4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-5843]

Pharmacia and Upjohn Co., et al.; Withdrawal of Approval of 19 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 19 new drug applications (NDAs) 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137.

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 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
NDA 004570	Heparin Sodium Injection, 1,000 units/milliliter (mL), 5,000 units/mL,	Pharmacia and Upjohn Co. (a subsidiary of Pfizer Inc.), 235 East 42nd St., New York,

	and 10,000 units/mL	NY 10017-7555
NDA 009838	Reserpine Tablets, 0.1 milligram (mg) and 0.25 mg	Sandoz Inc., 2555 W. Midway Blvd., Broomfield, CO 80020-1632
NDA 017063	Ismotic (isosorbide solution), 100 grams (g)/220 mL	Alcon Research, LLC, 6201 South Freeway, Fort Worth, TX 76134-2099
NDA 017521	Dextrose Injection, 0.2 g/mL, 0.3 g/mL, 0.4 g/mL, 0.5 g/mL, 0.6 g/mL, and 0.7 g/mL	Baxter Healthcare Corp., 1 Baxter Parkway, Deerfield, IL 60015
NDA 017690	Imodium (loperamide hydrochloride (HCl)) Capsules, 2 mg	Johnson and Johnson Consumer Inc., McNeil Consumer Healthcare Division, 7050 Camp Hill Rd., Fort Washington, PA 19034
NDA 017694	Imodium (loperaminde HCl) Capsules, 2 mg	Do.
NDA 018361	Serophene (clomiphene citrate) Tablets, 50 mg	EMD Serono, Inc., 1 Technology Pl., Rockland, MA 02370
NDA 020262	Taxol (paclitaxel) Injection, 6 mg/mL	HQ Specialty Pharma Corp., 120 Route 17 North, Paramus, NJ 07652
NDA 020264	Megace (megestrol acetate) Oral Suspension, 40 mg/mL	Bristol-Myers Squibb Co., P.O. Box 4000, Mail Stop: D.2341, Princeton, NJ 08543-4000
NDA 020413	Zerit (stavudine) for Oral Solution, 1 mg/mL	Do.
NDA 020823	Exelon (rivastigmine tartrate) Capsules, equivalent to (EQ) 1.5 mg base, EQ 3 mg base, EQ 4.5 mg base, and EQ 6 mg base	Novartis Pharmaceuticals Corp.
NDA 021025	Exelon (rivastigmine tartrate) Solution, EQ 2 mg base/mL	Do.
NDA 021217	Exalgo (hydromorphone HCl) Extended-Release Tablets, 8 mg, 12 mg, 16 mg, and 32 mg	SpecGx LLC, 385 Marshall Ave., Webster Groves, MO 63119
NDA 022046	Bupivacaine HCl and epinephrine bitartrate Injection, 0.5%/0.0091 mg/mL	Hospira, Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045
NDA 050632	Azactam (aztreonam) 10 mg/mL, 20 mg/mL, and 40 mg/mL	Bristol-Myers Squibb Co.
NDA 202342	Esomeprazole Strontium Delayed-Release Capsules, EQ 20 mg base and EQ 40 mg base	R2 Pharma, LLC, 11550 North Meridian St., Suite 290, Carmel, IN 46032-5505
NDA 207931	Technivie (ombitasvir, paritaprevir, and ritonavir) Tablets, 12.5 mg/75 mg/50 mg	AbbVie Inc., 1 North Waukegan Rd., Dept. PA77/Bldg. AP30, North Chicago, IL 60064
NDA 208603	Arymo ER (morphine sulfate) Extended-Release Tablets, 15 mg, 30 mg, and 60 mg	Zyla Life Sciences US Inc., 600 Lee Rd., Suite 100, Wayne, PA 19087

NDA 208624	Viekira XR (dasabuvir, ombitasvir, paritaprevir, and ritonavir) Extended-Release Tablets, 200 mg/8.33 mg/50 mg/33.33 mg	AbbVie Inc.

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 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: January 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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