Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2015–25924 Filed 10–9–15; 8:45 am]

**BILLING CODE 4184–01–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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**DATES:** *Effective Date:* November 12, 2015.

**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, 10% | Do. |
| 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. |
| NDA 018722 | Sodium Chloride 0.9%, and Potassium Chloride Injection | B. Braun Medical Inc. |
| NDA 018725 | Acetated Ringer's Injection | Do. |

TABLE 1—Continued

| Application No. | Drug | Applicant |
|---|---|---|
| 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 Dextrose 5% Injection | B. Braun Medical Inc. |
| 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. |
| ANDA 040093 | Digoxin Injection USP Carpuject, 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 USP, 50 mg and 100 mg | Do. |
| ANDA 062645 | Griseofulvin Tablets USP, 165 mg | Barr Laboratories, Inc. |
| ANDA 062646 | Ultramicrosize Griseofulvin Tablets USP, 330 mg | Do. |

TABLE 1—Continued

| Application No. | Drug | Applicant |
|---|---|---|
| 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. |
| 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. |
| 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. |
| 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. |

TABLE 1—Continued

| Application No. | Drug | Applicant |
|---|---|---|
| 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, 200 mcg, and 300 mcg. | Merck KGaA, c/o Icon Clinical Research, 212 Church Rd., North Wales, PA 19454. |
| 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 mg/200 mg. | Meda Pharmaceuticals Inc. |
| 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 | Spironolactone Tablets USP, 25 mg | Do. |
| ANDA 087267 | Spironolactone 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, 10 mg | Mutual Pharmaceutical Co., Inc. |
| 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. |

TABLE 1—Continued

| Application No. | Drug | Applicant |
|---|---|---|
| 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 November 12, 2015. 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.*

[FR Doc. 2015–25922 Filed 10–9–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2015–N–3456]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Recommended Recordkeeping for Cosmetic Good Manufacturing Practices

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on our proposed collection of certain information. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies must publish a notice in the **Federal Register** concerning each proposed collection of information, including collections of information in current guidance documents, and allow 60 days for public comment. This notice invites comments on the recommended recordkeeping associated with our draft guidance entitled, ''Draft Guidance for Industry: Cosmetic Good Manufacturing Practices.'' Our draft guidance remains unchanged by this notice. We are publishing this notice in compliance with the PRA. This notice does not represent any new regulatory initiative.

**DATES:** Submit either electronic or written comments on the collection of information by December 14, 2015.

**ADDRESSES:** You may submit comments as follows:

**Electronic Submissions**

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

**Written/Paper Submissions**

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2015–N–3456 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Recommended Recordkeeping for Cosmetic Good Manufacturing Practices.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION''. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other