4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2180]

Concordia Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 29 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 29 new drug applications (NDAs) from multiple applicants. The holders of the applications 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.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: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: The holders of the applications 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 011287	Kayexalate (sodium polystyrene sulfonate) Powder for Suspension, 453.6 gram (g)/bottle	Concordia Pharmaceuticals, Inc., c/o Mapi USA, Inc., 2343 Alexandria Dr., Lexington, KY 40504
NDA 012249	Librium (chlordiazepoxide hydrochloride (HCl)) Capsules, 5 milligram (mg), 10 mg, and 25 mg	Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807
NDA 016211	Miochol (acetylcholine chloride) for Ophthalmic Solution, 20 mg/vial	Novartis Pharmaceuticals Corp., One Health Pl., East Hanover, NJ 07936
NDA 018674	Metro I.V. (metronidazole) Injection, 500 mg/100 milliliter (mL)	B. Braun Medical, Inc., 901 Marcon Blvd., Allentown, PA 18109
NDA 018852	Sulfamethoxazole and Trimethoprim Tablets USP, 400 mg;80 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044
NDA 018854	Sulfamethoxazole and Trimethoprim Tablets USP, 800 mg;160 mg	Do.
NDA 018988	Vasocidin (prednisolone sodium phosphate and sulfacetamide sodium) Ophthalmic Solution, equivalent to (EQ) 0.23% phosphate/10%	Novartis Pharmaceuticals Corp.
NDA 019844	Isolyte H in Dextrose 5% in Plastic Container Injection	B. Braun Medical, Inc.
NDA 019870	Isolyte M in Dextrose 5% in Plastic Container Injection	Do.
NDA 019964	Terazol 3 (terconazole) Vaginal Cream, 0.8%	Janssen Pharmaceuticals, Inc., 1125 Trenton-Harbourton Rd., Titusville, NJ 08560
NDA 020000	Dextrose 5% in Ringer's in Plastic Container Injection	B. Braun Medical, Inc.
NDA 020393	Atrovent (ipratropium bromide) Nasal Spray, 0.021 mg/spray	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877-0368
NDA 020394	Atrovent (ipratropium bromide) Nasal Spray, 0.042 mg/spray	Do.
NDA 021180	Ortho Evra (ethinyl estradiol; norelgestromin) Transdermal Patch, 0.035 mg/24 h; 0.15 mg/24 h	Janssen Pharmaceuticals, Inc., 1000 U.S. Route 202, P.O. Box 300, Raritan, NJ 08869-0602
NDA 021633	Femtrace (estradiol acetate) Tablets, 0.45 mg, 0.9 mg, and 1.8 mg	Allergan Pharmaceuticals International, Ltd., c/o Allergan Sales, LLC, 2525 Dupont Dr., Irvine, CA 92612
NDA 022033	Luvox CR (fluvoxamine maleate) Extended-Release Capsules, 100 mg and 150 mg	Jazz Pharmaceuticals, Inc., 3180 Porter Dr., Palo Alto, CA 94304
NDA 022106	Doribax (doripenem) for Injection, 250 mg/vial and 500 mg/vial	Shionogi, Inc., 300 Campus Dr., Florham Park, NJ 07932
NDA 022386	PrandiMet (metformin HCl; repaglinide) Tablets, 500mg; 1 mg	Novo Nordisk, Inc., P.O. Box 846, Plainsboro, NJ 08536

Application No.	Drug	Applicant
	and 500 mg; 2 mg	
NDA 050201	Ophthocort (chloramphenicol, hydrocortisone acetate, polymyxin B sulfate) Ophthalmic Ointment USP, 10 mg/g; 5 mg/g; 10,000 units/g	Parkedale Pharmaceuticals, Subsidiary of Pfizer Inc., 235 East 42nd St., New York, NY 10017
NDA 050344	Statrol (neomycin sulfate; polymyxin B sulfate) Ophthalmic Ointment, EQ 3.5 mg base/g; 10,000 units/g	Alcon Laboratories, Inc., 6201 South Freeway, TC-45, Fort Worth, TX 76134
NDA 050442	Vibramycin (doxycycline hyclate) Injection, EQ to 200 mg base/vial and EQ 100 mg base/vial	Pfizer, Inc., 235 East 42nd St., New York, NY 10017
NDA 050497	Ticar (ticarcillin disodium) Injection, EQ 1 g base/vial, EQ 3 g base/vial, EQ 6 g base/vial, EQ 20 g base/vial, and EQ 30 g base/vial	GlaxoSmithKline, 1250 Collegeville Rd., Collegeville, PA 19426
NDA 050512	Duricef (cefadroxil monohydrate) USP Capsules, EQ 500 mg base and EQ 250 mg base	Warner Chilcott Co., LLC, 100 Enterprise Dr., Rockaway, NJ 07866
NDA 050527	Duricef (cefadroxil monohydrate) USP For Oral Suspension, EQ 125 mg base/5 mL, EQ 250 mg base/5 mL, and EQ 500 mg base/5 mL	Do.
NDA 050593	Eryc Sprinkles (erythromycin) Capsules, 125 mg	Hospira Inc., 275 North Field Dr., Lake Forest, IL 60045
NDA 050646	Ceptaz (ceftazidime) Injection, 500 mg/vial, 1 g/vial, 2 g/vial, and 10 g/vial	GlaxoSmithKline
NDA 050668	Lorabid (loracarbef) Capsules USP, 200 mg and 400 mg	King Pharmaceuticals, Inc., 501 Fifth St., Bristol, TN 37620
NDA 050792	Cefotaxime and Dextrose 2.4% in Plastic Container, EQ 2 g base, and Cefotaxime and Dextrose 3.9% in Plastic Container, EQ 1 g base	B. Braun Medical, Inc.
NDA 050807	Epirubicin HCl for Injection, 50 mg/vial, 200 mg/vial	Hospira, 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*]**. 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: July 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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