 30milligrams (mg) (Extended)	Morton Grove Pharmaceuticals, Inc., 6451 Main St., Morton Grove, IL 60053
ANDA 062349	Nystatin Oral Suspension, 100,000 units/milliters (mL)	G&W Laboratories, Inc., 301 Helen St., South Plainfield, NJ 07080
ANDA 062483	Griseofulvin V (griseofulvin microsize) Oral Suspension, 125 mg/5 mL	Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807
ANDA 063264	Amikacin Sulfate Injection USP, Equivalent to (EQ) 250 mg base/mL	Hospira, Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045
ANDA 072655	Amantadine Hydrochloride (HCl) Syrup USP, 50 mg/5 mL	G&W Laboratories, Inc.
ANDA 074176	Cimetidine HCl Oral Solution, EQ 300 mg base/5 mL	Do.
ANDA 075366	Sotalol HCl Tablets USP 80 mg, 120 mg, 160 mg, and 240 mg	Upsher-Smith Laboratories, LLC, 6701 Evenstad Dr., Maple Grove, MN 55369
ANDA 075887	Fluvoxamine Maleate Tablets, 25 mg, 50 mg, and 100 mg	Do.
ANDA 076709	Fentanyl Extended-Release Film, 25 micrograms (mcg)/hr, 50 mcg/hr, 75 mcg/hr, 100 mcg/hr	Actavis Laboratories UT, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc, 577 Chipeta Way, Salt Lake City, UT 84108
ANDA 076841	Mesalamine Enema, 4 grams (gm)/60 mL	G&W Laboratories, Inc.
ANDA 077062	Fentanyl Extended-Release Film, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, and 100 mcg/hr	Mayne Pharma LLC, 1240 Sugg Parkway, Greenville, NC 27834
ANDA 078426	Zolpidem Tartrate Tablets, 5 mg and 10 mg	Morton Grove Pharmaceuticals Inc.
ANDA 078653	Ranitidine HCl Tablets USP, EQ 150 mg base	Do.
ANDA 078701	Ranitidine HCl Tablets USP, EQ 150 mg base and EQ 300 mg base	Do.
ANDA 078884	Ranitidine HCl Tablets USP, EQ 75 mg base	Do.
ANDA 087811	Phrenilin (acetaminophen and butalbital) Tablets, 325 mg/50 mg	Bausch Health US, LLC
ANDA 088761	Prometh VC Plain (promethazine HCl and phenylephrine HCl) Syrup, 5 mg/5mL, and 6.25 mg/5 mL	G&W Laboratories, Inc.

Application No.	Drug	Applicant
ANDA 088762	Prometh w/ Dextromethorphan (promethazine HCl and dextromethorphan hydrobromide) Syrup, 6.25 mg/5 mL and 15 mg/5 mL	Do.
ANDA 090786	Carbidopa, Entacapone, and Levodopa Tablets, 12.5 mg/200 mg/50 mg	Morton Grove Pharmaceuticals Inc.
ANDA 091267	Donepezil HCl Tablets, 5 mg and 10 mg	Do.
ANDA 201947	Morphine Sulfate Oral Solution, 10 mg/5 mL and 20 mg/5 mL	VistaPharm, Inc., 7265 Ulmerton Rd., Largo, FL 33771

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 or products inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (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: November 25, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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