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4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0190]

Abbott Laboratories et al.; Withdrawal of Approval of 35 New Drug Applications and 64 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 35 new drug applications (NDAs) and 64 abbreviated new drug applications (ANDAs) 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

EFFECTIVE DATE: [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: The holders of the applications listed in table 1 in this document 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.

Table 1

Application No.	Drug	Applicant
NDA 005545	Dicumarol Tablets	Abbott Laboratories, PA77/Bldg. AP30-1E, 200 Abbott Park Rd., Abbott Park, IL 60064-6157
NDA 005845	Benadryl (diphenhydramine hydrochloride (HCl)), Benadryl with Ephedrine Sulfate, and Caladryl (diphenhydramine HCl and calamine)	McNeil Consumer Healthcare, Division of McNeil-PPC, Inc., 7050 Camp Hill Rd., Fort Washington, PA 19034-2299
NDA 006146	Benadryl (diphenhydramine HCl)) Injection	Do.
NDA 006773	Artane (trihexyphenidyl HCl) Tablets and Capsules and Artane (trihexyphenidyl) Elixir	Lederle Laboratories, d/b/a Wyeth Pharmaceuticals, P.O. Box 8299, Philadelphia, PA 19101-8299
NDA 009486	Benadryl (diphenhydramine HCl)) Injection Preservative Free	McNeil Consumer Healthcare
NDA 010021	Placidyl (ethchlorvynol) Capsules	Abbott Laboratories, 200 Abbott Park Rd., Abbott Park, IL 60064

Application No.	Drug	Applicant
NDA 011552	Stelazine (trifluoperazine HCl)	GlaxoSmithKline, P.O. Box 13398, Five Moore Dr., Research Triangle Park, NC 27709-3398
NDA 012524	Enduron (methyclothiazide) Tablets, 2.5 milligrams (mg) and 5 mg	Abbott Laboratories, PA77/Bldg. AP30-1E, 200 Abbott Park Rd., Abbott Park, IL 60064-6157
NDA 012775	Enduronyl and Enduronyl Forte (methyclothiazide and deserpidine) Tablets	Do.
NDA 014684	Aventyl (nortriptyline HCl) Capsules	Eli Lilly and Co., Lilly Corp. Center, Indianapolis, IN 46285
NDA 017577	Ditropan (oxybutynin chloride) Tablets	Janssen Pharmaceuticals Inc., c/o Johnson & Johnson Pharmaceutical Research and Development, LLC, 920 Route 202, P.O. Box 300, Raritan, NJ 08869
NDA 018473	Ventolin (albuterol) Inhalation Aerosol[1]	GlaxoSmithKline
NDA 018557	Fansidar (sulfadoxine and pyrimethamine)Tablets, 500 mg and 25 mg	Hoffman-La Roche, Inc., 340 Kingsland St., Nutley, NJ 07110-1199
NDA 018709	Capozide (captopril and hydrochlorothiazide) Tablets	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543-4000
NDA 018814	Heparin Sodium in 5% Dextrose Injection	Baxter Healthcare Corp., 1620 Waukegan Rd., MPGR-AL, McGaw Park, IL 60085

Application No.	Drug	Applicant
NDA 019297	Novantrone (mitoxantrone HCl) Injection	EMD Serono, One Technology Place, Rockland, MA 02370
NDA 019508	Axid (nizatidine) Capsules	SmithKline Beecham Corp., d/b/a GlaxoSmithKline, P.O. Box 13398, Five Moore Dr., Research Triangle Park, NC 27709-3398
NDA 019915	Monopril (fosinopril sodium) Tablets, 10 mg, 20 mg, and 40 mg	Bristol-Myers Squibb Co.
NDA 019946	Nuromax (doxacurium chloride) Injection 1 mg/milliliter (mL)	Abbott Laboratories, P76/Bldg. AP30-1E, Abbott Park, IL 60064-6157
NDA 019960	Manoplax (flosequinan) Tablets,	Do.
NDA 020057	Ceredase (alglucerase) Injection	Genzyme Corp., 500 Kendall St., Cambridge, MA 02142
NDA 020088	Norplant System (levonorgestrel) Implants	Wyeth Pharmaceuticals, Inc., P.O. Box 8299, Philadelphia, PA 19101-8299
NDA 020101	Prozac (fluoxetine HCl) Oral Solution, 20 mg/5 mL	Eli Lilly and Co.,
NDA 020236	Serevent (salmeterol xinafoate) Inhalation Aerosol[1]	GlaxoSmithKline
NDA 020286	Monopril-HCT (fosinopril sodium and hydrochlorothiazide) Tablets, 20 mg/12.5 mg and 10 mg/12.5 mg	Bristol-Myers Squibb Co.
NDA 020403	Zofran (ondansetron HCl)	Glaxo Wellcome Manufacturing Pte Limited, d/b/a GlaxoSmithKline,

Application No.	Drug	Applicant
	Injection	1250 Collegeville Rd., UP4110, Collegeville, PA 19426
NDA 020627	Norplant II System (levonorgestrel) Implants	Wyeth Pharmaceuticals, Inc.
NDA 020828	Fortovase (saquinavir) Capsules, 200 mg	Hoffman-La Roche, Inc.
NDA 020860	Levlite (ethinyl estradiol and levonorgestrel) Tablets	Bayer HealthCare Pharmaceuticals Inc., P.O. Box 1000, Montville, NJ 07045
NDA 020984	Raplon (rapacuronium bromide) for Injection	Organon USA Inc., 2000 Galloping Hill Rd., Kenilworth, NJ 07033
NDA 021120	Novantrone (mitoxantrone HCl) Injection	EMD Serono
NDA 021793	Reglan ODT (metoclopramide) Tablets	Meda Pharmaceuticals Inc., 200 North Cobb Parkway, Suite 428, Marietta, GA 30062
ANDA 040207	Prochlorperazine Maleate Tablets USP, 5 mg and 10 mg	Duramed Pharmaceuticals, Inc., 400 Chestnut Rd., Woodcliff Lake, NJ 07677
ANDA 040231	Chlorpromazine HCl Oral Concentrate USP, 30 mg/mL	Pharmaceutical Associates, Inc., 201 Delaware St., Greenville, SC 29605
NDA 050526	Staticin (erythromycin) Topical Solution, 1.5%	Bristol-Myers Squibb Co.
NDA 050687	Banan (cefpodoxime proxetil) Tablets, 100 mg and 200 mg	Daiichi Sankyo, Inc., 399 Thornall St., 11th Floor, Edison, NJ 08837

Application No.	Drug	Applicant
NDA 050688	Banan (cefpodoxime proxetil) Granules for Oral Suspension, 50 mg/5 mL and 100 mg/5 mL	Do.
ANDA 064098	Amikacin Sulfate Injection USP, 250 mg (base) /mL	Hospira, Inc., 275 North Field Dr., Bldg. H2-2, Lake Forest, IL 60045
ANDA 064106	Mitomycin for Injection USP, 20 mg Vial	Do.
ANDA 070505	Metoclopramide Injection USP, 5 mg/mL	Do.
ANDA 070506	Metoclopramide Injection USP, 5 mg/mL	Do.
ANDA 070566	Nitropress (sodium nitroprusside for Injection USP), 50 mg	Do.
ANDA 071015	Haloperidol Oral Solution USP, 2 mg/mL	Teva Pharmaceuticals USA, 1090 Horsham Rd., P.O. Box 1090, North Wales, PA 19454
ANDA 071554	Thiothixene HCl Oral Solution USP, 5 mg/mL	Do.
ANDA 073058	Fluphenazine HCl Oral Solution USP, 5 mg/mL	Do.
ANDA 073479	Pentamidine Isethionate for Injection, 300 mg Vial	Hospira, Inc.
ANDA 074636	Iopamidol Injection USP, 41%,	Do.

Application No.	Drug	Applicant
	51%, 61%, 76%	
ANDA 074898	Iopamidol Injection USP, 41%, 51%, 61%, 76%	Do.
ANDA 075065	Acyclovir Sodium for Injection	Do.
ANDA 075176	Haloperidol Decanoate Injection, 50 mg/mL and 100 mg/mL	Do.
ANDA 075409	Midazolam HCl Injection, 1 mg (base)/mL and 5 mg (base)/mL	Do.
ANDA 075884	Milrinone Lactate Injection, 1 mg/mL	Do.
ANDA 076306	Topiramate Tablets, 25 mg, 50 mg, 100 mg, and 200 mg	Roxane Laboratories, Inc., 1809 Wilson Rd., Columbus, OH 43228
ANDA 077138	Ciprofloxacin Injection USP in 5% Dextrose Injection	Teva Pharmaceuticals USA
ANDA 077223	Terbinafine HCl Tablets, 250 mg (base)	Roxane Laboratories, Inc.
ANDA 077784	Risperidone Tablets, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg	Ratiopharm Inc., c/o Columbia Pharma Consulting Services Inc., 490 Northwest Datewood Dr., Suite 400, Issaquah, WA 98027
ANDA 078241	Sumatriptan Succinate Tablets, 25 mg, 50 mg, and 100 mg (base)	Roxane Laboratories, Inc.
ANDA 078318	Sumatriptan Injection, 4 mg (base)/0.5 mL and 6 mg (base)/0.5 mL	TEVA Parenteral Medicines, Inc., 19 Hughes, Irvine, CA 92618

Application No.	Drug	Applicant
ANDA 078416	Prednisolone Sodium Phosphate Oral Solution, 5 mg (base)/5 mL	Vintage Pharmaceuticals, 120 Vintage Dr., Huntsville, AL 35811
ANDA 078517	Venlafaxine HCl Tablets, 25 mg (base), 37.5 mg (base), 50 mg (base), 75 mg (base), and 100 mg (base)	PLIVA Hrvatska d.o.o., c/o Barr Laboratories, Inc., 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677
ANDA 080997	Succinylcholine Chloride Injection USP, 20 mg/mL	Organon USA Inc.
ANDA 081125	Dexamethasone Sodium Phosphate Injection USP, 4 mg/mL	TEVA Parenteral Medicines, Inc., 19 Hughes, Irvine, CA 92618
ANDA 081126	Dexamethasone Sodium Phosphate Injection USP	Do.
ANDA 081298	Chlorzoxazone Tablets, 250 mg	Ranbaxy Inc., U.S. Agent for Ohm, 600 College Rd. East, Princeton, NJ 08540
ANDA 081299	Chlorzoxazone Tablets, 500 mg	Do.
ANDA 081310	Fluphenazine HCl Elixir USP, 2.5 mg/5 mL	Teva Pharmaceuticals USA
ANDA 087005	Trichlormethiazide Tablets, 4 mg	Par Pharmaceutical, Inc., One Ram Ridge Rd., Spring Valley, NY 10977
ANDA 087007	Trichlormethiazide Tablets, 2 mg	Do.

Application No.	Drug	Applicant
ANDA 087032	Chlorpromazine HCl Oral Concentrate USP, 30 mg/mL	Morton Grove Pharmaceuticals, Inc., U.S. Agent for Wockhardt EU Operations (Swiss) AG, 6451 West Main St., Morton Grove, IL 60053
ANDA 087053	Chlorpromazine HCl Oral Concentrate USP, 100 mg/mL	Do.
ANDA 087406	Oxycodone and Acetaminophen Tablets USP, 5 mg/325 mg	Barr Laboratories, Inc., 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677
ANDA 087585	Potassium Chloride for Injection Concentrate USP, 2 mEq/mL	Luitpold Pharmaceuticals, Inc., One Luitpold Dr., P.O. Box 9001, Shirley, NY 11967
ANDA 088143	Trifluoperazine Oral Solution USP, 10 mg/mL	Morton Grove Pharmaceuticals, Inc., U.S. Agent for Wockhardt EU Operations (Swiss) AG
ANDA 088194	Thioridazine HCl Tablets USP, 50 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677
ANDA 088227	Thioridazine HCl Oral Solution USP (Concentrate), 100 mg/mL	Morton Grove Pharmaceuticals, Inc., U.S. Agent for Wockhardt EU Operations (Swiss) AG
ANDA 088258	Thioridazine HCl Oral Solution USP (Concentrate), 30 mg/mL	Do.
ANDA 088270	Thioridazine HCl Tablets USP, 10 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA

Application No.	Drug	Applicant
ANDA 088271	Thioridazine HCl Tablets USP, 15 mg	Do.
ANDA 088272	Thioridazine HCl Tablets USP, 25 mg	Do.
ANDA 088273	Thioridazine HCl Tablets USP, 100 mg	Do.
ANDA 088456	Thioridazine HCl Tablets USP, 100 mg	Teva Pharmaceuticals USA
ANDA 088493	Thioridazine HCl Tablets USP, 10 mg	Do.
ANDA 088850	Hydroflumethiazide Tablets USP, 50 mg	Par Pharmaceutical, Inc.
ANDA 088907	Reserpine and Hydroflumethiazide Tablets, 0.125 mg/50 mg	Do.
ANDA 088933	Sulfinpyrazone Tablets, 100 mg	Do.
ANDA 088934	Sulfinpyrazone Capsules USP, 200 mg	Do.
ANDA 089135	Methyclothiazide Tablets, 2.5 mg	Do.
ANDA 089136	Methyclothiazide Tablets, 5 mg	Do.
ANDA 089173	A-MethaPred (methylprednisolone sodium	Hospira, Inc.

Application No.	Drug	Applicant
	succinate for injection USP), 500 mg (base)/Vial	
ANDA 089174	A-MethaPred (methylprednisolone sodium succinate for injection USP), 1 gram (base)/Vial	Do.
ANDA 089207	Methylprednisolone Tablets USP, 16 mg	Par Pharmaceutical, Inc.
ANDA 089208	Methylprednisolone Tablets USP, 24 mg	Do.
ANDA 089209	Methylprednisolone Tablets USP, 32 mg	Do.
ANDA 089457	Perphenazine Tablets USP, 16 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA
ANDA 089602	Thioridazine HCl Oral Solution USP, 30 mg/mL	Teva Pharmaceuticals USA
ANDA 089603	Thioridazine HCl Oral Solution USP, 100 mg/mL	Do.
ANDA 089624	Reversol (edrophonium chloride injection USP), 10 mg/mL)	Organon USA Inc.
ANDA 089657	Methocarbamol and Aspirin Tablets, 400 mg/325 mg	Par Pharmaceutical, Inc.
ANDA 089708	Perphenazine Tablets USP, 4 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA

[1] This product included an oral pressurized metered-dose inhaler that contained chlorofluorocarbons (CFCs) as a propellant. CFCs may no longer be used as a propellant for any albuterol or salmeterol metered-dose inhalers (see 70 FR 17168, April 4, 2005; 71 FR 70870, December 7, 2006).

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner, approval of the applications listed in table 1 in this document, and all amendments and supplements thereto, is hereby withdrawn, effective [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 FD&C Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in table 1 in this document that are in inventory on the date that this notice becomes effective (see the DATES

section) 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: February 16, 2012.

Janet Woodcock,

Director,

Center for Drug Evaluation and Research.

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