4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-1302]

Aspen Global Inc. c/o Lachman Consultant Services, Inc., et al.; Withdrawal of Approval of 46 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 46 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in table 1 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.

Table1.--NDAs for Which Approval Is Withdrawn

Application No.	Drug	Applicant
NDA 000552	Liquaemin Sodium (heparin sodium) injectable, 1,000 units/milliliter (mL), 5,000 units/mL, 10,000 units/mL, 20,000 units/mL, and 40,000 units/mL Liquaemin Sodium Preservative Free (heparin sodium) injectable, 1,000 units/mL, 5,000 units/mL, and 10,000 units/mL Liquaemin Lock Flush (heparin sodium) injectable, 100 units/mL Heparin Sodium (heparin sodium) injectable, 1,000 units/mL, 5,000 units/mL, and 10,000 units/mL	Aspen Global Inc. c/o Lachman Consultant Services, Inc., 1600 Stewart Ave., Westbury, NY 11590
NDA 008370	Bentyl (dicyclomine hydrochloride (HCl)) injectable, 10 milligrams (mg)/mL Bentyl Preservative Free (dicyclomine HCl) injectable, 10 mg/mL	AbbVie Inc., 1 N. Waukegan Rd., North Chicago, IL 60064
NDA 008943	Diamox (acetazolamide) tablets, 125 mg and 250 mg	Teva Branded Pharmaceutical Products R&D, Inc., 145 Brandywine Parkway, West Chester, PA 19380
NDA 011600	Triamcinolone Acetonide (triamcinolone acetonide) ointment, 0.025%, and 0.1%	Extrovis AG c/o Masuu Global Solutions LLC, 2255 Glades Rd., Suite 324A, Boca Raton, Fl 33431
NDA 012250	Carbocaine (mepivacaine HCl) injectable, 1%, 1.5%, and 2%	Hospira, Inc., a Pfizer company, 275 North Field Dr., Lake Forest, IL 60045
NDA 012623	Flagyl (metronidazole) tablets, 250 mg and 500 mg	Pfizer Inc., 66 Hudson Blvd. East, New York, NY 10001
NDA 017498	Micronase (glyburide) tablets, 1.25 mg, 2.5 mg, and 5 mg	Do.
NDA 017630	Sodium Iodide I-123 (sodium iodide I-123) capsules, 100	GE HealthCare, 3350 North Ridge Ave., Arlington Heights, IL 60004

	microcurie (μCi), 200 μCi, and solution, 2 millicurie (mCi)/mL	
NDA 017741	Florone (diflorasone diacetate) cream, 0.05%	Pfizer Inc.
NDA 017802	Lo/Ovral-28 (ethinyl estradiol; norgestrel) tablets, 0.03 mg; 0.3 mg	Wyeth Pharmaceuticals LLC c/o Pfizer Inc., 66 Hudson Blvd. East, New York, NY 10001
NDA 017948	Norminest Fe (tablets, ethinyl estradiol; norethindrone, 0.035 mg;0.5 mg, and tablets, ferrous fumarate, 75 mg)	Pfizer Inc.
NDA 018647	Corzide (bendroflumethiazide; nadolol) tablets, 5 mg;40 mg and 5 mg;80 mg	King Pharmaceuticals LLC, c/o Pfizer Inc., 66 Hudson Blvd. East, New York, NY 10001
NDA 018799	Protopam (pralidoxime chloride) injectable, 300 mg/mL	Baxter Healthcare Corp., 25212 W. Illinois Route 120, Round Lake, IL 60073
NDA 018926	Norquest Fe (tablets, ethinyl estradiol; norethindrone, 0.035 mg;1 mg, and tablets, ferrous fumarate, 75 mg)	Pfizer Inc.
NDA 018947	Sodium Lactate in Plastic Container (sodium lactate), injectable, 50 milliequivalents (mEq)/mL	Hospira, Inc.
NDA 019190	Triphasil-28 (ethinyl estradiol; levonorgestrel) tablets, 0.03 mg;0.05 mg, tablets, 0.04 mg;0.075 mg, and tablets, 0.03 mg;0.125mg	Wyeth Pharmaceuticals c/o Pfizer Inc.
NDA 019192	Triphasil-21 (ethinyl estradiol; levonorgestrel) tablets, 0.03 mg;0.05 mg, tablets, 0.04 mg;0.075 mg, and tablets, 0.03 mg;0.125mg	Do.
NDA 019885	Accupril (quinapril HCl) tablets, equivalent to (EQ) 5 mg base, EQ 10 mg base, EQ 20 mg base, and EQ 40 mg base	Pfizer Inc.
NDA 019941	Emla (lidocaine; prilocaine) cream, 2.5%; 2.5%	Teva Branded Pharmaceutical Products R&D Inc.
NDA 019966	Temovate (clobetasol propionate) solution, 0.05%	Fougera Pharmaceuticals Inc., c/o Sandoz (a subsidiary of Novartis), 100 College Rd., West, Princeton, NJ 08540
NDA 020051	Glynase (glyburide) tablets,	Pfizer Inc.

	1.5 mg, 3 mg, 4.5 mg, and 6 mg	
NDA 020125	Accuretic (hydrochlorothiazide; quinapril HCl) tablets, 12.5 mg;EQ 10 mg base, 12.5 mg;EQ 20 mg base, and 25 mg;EQ 20 mg base	Do.
NDA 020430	Orgaran (danaparaoid sodium) injectable, 750 units/0.6 mL	Aspen Global Inc. c/o Lachman Consultant Services, Inc.
NDA 020682	Glyset (miglitol) tablets, 25 mg, 50 mg, and 100 mg	Pfizer Inc.
NDA 020859	Sonata (zaleplon) capsules, 5 mg and 10 mg	Do.
NDA 020862	Hectorol (doxercalciferol) capsules, 0.5 microgram (mcg), 1 mcg, and 2.5 mcg	Genzyme Corp., a Sanofi company, 450 Water St., Cambridge, MA 02141
NDA 020868	Flagyl ER (metronidazole) extended-release tablet, 750 mg	Pfizer Inc.
NDA 021350	Triglide (fenofibrate) tablets, 50 mg and 160 mg	Jagotec AG c/o. ICON, 731 Arbor Way, Suite 100, Blue Bell, PA 19422
NDA 021520	Symbyax (fluoxetine HCl; olanzapine) capsules, EQ 25 mg base;EQ 3 mg base, EQ 25 mg base;EQ 6 mg base, EQ 25 mg base;EQ 12 mg base, EQ 50 mg base;EQ 6 mg base, and EQ 50 mg base;EQ 12 mg base	Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285
NDA 021688	Sensipar (cinacalcet HCl) tablets, EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base	Amgen, Inc., 1 Amgen Center Dr., Thousand Oaks, CA 91320-1799
NDA 022200	Bydureon (exenatide synthetic) extended-release injection for suspension, 2 mg/vial Bydureon Pen (exenatide synthetic) extended-release injection for suspension, 2 mg	AstraZeneca Pharmaceuticals LP, 1800 Concord Pike, Wilmington, DE 19803
NDA 050168	Cortisporin (bacitracin zinc; hydrocortisone; neomycin sulfate; polymyxin B sulfate) ointment, 400 units/gram (g); 1%; EQ 3.5 mg base/g; 5,000 units/g	Monarch Pharmaceuticals, LLC c/o Pfizer Inc., 66 Hudson Blvd. East, New York, NY 10001
NDA 050218	Cortisporin (hydrocortisone acetate; neomycin sulfate; polymyxin B sulfate) cream,	Do.

	0.5%; EQ 3.5 mg base/g; 10,000 units/g	
NDA 050420	Rifadin (rifampin) capsules, 150 mg and 300 mg	Sanofi-Aventis U.S. LLC, a Sanofi company, 55 Corporate Dr., Bridgewater, NJ 08807
NDA 050479	Cortisporin (hydrocortisone; neomycin sulfate; polymyxin B sulfate) otic solution/drops, 1%; EQ 3.5 mg base/mL; 10,000 units/mL	Monarch Pharmaceuticals, LLC c/o Pfizer Inc.
NDA 050533	Vibra-Tabs (doxycycline hyclate) tablet, EQ 100 mg base	Pfizer Inc.
NDA 050661	Idamycin (idarubicin HCL) powder, 5 mg/vial, 10 mg/vial, and 20 mg/vial	Pfizer Inc.
NDA 050705	Rifater (isoniazid; pyrazinamide; rifamin) tablets, 50 mg; 300 mg; 120 mg	Sanofi-Aventis U.S. LLC, a Sanofi company, 100 Morris St., Morristown, NJ 07960
NDA 201657	Paricalcitol (paricalcitol) solution, 0.002 mg/mL (0.002 mg/mL), 0.005 mg/mL (0.005 mg/mL), and 0.01 mg/2 mL (0.005 mg/mL)	Hospira, Inc.
NDA 204016	Zoledronic Acid (zoledronic acid) solution, EQ 4 mg base/100 mL (EQ 0.04 mg base/mL)	Do.
NDA 204300	Vazculep (phenylephrine HCL) solution, 10 mg/mL (10 mg/mL), 50 mg/5 mL (10 mg/mL), and100 mg/10 mL (10 mg/mL)	Exela Pharma Sciences, LLC, P.O. Box 818, 1245 Blowing Rock Blvd., Lenoir, NC 28645
NDA 207202	Abilify MyCite Kit (aripiprazole) tablets, 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg	Otsuka Pharmaceutical Co., Ltd., c/o Otsuka Pharmaceutical Development & Commercialization, Inc., 2440 Research Blvd., Rockville, MD 208500
NDA 208614	Doxercalciferol (doxercalciferol) injectable, 4 mcg/2 mL (2 mcg/mL) and 10 mcg/5 mL (2 mcg/mL)	Hospira, Inc.
NDA 209210	Bydureon BCise (exenatide synthetic) extended-release injection suspension, 2 mg/0.85 mL	AstraZeneca Pharmaceuticals LP
NDA 209269	Minolira (minocycline HCl) extended-release tablets, EQ 105 mg base and EQ 135 mg	EPI Health, LLC, 174 Meeting St., Suite 200, Charleston, SC 29401

	base	
NDA 209607	Azedra (iobenguane I- 131) solution, 15 mCi/mL	Progenics Pharmaceuticals, Inc., a Lantheus company, 201 Burlington Rd., South Building, Bedford, MA 01730

Therefore, approval of the applications listed in table 1, 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 included in the application but inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved NDA 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 table 1 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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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