

**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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.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 (dextrompheniramine 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 Genentech, 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 .....	Rybitx 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 ....	Cephadrine 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 ....	Ibuprofen (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 ....	Orgatrx (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 ....	Sulfipyrazone Tablets USP, 100 mg .....	Barr Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 087666 ....	Sulfipyrazone 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](mailto: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