DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0002]

Hospira, Inc. et al.; Withdrawal of Approval of 44 New Drug Applications and 158 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 44 new drug applications (NDAs) and 158 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.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 3, 2016.

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 005264	Heparin Sodium Injection	Hospira, Inc., 275 North Field Dr., Bldg. H2–2, Lake Forest, IL 60045–5046.
NDA 009470	Xylocaine Viscous (lidocaine hydrochloride (HCl)) Solution	Fresenius Kabi USA LLC, Three Corporate Dr., Lake Zurich, IL 60047.
NDA 009698	Miltown (meprobamate) Tablets, 200 milligrams (mg) and 400 mg.	Meda Pharmaceuticals, Inc., 265 Davidson Ave., Suite 300, Somerset, NJ 08873–4120.
NDA 009939	Senokot Granules (sennosides), 15 mg	Purdue Products, L.P., One Stamford Forum, Stamford, CT 06901.
NDA 010382	Tempra (acetaminophen) Syrup, 160 mg/5 milliliters (mL)	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 88543–4000.
NDA 011228	Liquamar (phenprocoumon) Tablets	Organon USA Inc., Subsidiary of Merck & Co., Inc., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.
NDA 011613	Ionamin (phentermine resin complex) Capsules, 15 mg and 30 mg.	UCB, Inc., 1950 Lake Park Dr., Smyrna, GA 30080.
NDA 011738	Numorphan (oxymorphone HCl) Suppositories, 5 mg	Endo Pharmaceuticals, Inc., 100 Endo Blvd., Chadds Ford, PA 19317.
NDA 012365	Soma Compound (carisoprodol and aspirin) Tablets	Meda Pharmaceuticals, Inc.
NDA 012940	Isordil (isosorbide dinitrate) Sublingual Tablets, 2.5 mg, 5 mg, and 10 mg.	Valeant International Bermuda, c/o Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
NDA 013483	Drixoral/Disophrol (dexbrompheniramine maleate and pseudoephedrine sulfate) Extended-Release Tablets, 6 mg/120 mg.	Merck Consumer Care, 556 Morris, Ave., Summit, NJ 07901.
NDA 014005	Maxibolin (ethylestrenol) Tablets	Organon USA Inc.
NDA 017087	Ethrane (enflurane USP)	Baxter Healthcare Corp., 32650 N. Wilson Rd., Round Lake, IL 60073.
NDA 017689	Methadone HCl Syrup	Sandoz, Inc., 4700 Sandoz, Dr., Wilson, NC 27893.
NDA 018766	Ansaid (flurbiprofen) Tablets, 50 mg and 100 mg	Pharmacia & Upjohn Co., c/o Pfizer, Inc., 235 East 42nd St., New York, NY 10017.
NDA 018812	Sulfamethoxazole and Trimethoprim Oral Suspension USP, 200 mg/5 mL and 40 mg/5 mL.	Teva Pharmaceuticals USA, Inc., 1090 Horsham Rd., P.O. Box 1090, North Wales, PA 19454.
NDA 019304	Tricor (fenofibrate) Micronized Capsules, 67 mg, 134 mg, and 200 mg.	AbbVie Inc., 1 N. Waukegan Rd., Dept. PA77/Bldg. AP30, North Chicago, IL 60064.
NDA 019384	Noroxin (norfloxacin) Tablets, 400 mg	Merck Sharp & Dohme Corp., 351 North Sumneytown Pike, P.O. Box 1000, North Wales, PA 19454.
NDA 020005	Cardene SR (nicardipine HCl) Extended-Release Capsules, 30 mg, 45 mg, and 60 mg.	Chiesi USA, Inc., 1255 Crescent Green Dr., Suite 250, Cary, NC 27518.
NDA 020073	Romazicon (flumazenil) Injection	Hoffman-LaRoche, Inc., c/o Genetech, Inc., 1 DNA Way MS #241B, South San Francisco, CA 94080–4900.
NDA 020084	Iobenguane Sulfate I–131 Injection, 2.3 millicuries	Pharmalucence, 10 DeAngelo Dr., Bedford, MA 01730.
NDA 020107	Novamine (amino acids) Injection	Baxter Healthcare Corp.
NDA 020229	Leustatin (cladribine) Injection, 1 mg/mL	Janssen Pharmaceuticals Inc., 920 Route 202 South, P.O. Box 300, Raritan, NJ 08869–0602.
NDA 020251	Zantac (ranitidine HCl) Effervescent Tablets, 25 mg and 150 mg Zantac (ranitidine HCl) Effervescent Granules, 150 mg.	Glaxo Group Limited, England d/b/a GlaxoSmithKline, Five Moore Dr., P.O. Box 13398, Research Triangle Park, NC 27709.
NDA 020312	Univasc (moexipril HCl) Tablets, 7.5 mg and 15 mg	UCB, Inc.
NDA 020346	Zyrtec (cetirizine HCl) Syrup, 1 mg/mL	Johnson and Johnson Consumer Inc., McNeil Consumer Healthcare Division, 7050 Camp Hill Rd., Fort Washington, PA 19034–2299.
NDA 020410	Gastromark (ferumoxsil) Oral Suspension	AMAG Pharmaceuticals, 100 Haydon Ave., Lexington, MA 02421.

TABLE 1—Continued

Application No.	Drug	Applicant
NDA 020416	Feridex I.V. (ferumoxides) Injection	Do.
NDA 020460	Cytovene (ganciclovir) Capsules, 250 mg and 500 mg	Roche Palo Alto LLC, c/o Genentech, Inc., 1 DNA Way, MS#241B, South San Francisco, CA 94080–4990.
NDA 020575	DentiPatch (lidocaine)	Noven Pharmaceuticals, Inc., 11960 SW. 144th St., Miami, FL 33186.
NDA 020638	Vistide (cidofovir) Injection, Equivalent to (EQ) 75 mg base/mL.	Gilead Sciences, Inc., 333 Lakeside Dr., Foster City, CA 94404.
NDA 020729	Uniretic (moexipril HCl and hydrochlorothiazide) Tablets, 7.5 mg/12.5 mg, 15 mg/12.5 mg, and 15 mg/25 mg.	UCB, Inc.
NDA 021044	Palladone (hydromorphone HCl) Extended-Release Capsules	Rhodes Pharmaceuticals L.P., 498 Washington St., Coventry, RI 02816.
NDA 021046	Celexa (citalopram hydrobromide) EQ 10 mg base/5 mL Oral Solution.	Forest Laboratories, Inc., Harborside Financial Center, Plaza V, Suite 1900, Jersey, City, NJ 07311.
NDA 021378	Combunox (Oxycodone HCl and Ibuprofen) Tablets	Do.
NDA 021671	DepoDur (morphine sulfate) Extended-Release Injection	Pacira Pharmaceuticals, Inc., 10450 Science Center Dr., San Diego, CA 92121.
NDA 021693	Rybix ODT (tramadol HCl) Orally Disintegrating Tablets	Shionogi, Inc., 300 Campus Dr., Suite 300, Florham Park, NJ 07932.
NDA 021768	Fludeoxyglucose F18 (FDG) Injection	Weill Medical College of Cornell University, c/o Citigroup Biomedical Imaging Center, 516 East 72nd St., New York, NY 10021.
NDA 022244	Lusedra (fospropofol disodium) Injection	Eisai, Inc., 155 Tice Blvd., Woodcliff Lake, NJ 07677.
NDA 022312	Docetaxel Injection	Apotex Inc., c/o Apotex Corp., 2400 North Commerce Parkway, Suite 400, Weston, FL 33326.
ANDA 040223	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/15 mg, 300 mg/30 mg, and 300 mg/60 mg.	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 040297	Estradiol Tablets USP, 0.5 mg, 1 mg, and 2 mg	Upsher-Smith Laboratories, Inc., 6701 Evenstad Dr., Maple Grove, MN 55369.
ANDA 040311	Medroxyprogesterone Acetate Tablets USP, 2.5 mg, 5 mg, and 10 mg.	Duramed Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 040318	Meperidine HCl Tablets USP, 50 mg and 100 mg	Do.
ANDA 040472	Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets.	Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
NDA 050143	Chloromycetin (chloramphenicol ophthalmic solution USP) Ophthalmic Solution.	Parkedale Pharmaceuticals, Inc., c/o King Pharmaceuticals, Inc., 501 Fifth St., Bristol, TN 37620.
NDA 050156	Chloromycetin (chloramphenicol ophthalmic ointment USP) Ophthalmic Ointment, 1%.	Do.
NDA 050443	Blenoxane (bleomycin sulfate) for Injection, EQ 15 units base/vial and 30 units base/vial.	Bristol-Myers Squibb Co.
NDA 050630	Primaxin (imipenem and cilastatin sodium) Powder, EQ 500 mg base/vial; 500 mg/vial and EQ 750 mg base/vial; 750 mg/vial.	Merck, Sharp & Dohme Corp.
ANDA 060306	Penicillin G Potassium Tablets USP	Teva Pharmaceuticals USA, Inc.
ANDA 060307	Penicillin G Potassium for Oral Solution USP	Do.
ANDA 061969	Cephalexin Capsules USP, EQ 250 mg base and EQ 500 mg base.	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 062240	Cloxacillin Sodium Capsules USP, EQ 250 mg base and EQ 500 mg base.	Teva Pharmaceuticals USA, Inc.
ANDA 062252	Oxacillin Sodium for Oral Solution USP, EQ 250 mg base/5 mL.	Teva Pharmaceuticals USA, Inc.
ANDA 062268	Cloxacillin Sodium for Oral Solution USP, EQ 125 mg base/5 mL.	Do.
ANDA 062653	Doryx (doxycycline hyclate) Delayed-Release Capsules, EQ 100 mg base.	Warner Chilcott Co., LLC, c/o Warner Chilcott (US), LLC, 100 Enterprise Dr., Rockaway, NJ 07866.
ANDA 062670	Nystatin Oral Suspension USP, 100,000 units/mL	Teva Pharmaceuticals USA, Inc.
ANDA 062683	Cephradine Capsules USP, 250 mg and 500 mg	Do.
ANDA 062695	Cefadroxil Capsules USP, EQ 500 mg base	Do.
ANDA 062751	Erythromycin Pledgets USP, 2%	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 062760	Cephalexin Capsules USP, EQ 250 mg base	Teva Pharmaceuticals USA, Inc.
ANDA 062761	Cephalexin Capsules USP, EQ 500 mg base	Do.
ANDA 062766	Cefadroxil Capsules USP, EQ 500 mg base	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 062767	Cephalexin for Oral Suspension USP, EQ 125 mg base/5 mL	Teva Pharmaceuticals USA, Inc.
ANDA 062768	Cephalexin for Oral Suspension USP, EQ 250 mg base/5 mL	Do.
ANDA 062775	Cephalexin Capsules USP, EQ 500 mg base	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 062853	Amoxicillin Capsules USP, 250 mg	Teva Pharmaceuticals USA, Inc.
ANDA 062854	Amoxicillin Capsules USP, 500 mg	Do.
ANDA 062946	Amoxicillin for Oral Suspension USP, 125 mg/5 mL	Do.
ANDA 063001	Amoxicillin for Oral Suspension USP, 250 mg/5 mL	Do.

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 063018	Cefazolin Sodium for Injection USP, EQ 5 grams (g) base/vial and EQ 10 g base/vial.	Do.
ANDA 063027	Clindamycin HCl Capsules USP, EQ 75 mg base	Do.
ANDA 063030	Amoxicillin Capsules USP, 250 mg	Do.
ANDA 063031	Amoxicillin Capsules USP, 500 mg	Do.
ANDA 064031	Amoxicillin Chewable Tablets, 125 mg and 250 mg	Do.
ANDA 064081	Cefaclor Capsules USP, EQ 250 mg base and EQ 500 mg base.	Do.
ANDA 064145	Cefaclor Capsules USP, EQ 250 mg base and EQ 500 mg base.	Do.
ANDA 065137	Clarithromycin Tablets USP, 250 mg and 500 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 070006	Sulfamethoxazole and Trimethoprim Tablets USP, 400 mg/80 mg.	Mutual Pharmaceutical Co., Inc., 1100 Orthodox St., Philadelphia, PA 19124.
ANDA 070007	Sulfamethoxazole and Trimethoprim Tablets USP, 800 mg/160 mg.	Do.
ANDA 070232	Propranolol HCl Tablets USP, 10 mg	Teva Pharmaceuticals USA, Inc.
ANDA 070234	Propranolol HCl Tablets USP, 40 mg	Do.
ANDA 070266	Indo-Lemmon (Indomethacin Capsules USP), 25 mg	Do.
ANDA 070267	Indo-Lemmon (Indomethacin Capsules USP), 50 mg	Do.
ANDA 070469	Ibuprohn (Ibuprofen Tablets USP), 400 mg	Ohm Laboratories, Inc., c/o Ranbaxy Inc., 600 College Rd. East, Princeton, NJ 08540.
ANDA 070618	Potassium Chloride Extended-Release Tablets USP, 8 milliequivalents.	Copley Pharmaceutical, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 070660	Metoclopramide HCl Tablets USP, EQ 10 mg base	Mutual Pharmaceutical Co., Inc.
ANDA 071145	Ibuprofen Tablets USP	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 071146	Ibuprofen Tablets USP, 600 mg	Do.
ANDA 071184	Thiothixene HCl Oral Solution USP, EQ 5 mg base/mL	Teva Pharmaceuticals USA, Inc.
ANDA 071342	Indomethacin Capsules USP, 25 mg	Do.
ANDA 071343	Indomethacin Capsules USP, 50 mg	Do.
ANDA 072438	Fenoprofen Calcium Capsules USP, EQ 300 mg base	Par Pharmaceutical, Inc., One Ram Ridge Rd., Spring Valley, NY 10977.
ANDA 072522	Fluocinonide Topical Solution USP, 0.05%	Teva Pharmaceuticals USA, Inc.
ANDA 072600	Clofibrate Capsules USP, 500 mg	Do.
ANDA 072692	Norethindrone and Ethinyl Estradiol Tablets USP, 0.5 mg/0.035 mg.	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals, USA, Inc.
ANDA 072999	Dopamine HCl Injection USP, 200 mg/5 mL	Teva Parenteral Medicines, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 073005	Cinoxacin Capsules USP, 250 mg	Teva Pharmaceuticals USA, Inc.
ANDA 073006	Cinoxacin Capsules USP, 500 mg	Do.
ANDA 073043	Baclofen Tablets USP, 10 mg	Do.
ANDA 073044	Baclofen Tablets USP, 20 mg	Do.
ANDA 073099	Leucovorin Calcium Tablets USP, EQ 5 mg base	Pharmachemie B.V., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 073101	Leucovorin Calcium Tablets USP, EQ 25 mg base	Do.
ANDA 073141	Ibuprofen Tablets USP, 200 mg	Teva Pharmaceuticals USA, Inc.
ANDA 073315	Atenolol Tablets USP, 50 mg	Do.
ANDA 073316	Atenolol Tablets USP, 100 mg	Do.
ANDA 073343	Ibuprofen Tablets USP, 400 mg	Do.
ANDA 073344	Ibuprofen Tablets USP, 600 mg	Do.
ANDA 073345	Ibuprofen Tablets USP, 800 mg	Do.
ANDA 073515	Ketoprofen Capsules USP, 25 mg	Do.
ANDA 073679	Diflunisal Tablets USP, 250 mg	Do.
ANDA 074067	Diltiazem HCl Tablets USP, 30 mg, 60 mg, 90 mg, and 120 mg.	Do.
ANDA 074107	Atenolol and Chlorthalidone Tablets USP, 50 mg/25 mg and 100 mg/25 mg.	Pliva, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 074120	Atenolol Tablets USP, 50 mg and 100 mg	Teva Pharmaceuticals USA, Inc.
ANDA 074123	Pindolol Tablets USP, 5 mg and 10 mg	G&W Laboratories, Inc., 111 Coolidge St., South Plainfield, NJ 07080.
ANDA 074124	Ciprofloxacin HCl Tablets, EQ 250 mg base, EQ 500 mg base, and EQ 750 mg base.	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 074143	Metoprolol Tartrate Tablets USP, 50 mg and 100 mg	Teva Pharmaceuticals USA, Inc.
ANDA 074216	Naproxen Tablets, 250 mg, 375 mg, and 500 mg	Do.
ANDA 074294	Alprazolam Tablets USP, 0.25 mg, 0.5 mg, 1 mg, and 2 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 074333	Metoprolol Tartrate Tablets USP, 50 mg and 100 mg	Teva Pharmaceuticals USA, Inc.
ANDA 074357	Trazodone HCl Tablets USP, 150 mg	Do.
ANDA 074365	Cimetidine Tablets USP, 200 mg, 300 mg, 400 mg, and 800 mg.	Do.

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 074446	Terazosin HCl Tablets, EQ 1 mg base, EQ 2 mg base, EQ 5 mg base, and EQ 10 mg base.	Do.
ANDA 074459	Diclofenac Sodium Delayed-Release Tablets USP, 25 mg, 50 mg, and 75 mg.	Do.
ANDA 074476	Hydroxyurea Capsules USP, 500 mg	Roxane Laboratories, Inc., 1809 Wilson Rd., Columbus, OH 43228.
ANDA 074504	Tamoxifen Citrate Tablets USP, EQ 10 mg base and EQ 20 mg base.	Teva Pharmaceuticals USA, Inc.
ANDA 074537	Selegiline HCl Tablets USP, 5 mg	G&W Laboratories, Inc.
ANDA 074555	Cholestyramine for Oral Suspension USP	Teva Pharmaceuticals, USA, Inc.
ANDA 074674	Acyclovir Capsules USP, 200 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 074745	Megestrol Acetate Tablets USP, 40 mg	Teva Pharmaceuticals USA, Inc.
ANDA 074771	Cholestyramine for Oral Suspension USP	Do.
ANDA 074847	Etodolac Tablets USP, 400 mg and 500 mg	Do.
ANDA 074883	Etodolac Tablets USP, 400 mg and 500 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 074895	Amiodarone HCl Tablets, 200 mg	Teva Pharmaceuticals USA, Inc.
ANDA 074914	Acyclovir Capsules USP, 200 mg	Do.
ANDA 074989	Labetalol HCl Tablets USP, 100 mg, 200 mg, and 300 mg	Do.
ANDA 075021	Acyclovir Tablets USP, 400 mg and 800 mg	Do.
ANDA 075557	Ranitidine HCl Capsules, EQ 150 mg base and EQ 300 mg base.	Do.
ANDA 075686	Bisoprolol Fumarate and Hydrochlorothiazide Tablets USP, 2.5 mg/6.25 mg, 5 mg/6.25 mg, and 10 mg/6.25 mg.	Do.
ANDA 075719	Sertraline HCl Tablets USP, EQ 25 mg base, EQ 50 mg base, and EQ 100 mg base.	Do.
ANDA 075726	Pemoline Tablets, 18.75 mg, 37.5 mg, and 75 mg	Mallinckrodt Inc., 675 McConnell Blvd., Hazelwood, MO 63042.
ANDA 075740	Tamoxifen Citrate Tablets USP, EQ 10 mg base and EQ 20 mg base.	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 075810	Fluoxetine HCl Tablets , EQ 10 mg base	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 075823	Calcitriol Injection USP, 0.001 mg/mL and 0.002 mg/mL	Teva Parenteral Medicines, Inc.
ANDA 075827	Gabapentin Tablets USP, 600 mg and 800 mg	Teva Pharmaceuticals USA, Inc.
ANDA 075862	Levonorgestrel and Ethinyl Estradiol Tablets USP, 0.1 mg/0.02 mg.	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 075865	Fluoxetine HCl Tablets , EQ 10 mg base and EQ 40 mg base.	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 075971	Metformin HCl Tablets USP, 500 mg, 850 mg, and 1 g	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 075975	Metformin HCl Tablets USP, 500 mg, 625 mg, 750 mg, 850 mg, and 1 g.	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 076094	Pergolide Mesylate Tablets, EQ 0.05 mg base, EQ 0.25 mg base, and EQ 1 mg base.	Do.
ANDA 076184	Alendronate Sodium Tablets USP, EQ 35 mg tablets and EQ 70 mg tablets.	Teva Pharmaceuticals USA, Inc.
ANDA 076198	Balziva-21 Tablets (norethindrone and ethinyl estradiol tablets USP), 0.4 mg/0.035 mg.	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 076244	Mirtazapine Tablets USP, 15 mg, 30 mg, and 45 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 076251	Fluoxetine HCl Capsules, EQ 40 mg base	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 076328	Metformin HCl Tablets USP, 500 mg, 850 mg, and 1 g	Teva Pharmaceuticals USA, Inc.
ANDA 076340	Finasteride Tablets USP, 5 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 076426	Ciprofloxacin HCl Tablets , EQ 100 mg base, EQ 250 mg base, EQ 500 mg base, and EQ 750 mg base.	Pliva, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 076496	Metformin HCl Extended-Release Tablets USP, 500 mg	Barr Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 076545	Metformin HCl Extended-Release Tablets USP, 500 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 076840	Sumatriptan Succinate Tablets, EQ 25 mg base, EQ 50 mg base, and EQ 100 mg base.	Teva Pharmaceuticals USA, Inc.
ANDA 076880	Nicotine Polacrilex Gum USP, EQ 2 mg base	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 076945	Fosinopril Sodium and Hydrochlorothiazide Tablets USP, 10 mg/12.5 mg and 20 mg/12.5 mg.	Teva Pharmaceuticals USA, Inc.
ANDA 077020	Cilostazol Tablets USP, 100 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 077082	Paroxetine Tablets USP, EQ 10 mg base, EQ 20 mg base, EQ 30 mg base, and EQ 40 mg base.	Teva Pharmaceuticals USA, Inc.

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 077775	Fentanyl Extended-Release Film, 25 micrograms (mcg), 50 mcg, 75 mcg, and 100 mcg.	Noven, Pharmaceuticals, Inc.
ANDA 077850	Nicotine Polacrilex Gum USP, EQ 4 mg base	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 077898	Cilostazol Tablets USP, 50 mg and 100 mg	Pliva Hrvatska DOO, c/o Teva Pharmaceuticals USA, Inc.,425 Privet Rd., Horsham, PA 19044.
ANDA 077973	Bicalutamide Tablets USP, 50 mg	Synthon Pharmaceuticals, Inc., 9000 Development Dr., P.O. Box 110487, Research Triangle Park, NC 27709.
ANDA 077995	Bicalutamide Tablets UPS, 50 mg	Kudco Ireland Limited, c/o Kremers Urban Pharmaceuticals, Inc., 1101 C Ave. West, Seymour, IN 47274.
ANDA 078079	Ciclopirox Topical Solution USP, 8%	Teva Pharmaceuticals USA, Inc.
ANDA 078221	Granisetron HCl Tablets USP, EQ 1 mg base	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 078263	Perindopril Erbumine Tablets, 2 mg, 4 mg, and 8 mg	Lupin Limited, c/o Lupin Pharmaceuticals, Inc., 111 South Calvert St., Harborplace Tower, 21st Floor, Baltimore, MD 21202.
ANDA 078567	Ciclopirox Topical Solution USP, 8%	Mylan Pharmaceuticals Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504.
ANDA 078666	Levonorgestrel Tablets, 0.75 mg	Watson Laboratories, Inc., 311 Bonnie Circle, Corona, CA 92880.
ANDA 078773	Atorvastatin Calcium Tablets, EQ 10 mg base, EQ 20 mg (base), EQ 40 mg base, and EQ 80 mg base.	Teva Pharmaceuticals USA, Inc.
ANDA 080400	Hydrocortisone Cream USP	Do.
ANDA 080828	Hydrocortisone Acetate Ophthalmic Ointment USP, 0.5%	Fera Pharmaceuticals LLC, 134 Birch Hill Rd., Locust Valley, NY 11560.
ANDA 083919	Meprobamate Tablets USP, 600 mg	Meda Pharmaceuticals Inc., 265 Davidson Ave., Suite 400, Somerset, NJ 08873.
ANDA 085022	Hydrochlorothiazide Tablets USP, 100 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 085855	A-Methapred (methylprednisolone sodium succinate for Injection USP), EQ 125 mg base/vial.	Hospira, Inc.
ANDA 086750	Ergotamine Tartrate Sublingual Tablets USP, 2 mg	Organon USA, Inc.
ANDA 087014	Orgatrax (hydroxyzine HCl Injection USP), 25 mg/mL and 50 mg/mL.	Do.
ANDA 087264	Thioridazine HCl Tablets USP, 25 mg	Mutual Pharmaceutical Co., Inc.
ANDA 087665	Sulfinpyrazone Tablets USP, 100 mg	Barr Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 087666	Sulfinpyrazone Capsules USP, 200 mg	Do.
ANDA 087760	Hydroxyzine Pamoate Capsules USP, EQ 50 mg HCl	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 087761	Hydroxyzine Pamoate Capsules USP, EQ 25 mg HCl	Do.
ANDA 088370	Thioridazine HCl Tablets USP, 50 mg	Mutual Pharmaceutical Co., Inc.
ANDA 088375	Thioridazine HCl Tablets USP, 10 mg	Do.
ANDA 088379	Thioridazine HCl Tablets USP, 100 mg	Do.
ANDA 088469	Dexamethasone Sodium Phosphate Injection USP, EQ 10 mg Phosphate/mL.	Fresenius Kabi USA, LLC.
ANDA 088900	Doxylamine Succinate Tablets USP, 25 mg	Copley Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088902	Chlorthalidone Tablets USP, 25 mg	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088903	Chlorthalidone Tablets USP, 50 mg	Do.
ANDA 088974	Procainamide HCl Extended-Release Tablets USP, 500 mg	ANI Pharmaceuticals, Inc.,.
ANDA 089109	Promethazine HCl Tablets USP, 25 mg	Teva Pharmaceuticals USA, Inc.
ANDA 090299	Melphalan HCl for Injection, EQ 50 mg base/vial	Mylan Institutional LLC, 4901 Hiawatha Dr., Rockford, IL 61103.
ANDA 090924	Ibutilide Fumarate Injection, 0.1 mg/mL	Do.
ANDA 091242	Anastrozole Tablets USP, 1 mg	Impax Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544.
ANDA 091638	Letrozole Tablets USP, 2.5 mg	Do.
ANDA 200792	Oxymorphone HCl Extended-Release Tablets, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg.	Par Pharmaceutical, Inc.
ANDA 204538	Zidovudine Injection USP, 10 mg/mL	Liaoning Chengda Biotechnology Co., Ltd., c/o Ruby Pharma, Inc., 116 Village Blvd, Suite 200, Princeton, NJ 08540.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the 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 November 3, 2016. 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 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: September 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–23893 Filed 10–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2880]

Microbiology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Microbiology Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on November 9 and 10, 2016, from 8 a.m. to 6 p.m.

ADDRESSES: Gaithersburg Holiday Inn Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD 20879. The hotel's telephone number is 301–948–8900. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

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–2016–N–2880 for ''Microbiology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' 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 applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, *aden.asefa@fda.hhs.gov,* 301–796–0400, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On November 9, 2016, during session one, the committee will