Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6221, Silver Spring, MD 20993–0002, 301–796–1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public workshop regarding scientific and clinical trial design considerations for the development of new TB drug regimens. As such, discussions will focus on drug development programs and studies intended to evaluate shorter and better tolerated TB drug regimens and new regimens that have efficacy for treatment of sensitive and drug-resistant TB.

II. Topics for Discussion at the Public Workshop

The FDA is conducting this workshop to focus on scientific considerations needed to advance the development of new TB treatment regimens. FDA is particularly interested in discussing pre-clinical and clinical considerations relevant to the development of new TB treatment regimens. Discussions are planned around the following topics:

- Current landscape and challenges in TB drug development.
- In vitro and in vivo nonclinical models that may help select or deselect new investigational TB drug regimens to enter into clinical development.
- Biomarkers that may help predict responses to therapy at a time earlier than standard liquid or solid culture results would allow.
- Surrogate endpoints that may be used to predict clinical benefit.
- An update on TB diagnostics.
- Options for assessing the contribution of individual drugs in a new TB treatment regimen.
- Clinical trial design challenges in pediatric and special populations.

The Agency encourages health care providers, other U.S. Government Agencies, academic experts, industry, and other stakeholders to attend this public workshop.

III. Participating in the Public Workshop

Registration: Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by July 14, 2017, midnight eastern standard time. To register, please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone to *TuberculosisWorkshop2017@fda.hhs.gov.* Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Jessica Barnes or Lori Benner (see **FOR FURTHER INFORMATION CONTACT**) no later than July 14, 2017.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by July 11, 2017. All requests to make oral presentations must be received by July 10, 2017. If selected for presentation, any presentation materials must be emailed to *TuberculosisWorkshop2017@fda.hhs.gov* no later than July 13, 2017. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast at the following site at *https://collaboration.fda.gov/tbdd071917.*

If you have never attended a Connect Pro event before, please test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the Internet at *http://www.fda.gov/Drugs/NewsEvents/ucm548365.htm* approximately 45 days after the workshop.

Dated: June 15, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–12906 Filed 6–20–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–3203]

Wyeth Pharmaceuticals Inc. et al.; Withdrawal of Approval of 121 New Drug Applications and 161 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 121 new drug applications (NDAs) and 161 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: The withdrawal is effective on July 21, 2017.

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 005897	Folvite (folic acid) Injection, 5 milligrams (mg)/milliliter (mL) ...	Wyeth Pharmaceuticals Inc., Subsidiary of Pfizer Inc., P.O. Box 8299, Philadelphia, PA 19101–8299.
NDA 006343	Wydase (hyaluronidase) Injection USP	Baxter Healthcare Corp., 32650 N. Wilson Rd., Round Lake, IL 60073.
NDA 007390	Banthine (methantheline bromide) Tablets, 50 mg	Shire Development Inc., 725 Chesterbrook Blvd., Wayne, PA 19087.
NDA 008126	Cortisone Acetate (cortisone acetate) Tablets, 5 mg, 10 mg, and 25 mg; and Injection, 25 mg/mL.	Pharmacia & Upjohn Co., Subsidiary of Pfizer Inc., 235 East 42nd St., New York, NY 10017.
NDA 008732	Pro-Banthine (propantheline bromide) Tablets, 7.5 mg and 15 mg.	Shire Development Inc.
NDA 011683	Thiotepa for Injection, 15 mg/vial	Immunex Corp., Subsidiary of Amgen, 1 Amgen Center Dr., MS 17 1B, Thousand Oaks, CA 91320–1799.
NDA 011836	Presamine (imipramine hydrochloride (HCl)) Tablets USP	Sanofi-Aventis U.S. LLC, 55 Corporate Dr., Bridgewater, NJ 08807.
NDA 012003	Akineton (biperiden HCl) Tablets, 2 mg	AbbVie Inc., 1 N. Waukegan Rd., Dept. PA77/Bldg. AP30–1, North Chicago, IL 60064.
NDA 012421	Medrol Acetate (methylprednisolone acetate) Topical Ointment, 0.25% and 1%.	Pharmacia & Upjohn Co.
NDA 013935	Herplex (idoxuridine) Ophthalmic Solution, 0.1%	Allergan, Inc., 2525 Dupont Dr., P.O. Box 19534, Irvine, CA 92623–9534.
NDA 013993	Chromitope Sodium (sodium chromate Cr 51) Injection USP, 2 millicuries (mCi)/vial and 200 microcuries (uCi)/mL.	Bracco Diagnostics Inc., 259 Prospect Plains Rd., Bldg. H, Monroe Township, NJ 08831.
NDA 014006	Maxibolin (ethylestrenol) Elixir, 2 mg/5 mL	Organon USA, Inc., Subsidiary of Merck & Co., Inc., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.
NDA 014214	NegGram (nalidixic acid) Tablets USP, 250 mg, 500 mg, and 1 gram (g).	Sanofi-Aventis U.S. LLC, c/o Sanofi U.S. Services Inc., 55 Corporate Dr., Bridgewater, NJ 08807.
NDA 014295	Conray 400 (iothalamate sodium) Injection USP, 66.8%	Mallinckrodt Inc., 675 McDonnell Blvd., Hazelwood, MO 63042.
NDA 016089	Rubratope-57 (cyanocobalamin CO-57) Capsules, 0.5–1 uCi and Rubratope-57 Kit (cobalt chloride CO-57, cyanocobalamin, cyanocobalamin CO-57, intrinsic factor).	Bracco Diagnostics Inc.
NDA 016672	Ovral (ethinyl estradiol and norgestrel) Tablets, 0.05 mg/0.5 mg.	Wyeth Pharmaceuticals Inc.
NDA 016692	M/6 Sodium Lactate (sodium lactate) Injection USP, 1.87 g/100 mL.	Baxter Healthcare Corp.
NDA 016696	Dextrose 10% and Sodium Chloride 0.9% Injection USP in Plastic Container.	Do.
NDA 016708	Sodium Chromate Cr 51 Injection, 100 μCi/mL	Mallinckrodt Nuclear Medicine LLC., 2703 Wagner Place, Maryland Heights, MO 63043.
NDA 016744	Noriday 1+50 FE (mestranol and norethindrone) Tablets	GD Searle LLC, Subsidiary of Pfizer Inc., 235 East 42nd St., New York, NY 10017.
NDA 016806	Ovral-28 (ethinyl estradiol and norgestrel) Tablets, 0.05 mg/0.5 mg.	Wyeth Pharmaceuticals Inc.
NDA 016860	Eskalith (lithium carbonate) Capsules, 300 mg	Noven Therapeutics, LLC., 11960 Southwest 144th St., Miami, FL 33186.
NDA 017038	Sodium Chloride Injection, 20 g/100 mL	B. Braun Medical Inc., 901 Marcon Blvd., Allentown, PA 18109.
NDA 017281	Technetium Tc99m Generator (Neutron)	Lantheus Medical Imaging, Inc., 331 Treble Cove Rd., North Billerica, MA 01862.
NDA 017283	Xenon Xe 133 Injection, 6.3 mCi/mL	Lantheus Medical Imaging, Inc.
NDA 017505	Noriday (mestranol and norethindrone) Tablets	GD Searle LLC.
NDA 017549	LidoPen (lidocaine HCl) Injection, 10%	Meridian Medical Technologies, Inc., Subsidiary of Pfizer Inc., 235 East 42nd Street, New York, NY 10017.
NDA 017576	Ovcon-50 (ethinyl estradiol and norethindrone) Tablets USP, 0.05 mg/1 mg.	Warner Chilcott Co., LLC, Union Street Road, 195 km 1.1, Fajrado, Puerto Rico 00738.
NDA 017670	Sodium Chloride 0.45% in Plastic Container, Irrigation	Hospira, Inc. 275 North Field Dr., Lake Forest, IL 60045.
NDA 017756	Tylenol (acetaminophen) Suppositories, 120 mg and 650 mg	Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division, 7050 Camp Hill Rd., Fort Washington, PA 19034.
NDA 017748	Noriday 1+50 (mestranol and norethindrone) Tablets	GD Searle LLC.
NDA 018031	Inderide (propranolol HCl and hydrochlorothiazide) Tablets, 40 mg/25 mg and 80 mg/25 mg.	Wyeth Pharmaceuticals Inc.
NDA 018039	Loxitane IM (loxapine HCl) Injection, Equivalent to (EQ) 50 mg base/mL.	Actavis Laboratories UT, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Road, Horsham, PA 19044.
NDA 018104	Hylorel (guanadrel sulfate) Tablets, 10 mg and 25 mg	Pharmacia and Upjohn Co.
NDA 018239	Propine (dipivefrin HCl) Ophthalmic Solution USP, 0.1%	Allergan, Inc.
NDA 018254	Ringer's and Dextrose 5% (calcium chloride, dextrose, potassium chloride, sodium chloride) Injection USP (in Plastic Container).	Hospira Inc.
NDA 018353	Flagyl I.V. (metronidazole HCl) for Injection, EQ 500 mg base/vial.	GD Searle LLC.
NDA 018388	Lidocaine HCl in Dextrose 5% in Plastic Container Injection ..	Hospira, Inc.

TABLE 1—Continued

Application No.	Drug	Applicant
NDA 018404	0.25% Acetic Acid Irrigation Solution	Do.
NDA 018406	PhysioSol (magnesium chloride, potassium chloride, sodium acetate, sodium chloride, sodium gluconate) Irrigation Solution.	Do.
NDA 018460	Dialyte (Peritoneal Dialysis Solution) Pattern LM (calcium chloride, dextrose, magnesium chloride, sodium acetate, sodium chloride) with Dextrose.	B. Braun Medical Inc.
NDA 018465	Soyacal (soybean oil) Injection, 10%	Grifols Biologicals Inc., 5555 Valley Blvd., Los Angeles, CA 90032.
NDA 018509	Baros (sodium bicarbonate, tartaric acid) Effervescent Granules, 460 mg/g; 420 mg/g).	Mallinckrodt Inc.
NDA 018713	Mycelex (clotrimazole) Troche/Lozenge, 10 mg	Bayer Healthcare Pharmaceuticals Inc., 100 Bayer Blvd., Whippany, NJ 07981.
ANDA 018730	Indomethacin Capsules USP, 25 mg and 50 mg	Zenith Laboratories, Inc., 140 LeGrand Ave., Northvale, NJ 07647.
NDA 018786	Soyacal(Soybean Oil) Injection, 20%	Grifols Biologicals Inc., 5555 Valley Blvd., Los Angeles, CA 90032.
NDA 018807	Dialyte (Peritoneal Dialysis Concentrates) (calcium chloride, dextrose, magnesium chloride, sodium acetate, sodium chloride) with Dextrose.	B. Braun Medical Inc.
NDA 018887	Intal (cromolyn sodium) Metered Dose Inhaler, 0.8 mg/inhalation.	King Pharmaceuticals Inc., Subsidiary of Pfizer Inc., 235 East 42nd St., New York, NY 10017.
NDA 018970	Liposyn III 20% (soybean oil) Injection	Hospira, Inc.
NDA 018991	Liposyn II 20% (safflower oil and soybean oil) Injection	Do.
NDA 018997	Liposyn II 10% (safflower oil and soybean oil) Injection	Do.
NDA 019038	Calan (verapamil HCl) Injection, 2.5 mg/mL	G.D. Searle LLC.
NDA 019121	Bretylium Tosylate in 5% Dextrose Injection	B. Braun Medical Inc.
NDA 019212	Theophylline and 5% Dextrose Injection	Do.
NDA 019229	Zinc Sulfate Injection, EQ 1 mg Zinc/mL	Abraxis Pharmaceutical Products, 6133 North River Rd., Suite 500, Rosemont, IL 60018.
NDA 019350	Cupric Sulfate Injection, EQ 0.4 mg Copper/mL	Do.
NDA 019415	Fertinex (urofollitropin) for Subcutaneous Injection, 75 international units (IU)/ampule and 150 IU/ampule, and Metrodin (urofollitropin) for Intramuscular Injection, 75 IU)/ampule and 150 IU/ampule.	EMD Serono, Inc., One Technology Pl., Rockland, MA 02370.
NDA 019510	Pepcid (famotidine) Injection, 10 mg/mL	Merck Sharp & Dohme Corp., Subsidiary of Merck & Co., Inc., 1 Merck Dr., P.O. Box 100, Whitehouse Station, NJ 08889.
NDA 019514	Ionosol T and 5% Dextrose Injection	Hospira, Inc.
NDA 019515	Ionosol B and 5% Dextrose Injection	Do.
NDA 019641	Terazol 3 (terconazole) Vaginal Suppositories, 80 mg	Janssen Pharmaceuticals, Inc., 1000 U.S. Highway 202, Raritan, NJ 08869.
NDA 019643	Mevacor (lovastatin) Tablets, 10 mg, 20 mg, and 40 mg	Merck Sharp & Dohme Corp.
NDA 019660	Tilade (nedocromil sodium) Metered Dose Inhaler, 1.75 mg/inhalation.	King Pharmaceuticals Inc.
NDA 019793	Pharmaseal Scrub Care (chlorhexidine gluconate) Sponge, 4%.	CareFusion 2200, Inc., 75 North Fairway Dr., Vernon Hills, IL 60061.
NDA 019802	Heparin Sodium in Sodium Chloride Injection	B. Braun Medical Inc.
NDA 019834	Plendil (felodipine) Extended-Release Tablets, 2.5 mg, 5 mg, and 10 mg.	AstraZeneca Pharmaceuticals LP, 1800 Concord Pike, Wilmington, DE 19803.
NDA 019907	Optipranolol (metipranolol HCl) Ophthalmic Solution, 0.3%	Bausch & Lomb, Inc., Subsidiary of Valeant Pharmaceuticals International, Inc., 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
NDA 019933	Lactated Ringer's (calcium chloride, potassium chloride, sodium chloride, sodium lactate) Irrigation Solution.	Baxter Healthcare Corp.
NDA 020092	Dilacor XR (diltiazem HCl) Extended-Release Capsules, 120 mg, 180 mg, and 240 mg.	Allergan Sales, LLC, 2525 Dupont Drive, Irvine, CA 92612.
NDA 020146	Nitrodisc (nitroglycerin) Transdermal System, 0.2 mg/hour (hr), 0.3 mg/hr, and 0.4 mg/hr.	GD Searle LLC.
NDA 020181	Liposyn III 30% (soybean oil) Injection	Hospira, Inc.
NDA 020249	Pepcid Preservative Free (famotidine) Injection, 0.4 mg/mL ..	Merck Sharp & Dohme Corp.
NDA 020291	Combivent (albuterol sulfate and ipratropium bromide) Metered Dose Inhaler, EQ 0.09 mg base/inhalation; 0.018 mg/inhalation.	Boehringer Ingelheim Pharmaceuticals Inc., 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877.
NDA 020292	FerriSeltz (ferric ammonium citrate) Powder for Oral Solution, 600 mg/packet.	Otsuka Pharmaceutical Co., Ltd., 508 Carnegie Center Dr., Princeton, NJ 08540.
ANDA 020360	Hepatasol Sulfite-free (amino acids) Injection, 8%	Baxter Healthcare Corp.
NDA 020409	Nasarel (flunisolide) Nasal Spray, 0.029 mg/spray	Teva Branded Pharmaceutical Products R&D, Inc., 74 NW 176th St., Miami, FL 33169.
NDA 020448	Imodium A–D (loperamide HCl) Tablets (Chewable), 2 mg	Johnson & Johnson Consumer Inc.
NDA 020506	Tiamate (diltiazem malate) Extended-Release Tablets	Merck & Co., Inc., P.O. Box 1000, UG2C–50, North Wales, PA 19454.

TABLE 1—Continued

Application No.	Drug	Applicant
NDA 020518	Retrovir (zidovudine) Tablets, 200 mg and 300 mg	ViiV Healthcare Co., Five Moore Dr., P.O. Box 13398, Research Triangle Park, NC 27709.
NDA 020569	Vitrasert (ganciclovir) Implant, 4.5 mg	Bausch & Lomb Inc.
NDA 020606	Imodium Multi-Symptom Relief (loperamide HCl and simethicone) Tablets (Chewable), 2 mg/125 mg.	Johnson & Johnson Consumer Inc.
NDA 020635	Levaquin (levofloxacin) Injection, EQ 250 mg/50 mL, EQ 500 mg/100 mL, and EQ 750 mg/150 mL.	Janssen Pharmaceuticals, Inc.
NDA 020745	Zantac (ranitidine HCl) Tablets (Effervescent), EQ 75 mg base.	Sanofi-Aventis U.S. LLC, 55 Corporate Drive, Bridgewater, NJ 08807.
NDA 020752	Pepcid RPD (famotidine) Orally Disintegrating Tablets, 20 mg and 40 mg.	Merck Sharp & Dohme Corp.
NDA 020799	Floxin Otic (ofloxacin) Otic Solution, 0.3%	Daiichi Sankyo Co., Ltd., 399 Thornall St., Edison, NJ 08837.
NDA 020813	Klonopin (clonazepam) Orally Disintegrating Tablets, 0.125 mg, 0.25 mg, 0.5 mg, 1 mg, and 2 mg.	Hoffmann La-Roche, Inc., c/o Genentech, Inc., 1 DNA Way MS #242, South San Francisco, CA 94080.
NDA 020902	Pepcid AC (famotidine) Tablets OTC, 10 mg	Johnson & Johnson Consumer Inc.
NDA 021097	Visicol (sodium phosphate, monobasic monohydrate, and sodium phosphate dibasic anhydrous) Tablets USP.	Salix Pharmaceuticals Inc., Subsidiary of Valeant Pharmaceuticals North America LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
NDA 021214	Rescula (unoprostone isopropyl) Ophthalmic Solution, 0.15%	R-Tech Ueno, Ltd., c/o Sucampo Pharma Americas, LLC, 805 King Farm Blvd., Suite 550, Rockville, MD 20850.
NDA 021224	Razadyne (galantamine hydrobromide) Oral Solution, 4 mg/mL.	Janssen Pharmaceuticals, Inc.
NDA 021317	Bayer Extra Strength Aspirin (aspirin) Tablets, 500 mg	Bayer Healthcare LLC, 100 Bayer Blvd., Whippany, NJ 07981.
NDA 021412	Tovalt ODT (zolpidem tartrate) Orally Disintegrating Tablets, 5 mg and 10 mg.	Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
NDA 021453	Zerit XR (stavudine) Extended-Release Capsules, 37.5 mg, 50 mg, 75 mg, and 100 mg.	Bristol-Myers Squibb Co., 5 Research Parkway, Wallingford, CT 06492.
NDA 021483	Geodon (ziprasidone HCl) Oral Suspension, EQ10 mg base/mL.	Pfizer Inc., 235 East 42nd St., New York, NY 10017.
NDA 021494	Axid (nizatidine) Oral Solution, 15 mg/mL	Braintree Laboratories, Inc., 60 Columbian St. West, P.O. Box 850929, Braintree, MA 02185.
NDA 021589	Kemstro (baclofen) Orally Disintegrating Tablets, 10 mg and 20 mg.	UCB, Inc.,1950 Lake Park Dr., Smyrna, GA 30080.
NDA 021595	Sanctura (trospium chloride) Tablets, 20 mg	Allergan, Inc.
NDA 021721	Levaquin (levofloxacin) Oral Solution, 25 mg/mL	Janssen Pharmaceuticals, Inc.
NDA 021763	Citalopram Hydrobromide Orally Disintegrating Tablets, EQ 10 mg base, EQ 20 mg base, and EQ 40 mg base.	Valeant International (Barbados) SRL Welches, Christ Church, Barbados, BB17154.
NDA 021864	Lybrel (ethinyl estradiol and levonorgestrel) Tablets, 0.02 mg/0.09 mg.	Wyeth Pharmaceuticals Inc.
NDA 022103	Sanctura XR (trospium chloride) Extended-Release Capsules, 60 mg.	Allergan, Inc.
NDA 022220	Trivaris (triamcinolone acetonide) Injectable Suspension, 80 mg/mL.	Do.
NDA 022294	Zidovudine Tablets, 60 mg	Aurobindo Pharma Limited, c/o Aurobindo Pharma USA, Inc., 2400 Route 130 North, Dayton, NJ 08810.
NDA 022377	Alsuma (sumatriptan succinate) Auto-Injector, EQ 6 mg base/0.5 mL Injectable.	Meridian Medical Technologies, Inc., 1945 Craig Rd., St. Louis, MO 63146.
NDA 022411	Oleptro (trazodone HCl) Extended-Release Tablets, 150 mg and 300 mg.	Angelini Pharma Inc., 8322 Helgerman Ct., Gaithersburg, MD 20877.
NDA 022494	Sodium Fluoride F 18 Injection, 10–200 mCi/mL	National Institutes of Health/National Cancer Institute, Cancer Imaging Program, 9609 Medical Center Dr., Room 4–W236, MSC 9729, Bethesda, MD 20892–9729.
NDA 022545	Tekamlo (aliskiren hemifumarate and amlodipine besylate) Tablets.	Novartis Pharmaceuticals Corp., One Health Plaza, East Hanover, NJ 07936.
ANDA 040032	Cyclophosphamide Tablets USP, 25 mg and 50 mg	Roxane Laboratories, Inc., 1809 Wilson Rd., Columbus, OH 43228.
ANDA 040262	Leucovorin Calcium for Injection, EQ 350 mg base/vial	Pharmachemie B.V., c/o SICOR Pharmaceuticals, Inc., 19 Hughes, Irvine, CA 92618.
ANDA 040772	Fluorouracil Injection USP, 50 mg/mL	Sandoz Inc., 100 College Road West, Princeton, NJ 08540.
ANDA 040793	A-Methapred (methylprednisolone sodium succinate) for Injection USP, EQ 40 mg base/vial.	Hospira, Inc.
ANDA 040827	A-Methapred (methylprednisolone sodium succinate) for Injection USP, EQ 125 mg base/vial.	Do.
NDA 050182	Erythrocin (erythromycin lactobionate) for Injection USP	Do.
NDA 050435	Geocillin (carbenicillin indanyl sodium) Tablets, EQ 382 mg base.	Pfizer, Inc.
NDA 050528	Duricef (cefadroxil) Tablets USP, EQ 1 g base	Warner Chilcott Co., Inc., 100 Enterprise Drive, Rockaway, NJ 07866.
NDA 050545	Pipracil (piperacillin sodium) Injection	Wyeth Pharmaceuticals Inc.
NDA 050590	Timentin (ticarcillin disodium and clavulanate potassium) for Injection.	GlaxoSmithKline.

TABLE 1—Continued

Application No.	Drug	Applicant
NDA 050658	Timentin Galaxy Plastic Container(ticarcillin disodium and clavulanate potassium) for Injection.	Do.
NDA 050664	Cefzil (cefprozil) Tablets, 250 mg and 500 mg	Corden Pharma Latina, S.p.A. , c/o Clinipace, Inc., 4840 Pearl East Circle, Suite 210E, Boulder, CO 80301.
NDA 050665	Cefzil (cefprozil) Oral Suspension, 125 mg/5 mL and 250 mg/5 mL.	Do.
ANDA 060076	Streptomycin Sulfate Powder for Injection, EQ 1 g base/vial and EQ 5 g base/vial.	Pfizer Inc.
ANDA 060111	Streptomycin Sulfate Powder for Injection, EQ 1 g base/2.5 mL.	Do.
ANDA 060607	Neomycin Sulfate Tablets, 500 mg	Lannett Co., Inc., 9000 State Rd., Philadelphia, PA 19136.
ANDA 061578	Poly-Rx (polymyxin B sulfate USP) for Prescription Compounding.	X–GEN Pharmaceuticals, Inc., 300 Daniel Zenker Dr., Horseheads, NY 14845.
ANDA 061580	Baci-Rx (bacitracinUSP) for Prescription Compounding	Do.
ANDA 061645	Econochlor (chloramphenicol) Ophthalmic Solution USP, 0.5%.	Alcon Laboratories, Inc., 6201 South Freeway, TC–45, Fort Worth, TX 76134–2099.
ANDA 061648	Chloramphenicol Ophthalmic Ointment, 1%	Do.
ANDA 062118	Cephalexin Capsules USP, EQ 250 mg base and EQ 500 mg base.	Do.
ANDA 062206	Cefaclor for Oral Suspension USP, EQ 125 mg base/5 mL, EQ 187 mg base/5 mL, EQ 250 mg base/5 mL, and EQ 375 mg base/5 mL.	Do.
ANDA 062339	Statrol (neomycin sulfate and polymyxin B sulfate) Ophthalmic Solution, EQ 3.5 mg base/mL and 16,250 units/mL.	Alcon Laboratories, Inc.
ANDA 062523	Gentamicin Sulfate Ophthalmic Solution USP, EQ 0.3% base	Do.
ANDA 062628	Chloramphenicol Ophthalmic Solution USP, 0.5%	Do.
ANDA 062691	Timentin ADD-Vantage (ticarcillin disodium and clavulanate potassium) for Injection USP, EQ 3 g base/vial and EQ 100 mg base/vial.	GlaxoSmithKline.
ANDA 062714	Neomycin Sulfate and Dexamethasone Sodium Phosphate Ophthalmic Solution, EQ 3.5 mg base/mL and EQ 0.1% and.	Alcon Pharmaceuticals Ltd., 6201 South Freeway, Fort Worth, TX 76134.
ANDA 062721	Neomycin and Polymyxin B Sulfate and Dexamethasone Ophthalmic Suspension USP, EQ 3.5 mg base/mL; 10,000 units/mL; 0.1%.	Do.
ANDA 062822	Pediotic (neomycin sulfate and polymyxin B sulfate and hydrocortisone) Otic Suspension USP.	Monarch Pharmaceuticals, Inc., Subsidiary of Pfizer Inc., 235 East 42nd St., New York, NY 10017–7555.
ANDA 063176	Tobramycin Ophthalmic Solution USP, 0.3%	Alcon Pharmaceuticals, Ltd.
ANDA 063208	Cefazolin for Injection USP, EQ 1 g base/100 mL vial	Steri-Pharma, LLC, 429 South West St., Syracuse, NY 13202.
ANDA 063216	Cefazolin for Injection USP, EQ 500 mg base/100 mL vial	Do.
ANDA 063283	Amikacin Sulfate Injection, EQ 62.5 mg base/mL	Hospira, Inc.
ANDA 064169	Cefazolin for Injection USP, EQ 500 mg base/vial and EQ 1 g base/vial.	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 064170	Cefazolin for Injection USP, EQ 10 g base/vial and EQ 20 g base/vial.	Do.
ANDA 065010	Neo-Fradin (neomycin sulfate) Oral Solution USP, EQ 87.5 mg base/5 mL.	X–GEN Pharmaceuticals, Inc.
ANDA 065011	Cefoxitin (cefoxitin sodium) for Injection, EQ 10 g base/Vial ..	Fresenius Kabi USA, LLC.
ANDA 065012	Cefoxitin for Injection USP, EQ 1 g base/vial and EQ 2 g base/vial.	Do.
ANDA 065245	Ceftriaxone for Injection USP, EQ 250 mg base/vial, EQ 500 mg base/vial, EQ 1 g base/vial, and EQ 2 g base/vial.	Do.
ANDA 065252	Ceftriaxone for Injection, EQ 10 g base/vial	Do.
ANDA 065324	Amoxicillin Tablets for Oral Suspension USP, 200 mg and 400 mg.	Aurobindo Pharma Limited.
ANDA 065339	Epirubicin HCl Injection, 50 mg/25 mL and 200 mg/100 mL ..	Sandoz, Inc.
ANDA 065465	Ceftriaxone for Injection USP, EQ 250 mg base/vial, EQ 500 mg base/vial, EQ 1 g base/vial, and EQ 2 g base/vial.	Bedford Laboratories, c/o PAREXEL International, 4600 East-West Highway, Suite 350, Bethesda, MD 20814.
ANDA 065475	Ceftriaxone for Injection USP, EQ 10 g base/vial	Do.
ANDA 070088	Ibuprofen Tablets USP, 600 mg	BASF Corp., 5738 County Rd. 4, Bishop, TX 78343.
ANDA 070187	Disopyramide Phosphate Capsules USP, EQ 150 mg base ..	Ivax Pharmaceuticals Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Road, Horsham, PA 19044.
ANDA 070587	Bupivacaine HCl Injection USP, 0.75%	Hospira, Inc.
ANDA 070659	Clonidine HCl Tablets, 0.3 mg	Teva Pharmaceuticals USA Inc., 1090 Horsham Rd., P.O. Box 1090, North Wales, PA 19454.
ANDA 070702	Clonidine HCl Tablets, 0.2 mg	Do.
ANDA 070747	Clonidine HCl Tablets, 0.1 mg	Do.
ANDA 070804	Metaproterenol Sulfate Inhalation Solution USP, 0.6%	Mylan Specialty, L.P., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504.
ANDA 071067	Methyldopa Tablets USP, 500 mg	Teva Pharmaceuticals USA, Inc.

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 071101	Clonidine HCl Tablets USP, 0.3 mg	Duramed Pharmaceuticals, Inc., 2 Quaker Rd., P.O. Box 2900, Pomona, NY 10970.
ANDA 071102	Clonidine HCl Tablets USP, 0.2 mg	Do.
ANDA 071103	Clonidine HCl Tablets USP, 0.1 mg	Do.
ANDA 071105	Methyldopa Tablets USP, 125 mg	Teva Pharmaceuticals USA, Inc.
ANDA 071106	Methyldopa Tablets USP, 250 mg	Do.
ANDA 071426	Vincasar PFS (vincristine sulfate) Injection USP, 1 mg/mL	Teva Parenteral Medicines Inc., 19 Hughes, Irvine, CA 92618.
ANDA 071584	Diazepam Injection USP, 5 mg/mL	Hospira, Inc.
ANDA 071786	Metaproterenol Sulfate Inhalation Solution USP, 0.4%	Mylan Specialty L.P.
ANDA 072323	Acetylcysteine Solution USP, 10%	Roxane Laboratories, Inc.
ANDA 072324	Acetylcysteine Solution USP, 20%	Do.
ANDA 073034	Metaproterenol Sulfate Oral Solution USP, 10 mg/5 mL	G&W Laboratories Inc., 111 Coolidge St., South Plainfield, NJ 07080.
ANDA 073636	Dipivefrin HCl Ophthalmic Solution USP, 0.1%	Alcon Pharmaceuticals, Ltd.
ANDA 073676	Atenolol Tablets, 50 mg and 100 mg	GD Searle LLC.
ANDA 074023	Ranitidine Tablets USP, 150 mg and 300 mg	Mylan Pharmaceuticals Inc.
ANDA 074160	Bumetanide Injection USP, 0.25 mg/mL	Hospira, Inc.
ANDA 074269	Cimetidine in Sodium Chloride 0.9% Injection USP, EQ6 mg base/mL).	Do.
ANDA 074300	Lorazepam Injection USP, 2 mg/mL and 4 mg/mL	Do.
ANDA 074396	Enflurane Inhalation , 99.9%	Piramal Critical Care, Inc., 3950 Schelden Circle, Bethlehem, PA 18017.
ANDA 074546	Clozapine Tablets USP, 25 mg and 100 mg	Sandoz, Inc.
ANDA 074632	Atracurium Besylate Injection, 10 mg/mL	Hospira, Inc.
ANDA 074851	Levobunolol HCl Ophthalmic Solution USP, 0.25%	Alcon Laboratories, Inc.
ANDA 074927	Etodolac Tablets USP, 400 mg	Lehigh Valley Technologies, Inc., 514 North 12th St., Allentown, PA 18102.
ANDA 075117	Orapred (prednisolone sodium phosphate) Oral Solution, EQ 15 mg base/5 mL.	Concordia Pharmaceuticals, Inc., c/o Mapi USA, Inc., 2343 Alexandria Dr., Suite 100, Lexington, KY 40504.
ANDA 075436	Paclitaxel Injection USP, 6 mg/mL	Accord Healthcare Inc., 1009 Slater Rd., Suite 210–B, Durham, NC 27703.
ANDA 075721	Leuprolide Acetate Injection, 1 mg/0.2 mL	Genzyme Corp., 500 Kendall St., Cambridge, MA 02142.
ANDA 075963	Tramadol HCl Tablets, 50 mg	Ivax Pharmaceuticals Inc.
ANDA 076234	Flavoxate HCl Tablets, 100 mg	Impax Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544.
ANDA 076296	Vincristine Sulfate Injection USP, 1 mg/mL	Fresenius Kabi USA, LLC.
ANDA 076394	Amiodarone HCl Injection, 50 mg/mL	Par Sterile Products, LLC, Morris Corporate Center 2, One Upper Pond Rd., Parsippany, NJ 07054.
ANDA 076401	Vincristine Sulfate Injection USP, 1 mg/mL	Fresenius Kabi USA, LLC.
ANDA 076414	Milrinone Lactate in 5% Dextrose Injection, EQ 20 mg base/100 mL.	B. Braun Medical Inc.
ANDA 076563	Diltiazem HCl Extended-Release Capsules USP, 120 mg, 180 mg, 240 mg, 300 mg, 360 mg, 420 mg.	Nesher Pharmaceuticals (USA) LLC, 13910 St. Charles Rock Rd., Bridgeton, MO 63044.
ANDA 076699	Parcopa (carbidopa and levodopa) Orally Disintegrating Tablets, 10 mg/100 mg, 25 mg/100 mg, and 25 mg/250 mg.	UCB, Inc., 1950 Lake Park Dr., Bldg. 2100, Smyrna, GA 30080.
ANDA 077275	Didanosine Tablets for Oral Suspension USP, 100 mg, 150 mg, and 200 mg.	Aurobindo Pharma Limited.
ANDA 077774	Stavudine for Oral Solution USP, 1 mg/mL	Do.
ANDA 077887	Carvedilol Tablets USP, 3.125 mg, 6.25 mg, 12.5 mg, 25 mg	Hikma Pharmaceuticals, c/o West-Ward Pharmaceuticals Corp., 401 Industrial Way West, Eatontown, NJ 07724.
ANDA 077968	Alprazolam Extended-Release Tablets, 0.5 mg, 1 mg, 2 mg, and 3 mg.	Impax Laboratories, Inc.
ANDA 077996	Alprazolam Extended-Release Tablets, 0.5 mg, 1 mg, 2 mg, 3 mg.	Do.
ANDA 078112	Didanosine for Oral Solution USP, 10 mg/mL	Aurobindo Pharma Limited.
ANDA 078240	Carvedilol Tablets, 3.125 mg, 6.25 mg, 12.5 mg, and 25 mg	Pliva Hrvatska d.o.o., Subsidiary of Teva Pharmaceutical Industries Ltd., 425 Privet Rd., Horsham, PA 19044.
ANDA 078254	Atenolol Tablets USP, 25 mg, 50 mg, and 100 mg	Northstar Healthcare Holdings, c/o Quality Regulatory Consultants, 1966 Anglers Cove, Vero Beach, FL 32963.
ANDA 078285	Bicalutamide Tablets USP, 50 mg	Roxane Laboratories, Inc.
ANDA 078298	Sumatriptan Succinate Tablets USP, EQ 25 mg base, EQ 50 mg base, EQ 100 mg base.	Hikma Pharmaceuticals.
ANDA 078310	Lamotrigine Tablets USP, 25 mg, 100 mg, 150 mg, and 200 mg.	Pharmascience Inc., c/o Pharmascience Laboratories Inc., 295 Firetower Rd., Tonawanda, NY 14150.
ANDA 078334	Granisol (granisetron HCl Oral Solution, 2 mg base/10mL	PediatRx, Inc., c/o Cardinal Health Regulatory Sciences, 7400 West 110th St., Commerce Plaza II, Suite 300, Overland Park, KS 66210.
ANDA 078374	Metoclopramide Tablets USP, EQ 5 mg base and EQ 10 mg base.	Northstar Healthcare Holdings.
ANDA 078408	Vinorelbine Injection USP, EQ 10 mg base/mL	Sandoz Inc.

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 078501	Dronabinol Capsules USP, 2.5 mg, 5 mg, and 10 mg	Insys Therapeutics, Inc., 1333 South Spectrum Blvd., Suite 100, Chandler, AZ 85286.
ANDA 078577	Levofloxacin Injection, EQ 750 mg/30 mL and EQ 500 mg/20 mL.	Hospira Inc.
ANDA 078782	Gabapentin Tablets USP, 600 mg and 800 mg	Hikma Pharmaceuticals.
ANDA 078808	Granisetron HCl Injection USP, EQ 0.1 mg base/mL	Sandoz Inc.
ANDA 078812	Oxaliplatin Injection USP, 50 mg/10 mL and 100 mg/20 mL ..	Do.
ANDA 078952	Glimepiride Tablets USP, 1 mg, 2 mg, and 4 mg	Hikma Pharmaceuticals.
ANDA 079033	Fomepizole Injection, 1.5 g/1.5 mL	Mylan Institutional LLC, 4901 Hiawatha Dr., Rockford, IL 61103.
ANDA 080020	Isopto Cetamide (sulfacetamide sodium) Ophthalmic Solution, 15%.	Alcon Laboratories, Inc.
ANDA 080021	Sulfacetamide Sodium Ophthalmic Ointment, 10%	Do.
ANDA 080229	Naphcon Forte (naphazoline HCl) Ophthalmic Solution USP 0.1%.	Do.
ANDA 080248	Albalon (naphazoline HCl) Ophthalmic Solution USP, 0.1% ...	Allergan, Inc.
ANDA 080472	Hytone (hydrocortisone) Cream, 1% and 2.5%	Valeant International (Barbados) SRL, c/o Valeant Pharmaceuticals North America LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
ANDA 080473	Hytone (hydrocortisone) Lotion, 1% and 2.5%	Do.
ANDA 081043	Prednisolone Sodium Phosphate Ophthalmic Solution USP, EQ 0.11% phosphate.	Alcon Pharmaceuticals, Ltd.
ANDA 081044	Prednisolone Sodium Phosphate Ophthalmic Solution USP, EQ 0.9% phosphate.	Do.
ANDA 083205	Orabase HCA (hydrocortisone acetate) Topical Paste, 0.5%	Colgate-Palmolive Co., 909 River Rd., P.O. Box 1343, Piscataway, NJ 08855–1343.
ANDA 083342	Maxidex (dexamethasone sodium phosphate) Ophthalmic Ointment, EQ 0.05% phosphate.	Alcon Laboratories, Inc.
ANDA 084645	Chlordiazepoxide HCl Capsules USP, 25 mg	Upsher-Smith Laboratories, Inc.
ANDA 084927	Methocarbamol Tablets USP, 500 mg	Impax Laboratories, Inc.
ANDA 084928	Methocarbamol Tablets USP, 750 mg	Do.
ANDA 085000	Chlordiazepoxide HCl Capsules USP, 10 mg	Hikma Pharmaceuticals.
ANDA 085014	Chlordiazepoxide HCl Capsules USP, 5 mg	Do.
ANDA 085095	Statobex-G (phendimetrazine tartrate) Tablets, 35 mg	Teva Pharmaceuticals USA, Inc.
ANDA 085294	Chlordiazepoxide HCl Capsules USP, 25 mg	Hikma Pharmaceuticals.
ANDA 085380	Butisol Sodium (butabarbital sodium) Oral Solution USP, 30 mg/5 mL.	Meda Pharmaceuticals Inc., 265 Davidson Ave., Suite #4300, Somerset, NJ 08873.
ANDA 085734	Ammonium Chloride Injection USP, 40 mEQ/100 mL	B. Braun Medical Inc.
ANDA 085981	Hydrocortisone Acetate USP Micronized for Prescription Compounding, 100%.	X-Gen Pharmaceuticals, Inc.
ANDA 085982	Hydro-Rx (hydrocortisone) USP Micronized for Prescription Compounding, 100%.	Do.
ANDA 085995	Pediatric LTA Kit (lidocaine HCl) Topical Solution USP, 2% ..	Hospira, Inc.
ANDA 086535	Acticort (hydrocortisone) Lotion USP, 1%	Baker Norton Pharmaceuticals Inc., 8800 N.W. 36 St., Miami, FL 33178–2404.
ANDA 086911	Phentermine HCl Capsules USP, 30 mg	Teva Pharmaceuticals USA, Inc.
ANDA 087547	Isopto Cetapred (sulfacetamide sodium and prednisolone acetate) Ophthalmic Ointment USP, 10%/0.25%.	Alcon Laboratories, Inc.
ANDA 087771	Cetapred (sulfacetamide sodium and prednisolone acetate) Ophthalmic Ointment USP, 10%/0.25%.	Do.
ANDA 087907	Epinephrine Inhalation Aerosol USP, 0.2 mg/inhalation)	Armstrong Pharmaceuticals, Inc., 25 John Rd., Canton MA 02021.
ANDA 088613	Phentermine HCl Capsules USP, 30 mg	Teva Pharmaceuticals USA, Inc.
ANDA 088614	Phentermine HCl Capsules USP, 30 mg	Do.
ANDA 088630	Pseudoephedrine HCl and Triprolidine HCl Tablets, 60 mg/2.5 mg.	Do.
ANDA 088631	Butabarbital Sodium Tablets, 30 mg	Do.
ANDA 088632	Butabarbital Sodium Tablets, 15 mg	Do.
ANDA 088797	Phentermine HCl Capsules USP, 30 mg	USL Pharma Inc., 301 South Cherokee St., Denver, CO 80223
ANDA 088910	Phentermine HCl Tablets USP, 37.5 mg	Do.
ANDA 088917	Phentermine HCl Tablets USP, 37.5	Do.
ANDA 088999	Dipyridamole Tablets USP, 25 mg	Glenmark Generics Limited, c/o Glenmark Generics Inc., USA, 750 Corporate Dr., Mahwah, NJ 07430.
ANDA 089000	Dipyridamole Tablets USP, 50 mg	Do.
ANDA 089001	Dipyridamole Tablets USP, 75 mg	Do.
ANDA 089068	Sulfacetamide Sodium Ophthalmic Solution, 30%	Alcon Pharmaceuticals, Ltd.
ANDA 089172	Tropicamide Ophthalmic Solution, 1%	Do.
ANDA 089422	Imipramine HCl Tablets USP, 10 mg	Par Pharmaceutical Inc., One Ram Ridge Rd., Spring Valley, NY 10977.
ANDA 089440	Hydrocortisone Acetate and Pramoxine HCl Topical Aerosol, 1%/1%.	Vintage Pharmaceuticals, 150 Vintage Dr., Huntsville, AL 35811.

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 089497	Imipramine HCl Tablets USP, 25 mg	Par Pharmaceutical Inc.
ANDA 089628	Leucovorin Calcium for Injection, EQ 50 mg base/vial	Pharmachemie USA Inc., 323 Davis St., Northborough, MA 01532.
ANDA 089681	Bromfed-DM (brompheniramine maleate, dextromethorphan hydrobromide, and pseudoephedrine HCl) Syrup, 2 mg/5 mL; 10mg/5 mL; 30mg/5 mL.	Wockhardt Bio AG, c/o Morton Grove Pharmaceuticals, Inc., 6451 Main St., Morton Grove, IL 60053.
ANDA 089915	Leucovorin Calcium for Injection, EQ 100 mg base/vial	Pharmachemie USA Inc.
ANDA 090098	Tretinoin Cream USP, 0.0375%	Allergan Sales, LLC.
ANDA 090137	Irinotecan HCl Injection, 40 mg/2 mL and 100 mg/5 mL	Sandoz Inc.
ANDA 090190	Pramipexole Dihydrochloride Tablets, 0.125 mg, 0.25 mg, 0.5 mg, 0.75 mg, 1 mg, and 1.5 mg.	Do.
ANDA 090220	Adenosine Injection USP, 3 mg/mL	Wockhardt Limited, c/o Wockhardt USA LLC, 20 Waterview Blvd., 3rd Floor, Parsippany, NJ 07054.
ANDA 090300	Children's Cetirizine HCl Allergy and Hives Relief Oral Solution OTC, 5 mg/5 mL.	Cypress Pharmaceutical, Inc., 10 North Park Place, Suite 210, Morristown, NJ 07960.
ANDA 090751	Cetirizine HCl Oral Solution USP, 5 mg/5 mL	Aurobindo Pharma Limited.
ANDA 090985	Octreotide Acetate Preservative Free Injection EQ 0.05 mg base/mL, EQ 0.1 mg base/mL, and EQ 0.5 mg base/mL.	Wockhardt Limited.
ANDA 090986	Octreotide Acetate Injection EQ 0.2 mg base/mL and EQ 1 mg base/mL.	Do.
ANDA 091068	Ceftriaxone for Injection USP, EQ 10 g base/vial	Agila Specialties Private Limited, c/o Agila Specialties Inc., 201 South Main St., Suite 3, Lambertville, NJ 08530.
ANDA 091185	Topiramate Tablets USP, 25 mg, 50 mg, 100 mg, and 200 mg.	Hikma Pharmaceuticals.
ANDA 091293	Idarubicin HCl Injection, 1 mg/mL	Sandoz Inc.
ANDA 091299	Fluorouracil Injection USP, 2.5 g/50 mL and 5 g/100 mL	Do.
NDA 200045	Amturnide (aliskiren hemifumarate, amlodipine, andhydrochlorothiazide) Tablets.	Novartis Pharmaceuticals Corp.
ANDA 200146	Doxorubicin HCl Injection USP, 2 mg/mL	Sandoz Inc.
NDA 200199	Topotecan Injection, EQ 1 mg base/mL, EQ 3 mg base/3 mL, and EQ 4 mg base/4 mL.	Do.
ANDA 201211	Bromfenac Sodium Ophthalmic Solution, EQ 0.09% acid	Coastal Pharmaceuticals, 1240 Sugg Parkway, Greenville, NC 27834.
NDA 201917	Incivek (telaprevir) Tablets, 375 mg	Vertex Pharmaceuticals, Inc., 50 Northern Ave., Boston, MA 02210.
NDA 202088	Suprenza (phentermine HCl) Orally Disintegrating Tablets, 15 mg, 30 mg, and 37.5 mg.	Citius Pharmaceuticals, LLC, 11 Commerce Dr., First Floor, Cranford, NJ 07016.
ANDA 202209	Tretinoin Cream USP, 0.075%	Allergan Sales, LLC.
NDA 202513	Gelnique (oxybutynin) Gel, 3%	Do.
NDA 203595	Suclear (magnesium sufate, polyethylene glycol 3350, potassium chloride, potassium sulfate, sodium bicarbonate, sodium chloride, and sodium sulfate) Oral Solution.	Braintree Laboratories, Inc.
NDA 204508	Clinolipid 20% (olive oil and soybean oil) USP, 16%/4%	Baxter Healthcare Corp.
NDA 206510	Dutrebis (lamivudine and raltegravir potassium) Tablets, 150 mg/EQ 300 mg base.	Merck Sharp & Dohme Corp.

Therefore, under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic 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: June 15, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–12908 Filed 6–20–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[CFDA Number: 93.085]

Awards Unsolicited Proposal for the Professionalism and Integrity in Research Program

AGENCY: Office of Research Integrity, Office of the Assistant Secretary for Health, Department of Health and Human Services.

ACTION: Notice of award of a single-source unsolicited grant to Washington University in St. Louis, Missouri.

SUMMARY: The Office of Research Integrity (ORI) announces the award of a single-source, grant in response to an unsolicited proposal from Washington University, St. Louis, Missouri. The proposal submitted was not solicited either formally or informally by any federal government official.

FOR FURTHER INFORMATION CONTACT: Kathryn Partin at *kathryn.partin@hhs.gov* or by telephone at 240–453–8200.

SUPPLEMENTARY INFORMATION:

Recipient: Washington University, St. Louis, Missouri.

Purpose of the Award: Grant to provide remediation training through