



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3432]

Organon USA Inc. et al.; Withdrawal of Approval of 67 New Drug Applications and 128

Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 67 new drug applications (NDAs) and 128 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.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: 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 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 001104	Doca (desoxycorticosterone acetate) Injection, 5 milligrams (mg)/milliliter (mL)	Organon USA Inc., Subsidiary of Merck Sharp & Dohme Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033
NDA 004589	Alcohol in Dextrose Injection USP, 10 mL/100 mL and 5 grams (g)/100 mL	B. Braun Medical Inc., 901 Marcon Blvd., Allentown, PA 18109
NDA 006170	Hyprotigen (modified protein hydrolysate) Injection, 5%	Do.
NDA 012154	Ureaphil (urea) for Injection, 40 g/vial	Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045
NDA 012449	Oratrol (dichlorphenamide) Tablets, 50 mg	Alcon Laboratories Inc., 6201 South Freeway, P.O. Box 1959, Fort Worth, TX 76134
NDA 012699	Lomotil (atropine sulfate and diphenoxylate hydrochloride (HCl)) Solution 0.025 mg/5 mL and 2.5 mg/5 mL	G.D. Searle, LLC, 235 East 42nd St., New York, NY 10017
NDA 012892	Uracil Mustard Capsule	Shire Development Inc., 725 Chesterbrook Blvd., Wayne, PA 19087-5637
NDA 014738	Mannitol Injection USP, 20%	B. Braun Medical Inc.
NDA 016080	Mannitol Injection USP	Do.
NDA 016096	Mintezol (thiabendazole) Tablets	Merck Sharp & Dohme Corp., 1 Merck Drive, P.O. Box 100, Whitehouse Station, NJ 08889
NDA 016097	Mintezol (thiabendazole) Oral Suspension	Do.
NDA 016695	Dextrose Injection, 5% (in Ringer's)	Baxter Healthcare Corp. 32650 N. Wilson Rd., Round Lake, IL 60073
NDA 017390	Plasma-Lyte M and Dextrose 5% Injection	Do.
NDA 017438	Plasma-Lyte R Injection	Do.
NDA 017451	Plasma Lyte 148 and Dextrose 5% Injection	Do.
NDA 017493	Travasol (amino acids) Injection,	Do.

Application No.	Drug	Applicant
	10%	
NDA 017510	Dextrose 5% Injection (in lactated Ringer's)	B. Braun Medical Inc.
NDA 017636	Sorbitol-Mannitol Irrigation, 2.7 g/100 mL-540 mg/100 mL	Hospira, Inc.
NDA 017698	Serile Urea Injection	Do.
NDA 017911	Clinoril (sulindac) Tablets, 150 mg and 200 mg	Merck Sharp & Dohme Corp.
NDA 017957	Novamine (amino acids) Injection	Hospira, Inc.
NDA 017995	Dextrose Injection USP, 60%	B. Braun Medical Inc.
NDA 018191	Drixoral Non-Drowsy (pseudoephedrine sulfate) Extended-Release Tablets, 120 mg	MSD Consumer Care, Inc., 556 Morris Ave., Summit, NJ 07901
NDA 018242	Sulfamethoxazole and Trimethorim Tablets USP	Teva Pharmaceuticals USA, 425 Privet Rd., Horsham, PA 19044
NDA 018258	Dextrose Injection 5% (in acetated Ringer's)	B. Braun Medical Inc.
NDA 018268	Dextrose, Sodium Chloride, and Potassium Chloride Injection USP, 5%	Do.
NDA 018307	Thyro-Block (potassium iodide tablets USP)	Meda Pharmaceuticals Inc., 265 Davidson Ave., Suite 400, Somerset, NJ 08873
NDA 018308	Thyro-Block (potassium iodide solution), 21 mg	Do.
NDA 018312	Calderol (calcifediol) Capsules	Organon USA Inc., Subsidiary of Merck & Co., Inc.
NDA 018376	Dextrose and Sodium Chloride Injection, 2.5% /0.9%	B. Braun Medical Inc.
NDA 018531	Nitroglycerin Injection USP, 5 mg/mL	Hospira, Inc.
NDA 018533	Nizoral (ketoconazole) Tablets, 200 mg	Janssen Pharmaceuticals, Inc., c/o Janssen Research & Development, LLC, 920 Route 202 South, P.O. Box 300, Raritan, NJ 08869-0602
NDA 018684	Branchamin (amino acids) Injection, 4%	Baxter Healthcare Corp.

Application No.	Drug	Applicant
NDA 018722	Sodium Chloride 0.9%, and Potassium Chloride Injection	B. Braun Medical Inc.
NDA 018725	Acetated Ringer's Injection	Do.
NDA 018744	Dextrose and Potassium Chloride Injection	Do.
NDA 018818	Metronidazole Tablets USP, 250 mg and 500 mg	Mutual Pharmaceutical Co., Inc., 1100 Orthodox St., Philadelphia, PA 19124
NDA 018840	Dextrose 5%, and Electrolyte No. 75 Injection	Baxter Healthcare Corp.
NDA 019037	Imodium (loperamide HCl) Oral Solution, 1 mg/5 mL	Janssen Pharmaceuticals, Inc., c/o Janssen Research & Development, LLC, 1125 Trenton-Harbourton Rd., P.O. Box 200, Titusville, NJ 08560
NDA 019047	Plasma-Lyte 56 (electrolyte solution) Injection	Baxter Healthcare Corp.
NDA 019439	K-Dur (potassium chloride) Extended-Release Tablets, 10 milliequivalents (mEq) and 20 mEq	Merck Sharp & Dohme Corp.
NDA 019645	Toradol (ketorolac tromethamine) Tablets, 10 mg	Roche Palo Alto LLC, c/o Genetech, Inc., 1 DNA Way, South San Francisco, CA 94080-4990
NDA 019681	Aminosyn II in Dextrose Injection	Hospira, Inc.
NDA 019682	Aminosyn II with Electrolytes and Adjusted Phosphate in Dextrose Injection	Do.
NDA 019683	Aminosyn II with Electrolytes in Dextrose with Calcium Injection	Do.
NDA 019718	Isolyte E (multi-electrolyte) Injection	B. Braun Medical Inc.
NDA 019778	Prinzide (lisinopril and hydrochlorothiazide) Tablets, 10 mg/12.5 mg, 20 mg/12.5 mg, and 20 mg/25 mg	Merck Sharp & Dohme Corp.
NDA 019843	Isolyte S (multi-electrolyte) in	B. Braun Medical Inc.

Application No.	Drug	Applicant
	Dextrose 5% Injection	
NDA 019864	Isolyte R (multi-electrolyte) in Dextrose 5% Injection	Do.
NDA 019867	Isolyte E (multi-electrolyte) in Dextrose 5% Injection	Do.
NDA 020004	Sodium Lactate Injection USP, 1/6 molar	Do.
NDA 020173	Travasol (amino acids) Injection With Electrolytes in Dextrose	Baxter Healthcare Corp.
NDA 020177	Travasol (amino acids) Injection With Electrolytes	Do.
NDA 020536	Nicotrol (nicotine transdermal system), 15 mg	McNeil Consumer Healthcare, 7050 Camp Hill Rd., Fort Washington, PA 19034
NDA 020004	Sodium Lactate Injection USP, 1/6 molar	B. Braun Medical Inc.
NDA 020173	Travasol (amino acids) Injection With Electrolytes in Dextrose	Baxter Healthcare Corp.
NDA 020177	Travasol (amino acids) Injection With Electrolytes	Do.
NDA 020811	Acular PF (ketorolac tromethamine) Ophthalmic Solution, 0.5%	Allergan, Inc., 2525 Dupont Dr., P.O. Box 19534, Irvine, CA 92623-9534
NDA 021260	Avinza (morphine sulfate) Extended-Release Capsules	King Pharmaceuticals LLC, 235 East 42nd St., New York, NY 10017
NDA 021415	Metvixia (methyl aminolevulinate HCl) Cream, 16.8%	Galderma Laboratories, L.P., 14501 North Freeway, Fort Worth, TX 76177
NDA 021460	Metaglip (glipizide and metformin HCl) Tablets, 2.5 mg/250 mg, 2.5 mg/500 mg, and 5 mg/500 mg	Bristol-Myers Squibb, P.O. Box 4000 (Mailstop D12-02), Princeton, NJ 08543-4000
NDA 021788	Synthetic Conjugated Estrogens, A Vaginal Cream, 0.625 mg/gram (g)	Teva Women's Health, Inc., 41 Moores Rd., P.O. Box 4011, Frazer, PA 19355
NDA 021961	Simvastatin Orally Disintegrating Tablets, 10 mg, 20 mg, 40 mg, and 80 mg	Synthon Pharmaceuticals, Inc., 9000 Development Dr., P.O. Box 110487, Research Triangle Park, NC 27709

Application No.	Drug	Applicant
ANDA 040093	Digoxin Injection USP Carpject, 250 micrograms (mcg)/mL	Hospira, Inc.
ANDA 040233	Methotrexate Tablets USP, 2.5 mg	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677
ANDA 040285	Hydrocodone Bitartrate and Homatropine Methylbromide Syrup, 5 mg/5 mL and 1.5 mg/5 mL	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677
ANDA 040287	Prednisolone Syrup, 15 mg/5 mL	Do.
ANDA 040435	Extended Phenytoin Sodium Capsules USP, 100 mg	ANI Pharmaceuticals, Inc., 210 Main St. West, Baudette, MN 56623
ANDA 040443	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/15 mg, 300 mg/30 mg, and 300 mg/60 mg	Watson Laboratories, Inc. – Florida, 2945 West Corporate Lakes Blvd., Suite B, Weston, FL 33331
NDA 050336	Tao (troleandomycin) Capsule	Pfizer, Inc., 235 East 42nd St., New York, NY 10017
NDA 050520	Spectrobid (bacampicillin HCl) Tablets	Do.
NDA 050556	Spectrobid (bacampicillin HCl) Oral Suspension	Do.
NDA 050809	Azithromycin for Injection, 500 mg/vial and 2.5 g/vial	Teva Parenteral Medicines, Inc., Subsidiary of Teva Pharmaceuticals USA, 19 Hughes, Irvine, CA 92618-1902
ANDA 061370	Ampicillin Trihydrate for Oral Suspension, 125 mg/5 mL, 250 mg/5 mL	Teva Pharmaceuticals USA, 425 Privet Rd., Horsham, PA 19044
ANDA 061461	Erythromycin Stearate Tablets USP, 250 mg and 500 mg	ANI Pharmaceuticals, Inc.
ANDA 062338	Eryc (erythromycin delayed- release capsules USP), 250 mg	Warner Chilcott (US) Inc., 100 Enterprise Dr., Rockaway, NJ 07866
ANDA 062391	Doxycycline Hyclate Tablets USP, 100 mg	Mutual Pharmaceutical Co., Inc.
ANDA 062418	Doxycycline Hyclate Capsules	Do.

Application No.	Drug	Applicant
	USP, 50 mg and 100 mg	
ANDA 062645	Griseofulvin Tablets USP, 165 mg	Barr Laboratories, Inc.
ANDA 062646	Ultramicrosize Griseofulvin Tablets USP, 330 mg	Do.
ANDA 062777	Cephalexin for Oral Suspension USP, 250 mg/5 mL	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, 425 Privet Rd., Horsham, PA 19044
ANDA 062778	Cephalexin for Oral Suspension USP, 125 mg/5 mL	Do.
ANDA 062826	Cephalexin Tablets USP, 250 mg	Do.
ANDA 062827	Cephalexin Tablets USP, 500 mg	Do.
ANDA 062895	Cyclacillin Tablets, 250 mg and 500 mg	Teva Pharmaceuticals, USA
ANDA 062930	Clindamycin Phosphate Topical Solution, 1%	Vintage Pharmaceuticals, 150 Vintage Dr., Huntsville, AL 35811
ANDA 064061	Cefaclor Capsules USP, 250 mg and 500 mg	Ivax Pharmaceuticals, Inc.
ANDA 064070	Cefaclor Oral Suspension USP, 375 mg/5 mL	Do.
ANDA 064085	Cefaclor Oral Suspension USP, 250 mg/5 mL	Do.
ANDA 064086	Cefaclor Oral Suspension UPS, 187 mg/5 mL	Do.
ANDA 064087	Cefaclor Oral Suspension USP, 125 mg/5 mL	Do.
ANDA 065297	Azithromycin for Oral Suspension, 100 mg/5 mL and 200 mg/5 mL	Sandoz Inc., 4700 Sandoz Dr., Wilson, NC 27893
ANDA 070067	Indomethacin Capsules USP, 25 mg	Mutual Pharmaceutical Co., Inc.
ANDA 070068	Indomethacin Capsules USP, 50 mg	Do.
ANDA 070081	Ibuprofen Tablets, 400 mg	McNeil Consumer Healthcare, 7050 Camp Hill Rd., Fort Washington, PA 19034
ANDA 070215	Sulfamethoxazole and Trimethoprim Tablets USP, 400 mg/80 mg	Pliva Inc., Subsidiary of Teva Pharmaceuticals USA, 425 Privet Rd., Horsham, PA 19044

Application No.	Drug	Applicant
ANDA 070466	Allopurinol Tablets USP, 100 mg	Mutual Pharmaceutical Co., Inc.
ANDA 070467	Allopurinol Tablets USP, 300 mg	Do.
ANDA 070472	Lorazepam Tablets USP, 0.5 mg	Do.
ANDA 070473	Lorazepam Tablets USP, 1 mg	Do.
ANDA 070474	Lorazepam Tablets USP, 2 mg	Do.
ANDA 070482	Verapamil HCl Tablets, 80 mg	Do.
ANDA 070483	Verapamil HCl Tablets, 120 mg	Do.
ANDA 070578	Furosemide Injection USP, 10 mg/mL	Hospira, Inc.
ANDA 070795	Amiloride HCl and Hydrochlorothiazide Tablets USP, 5 mg/50 mg	Teva Pharmaceuticals USA
ANDA 070819	Metoclopramide Oral Solution USP, 5 mg/5 mL	Do.
ANDA 071259	Trimethoprim Tablets, 200 mg	Do.
ANDA 071315	Metoclopramide Oral Solution USP, 5 mg/5 mL	Do.
ANDA 071769	Ibuprofen Tablets USP, 800 mg	Ivax Pharmaceuticals, Inc.
ANDA 072126	Methyldopa Tablets, 125 mg	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677
ANDA 072127	Methyldopa Tablets, 250 mg	Do.
ANDA 072128	Methyldopa Tablets, 500 mg	Do.
ANDA 072557	Fenoprofen Calcium Tablets USP, 600 mg	Ivax Pharmaceuticals, Inc.
ANDA 072779	Albuterol Tablets USP, 2 mg	Teva Pharmaceuticals USA
ANDA 072780	Albuterol Tablets USP, 4 mg	Do.
ANDA 073115	Amantadine HCl Oral Solution USP, 50 mg/5 mL	Do.
ANDA 073478	Loperamide HCl Oral Solution, 1 mg/5 mL	Do.
ANDA 073497	Lactulose Solution USP, 10 g/15 mL (Evalose)	Do.
ANDA 073504	Lactulose Solution USP, 10 g/15 mL (Heptalac)	Do.

Application No.	Drug	Applicant
ANDA 074101	Atenolol Tablets, 25 mg, 50 mg, and 100 mg	Pliva, Inc., Subsidiary of Teva Pharmaceuticals USA
ANDA 074103	Piroxicam Capsules USP, 10 mg and 20 mg	Teva Pharmaceuticals USA
ANDA 074148	Piroxicam Capsules USP, 10 mg and 20 mg	Ivax Pharmaceuticals, Inc.
ANDA 074344	Cimetidine Injection USP, 300 mg/2 mL	Hospira, Inc.
ANDA 074345	Cimetidine Injection USP, 300 mg/2 mL	Do.
ANDA 074347	Cholestyramine for Oral Suspension USP, 4 g	Teva Pharmaceuticals USA
ANDA 074348	Cholestyramine for Oral Suspension USP, 4 g	Do.
ANDA 074368	Nadolol Tablets USP, 80 mg, 120 mg, and 160 mg	Do.
ANDA 074390	Diclofenac Sodium Delayed-Release Tablets USP, 75 mg	Do.
ANDA 074401	Cimetidine Tablets USP, 200 mg, 300 mg, and 400 mg	Ivax Pharmaceuticals, Inc.
ANDA 074402	Cimetidine Tablets USP, 800 mg	Do.
ANDA 074411	Flurbiprofen Tablets USP, 50 mg and 100 mg	Do.
ANDA 074500	Minoxidil Topical Solution, 2%	Copley Pharmaceutical, Inc., Subsidiary of Teva Pharmaceuticals USA, 425 Privet Rd., Horsham, PA 19044
ANDA 074530	Terazosin HCl Tablets, 1 mg, 2 mg, 5 mg, and 10 mg	Ivax Pharmaceuticals, Inc.
ANDA 074590	Captopril Tablets USP, 12.5 mg, 25 mg, 50 mg, and 100 mg	Do.
ANDA 074619	Glipizide Tablets USP, 5 mg and 10 mg	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677
ANDA 074859	Cimetidine HCl Oral Solution, 300 mg/5 mL	ANI Pharmaceuticals, Inc.

Application No.	Drug	Applicant
ANDA 074873	Tretinoin Topical Solution USP, 0.05%	Teva Pharmaceuticals USA
ANDA 074899	Etodolac Capsules USP, 200 mg and 300 mg	ANI Pharmaceuticals, Inc.
ANDA 074920	Clonazepam Tablets USP, 0.5 mg, 1 mg, and 2 mg	Teva Pharmaceuticals USA
ANDA 075020	Hydroxyurea Capsule USP, 250 mg and 500 mg	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677
ANDA 075055	Captopril and Hydrochlorothiazide Tablets USP, 25/15 mg, 25/25 mg, 50/15 mg, and 50/25 mg	Ivax Pharmaceuticals, Inc.
ANDA 075110	Cimetidine HCl Solution, 300 mg/5 mL	ANI Pharmaceuticals, Inc.
ANDA 075448	Isosorbide Mononitrate Extended-Release Tablets, 30 mg, 60 mg, and 120 mg	Ivax Pharmaceuticals, Inc.
ANDA 075482	Enalapril Maleate Tablets USP, 2.5 mg, 5 mg, 10 mg, and 20 mg	Do.
ANDA 075734	Hydroxyurea Tablets USP, 1,000 mg	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677
ANDA 075763	Nefazodone HCl Tablets USP, 50 mg, 100 mg, 150 mg, 200 mg, and 250 mg	Ivax Pharmaceuticals, Inc.
ANDA 076136	Ciprofloxacin Tablets USP, 250 mg, 500 mg, and 750 mg	Teva Pharmaceuticals USA
ANDA 076169	Fexofenadine HCl Capsules, 60 mg	Barr Laboratories, Inc., 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677
ANDA 076752	Levothyroxine Sodium Tablets USP, 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 150 mcg, 175 mcg	Merck KGaA, c/o Icon Clinical Research, 212 Church Rd., North Wales, PA 19454

Application No.	Drug	Applicant
	mcg, 200 mcg, and 300 mcg	
ANDA 076988	Prednisolone Sodium Phosphate Oral Solution USP, Prednisolone Base 15 mg/5 mL	Nesher Pharmaceuticals (USA) LLC, 13910 Saint Charles Rock Rd., Bridgeton, MO 63044
ANDA 077176	Metoprolol Succinate Extended-Release Tablets, 50 mg	Do.
ANDA 077779	Metoprolol Sucinate Extended-Release Tablets, 25 mg	Do.
ANDA 080391	Edetate Calcium Disodium Injection	Watson Laboratories, Inc., Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054
ANDA 080505	Carmol HC Cream	Fougera Pharmaceuticals Inc., 60 Baylis Rd., P.O. Box 2006, Melville, NY 11747
ANDA 080701	Prednisone Tablets USP, 5 mg	Mutual Pharmaceutical Co., Inc.
ANDA 081054	Hydroxyzine HCl Tablets, 100 mg	Pliva, Inc., Subsidiary of Teva Pharmaceuticals USA
ANDA 083729	Imipramine HCl Tablets USP, 10 mg, 25 mg, and 50 mg	Teva Pharmaceuticals USA
ANDA 083734	Probenecid and Colchicine Tablets USP, 500 mg/0.5 mg	Ivax Pharmaceuticals, Inc.
ANDA 083740	Probenecid Tablets USP, 500 mg	Do.
ANDA 084106	Hydralazine HCl Tablets USP, 25 mg	Mutual Pharmaceutical Co., Inc.
ANDA 084107	Hydralazine HCl Tablets USP, 50 mg	Do.
ANDA 084506	Diphenhydramine HCl Capsules USP, 25 mg	Do.
ANDA 084595	Procainainde HCl Capsules USP, 375 mg	Ivax Pharmaceuticals, Inc.
ANDA 084606	Procainamide HCl Capsules USP, 500 mg	Do.
ANDA 084634	Prednisone Tablets USP, 20 mg	Mutual Pharmaceutical Co., Inc.
ANDA 084978	Micrainin (aspirin and meprobamate) Tablets, 325	Meda Pharmaceuticals Inc.

Application No.	Drug	Applicant
	mg/200 mg	
ANDA 085627	Amitriptyline HCl Tablets USP, 25 mg	Mutual Pharmaceutical Co., Inc.
ANDA 085742	Amitriptyline HCl Tablets USP, 100 mg	Do.
ANDA 085743	Amitriptyline HCl Tablets USP, 75 mg	Do.
ANDA 085744	Amitriptyline HCl Tablets USP, 10 mg	Do.
ANDA 085745	Amitriptyline HCl Tablets USP, 50 mg	Do.
ANDA 085836	Amitriptyline HCl Tablets USP, 100 mg	Teva Pharmaceuticals USA
ANDA 086595	Prednisone Tablets USP, 10 mg	Mutual Pharmaceutical Co., Inc.
ANDA 087265	Spirolactone Tablets USP, 25 mg	Do.
ANDA 087267	Spirolactone and Hydrochlorothiazide Tablets USP, 25 mg/25 mg	Do.
ANDA 087292	Chlorthalidone Tablets USP, 25 mg	Do.
ANDA 087293	Chlorthalidone Tablets USP, 50 mg	Do.
ANDA 087857	Hydroxyzine HCl Tablets USP, 25 mg	Do.
ANDA 087860	Hydroxyzine HCl Tablets USP, 50 mg	Do.
ANDA 087913	Methyclothiazide Tablets USP, 2.5 mg	Ivax Pharmaceuticals, Inc.
ANDA 088409	Hydroxyzine HCl Tablets USP, 10 mg	Mutual Pharmaceutical Co., Inc.
ANDA 088626	Bromodiphenhydramine HCl and Codeine Phosphate Syrup, 12.5 mg/5 mL and 10 mg/5 mL	Wockhardt Bio AG, c/o Morton Grove Pharmaceuticals, Inc., 6451 Main St., Morton Grove, IL 60053
ANDA 088728	Hydralazine HCl Tablets USP,	Mutual Pharmaceutical Co., Inc.

Application No.	Drug	Applicant
	10 mg	
ANDA 088804	Trimethobenzamide HCl Injection USP, 100 mg/mL	Hospira, Inc.
ANDA 088883	Amitriptyline HCl Tablets USP, 10 mg	Pliva, Inc., Subsidiary of Teva Pharmaceuticals USA
ANDA 088884	Amitriptyline HCl Tablets USP, 25 mg	Pliva Hrvatska d.o.o., Subsidiary of Teva Pharmaceuticals USA, 425 Privet Rd., Horsham, PA 19044
ANDA 088885	Amitriptyline HCl Tablets USP, 50 mg	Pliva, Inc., Subsidiary of Teva Pharmaceuticals USA
ANDA 088886	Amitriptyline HCl Tablets USP, 75 mg	Do.
ANDA 088887	Amitriptyline HCl Tablets USP, 100 mg	Do.
ANDA 088888	Amitriptyline HCl Tablets USP, 150 mg	Pliva Hrvatska d.o.o., Subsidiary of Teva Pharmaceuticals USA
ANDA 088891	Ergoloid Mesylates Tablets USP, 1 mg	Mutual Pharmaceutical Co., Inc.
ANDA 089238	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg	Mikart, Inc., 1750 Chattahoochee Ave., Atlanta, GA 30318
ANDA 089244	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/60 mg	Do.
ANDA 089423	Amitriptyline HCl Tablets USP, 150 mg	Mutual Pharmaceutical Co., Inc.
ANDA 090849	Oxaliplatin for Injection USP, 50 mg/vial and 100 mg/vial	Sandoz Inc., 506 Carnegie Center, Suite 400, Princeton, NJ 08540

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director of Food and Drugs, 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 Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in table 1 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: October 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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