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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-3658]

Eli Lilly and Co., et al.; Withdrawal of Approval of 25 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 25 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.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 007529	Quinidine Gluconate Injection, 80 milligrams (mg)/milliliters (mL)	Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285
NDA 016096	Mintezol (thiabendazole) Chewable	Merck Sharp and Dohme Corp., a subsidiary

	Tablet, 500 mg	of Merck and Co., Inc., 1 Merck Dr., P.O. Box 100, Whitehouse Station, NJ 08889-0100
NDA 016097	Mintezol (thiabendazole) Suspension 500mg/5mL	Do.
NDA 017439	Hydroxyprogesterone Caproate Injection, 125 mg/mL and 250 mg/mL	Allergan Sales, LLC., 5 Giralda Farms, Madison, NJ 07940
NDA 017831	Didronel (etidronate disodium) Tablet, 200 mg and 400 mg	Allergan Pharmaceuticals International Limited, c/o Allergan Sales, LLC., 2525 Dupont Dr., Irvine, CA 92612
NDA 019081	Estraderm (estradiol transdermal system), 0.05 mg/24 hour (h) and 0.1 mg/24 h	Novartis Pharmaceuticals Corp., 1 Health Plaza, East Hanover, NJ 07936-1080
NDA 019596	Magnevist (gadopentetate dimeglumine) Injection, 469.01 mg/mL	Bayer HealthCare Pharmaceuticals, Inc., 100 Bayer Blvd., P.O. Box 915, Whippany, NJ 07981-0915
NDA 020071	Desogen (desogestrel and ethinyl estradiol) Tablets, 0.15 mg/0.03 mg	Organon USA, Inc., a subsidiary of Merck and Co., Inc., 2000 Galloping Hill Rd., Kenilworth, NJ 07033
NDA 020120	AllerNaze (triamcinolone acetonide) Nasal Spray, 0.05 mg/spray	Lupin Atlantis Holdings, S.A., c/o Lupin Pharmaceuticals, Inc., 111 South Calvert St., Harborplace Tower, 24th Floor, Baltimore, MD 21202
NDA 020628	Invirase (saquinavir mesylate) Capsules, equivalent to (EQ) 200 mg base	Hoffmann-La Roche, Inc., 1 DNA Way, South San Francisco, CA, 94080-4990
NDA 020937	Optimark (gadoversetamide) Injection, 330.9 mg/mL	Liebel-Flarsheim Co., LLC., 1034 South Brentwood Blvd., Suite 800, Richmond Heights, MO 63117
NDA 020947	Pennsaid (diclofenac sodium) Topical Solution, 1.5% weight by weight (w/w)	Nuvo Pharmaceuticals, Inc., c/o Dwayne R. J Moore, 41 Campus Dr., Suite 202, New Gloucester, ME 04260
NDA 020975	Optimark (gadoversetamide) Injection, 330.9 mg/mL	Liebel-Flarsheim Co., LLC
NDA 020976	Optimark (gadoversetamide) Injection, 330.9 mg/mL	Do.
NDA 021037	Magnevist (gadopentetate dimeglumine) Injection, 469.01 mg/mL	Bayer HealthCare Pharmaceuticals, Inc.
NDA 021105	Sulfamethoxazole and Trimethoprim Tablets, 800 mg/160 mg; and Phenazopyridine HCL Tablets, 200 mg	Able Laboratories, Inc., 1 Able Dr., Cranbury, NJ 08512
NDA 021144	Ketek (telithromycin) Tablets, 300 mg and 400 mg	Sanofi-Aventis U.S., LLC., 55 Corporate Dr., Bridgewater, NJ 08807
NDA 021178	Glucovance (glyburide and metformin hydrocholoride (HCl)) Tablets, 1.25 mg/250 mg, 2.5 mg/500 mg, 5 mg/ 500 mg	Bristol-Myers Squibb Co., P.O. Box 4000, Mail Stop: D.2341, Princeton, NJ 08543-4000
NDA 021235	Prozac Weekly (fluoxetine delayed-release capsules) 90 mg	Eli Lilly and Co.
NDA 021490	Femcon Fe (ethinyl estradiol and	Allergan Pharmaceuticals International

	norethindrone tablets, 0.035 mg/0.4 mg; and ferrous fumarate tablets, 75 mg)	Limited, c/o Allergan Sales, LLC., 5 Giralda Farms, Madison, NJ 07940
NDA 022011	Tyzeka (telbivudine) Tablets, 600 mg	Novartis Pharmaceuticals Corp.
NDA 022154	Tyzeka (telbivudine) Solution, 100 mg/5 mL	Do.
NDA 022328	Intermezzo (zolpidem tartrate) Sublingual Tablets, 1.75 mg and 3.5 mg	Purdue Pharmaceutical Products L.P., 1 Stamford Forum, Stamford, CT 06901-3431
NDA 050456	Statrol (neomycin sulfate and polymyxin B sulfate ophthalmic solution, USP) EQ 3.5 mg base/mL; equal to 16,250 units polymyxin B/mL	Alcon Laboratories, Inc., 6201 South Freeway, Mail Stop: TC-45, Fort Worth, TX 76134-2099
NDA 204553	ColPrep Kit (magnesium sulfate, potassium sulfate, and sodium sulfate) for Oral Solution, 1.6 grams (g)/3.13 g/17.5 g	Gator Pharmaceuticals, Inc., 194 Inlet Dr., Saint Augustine, FL 32080

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: September 3, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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