and verification requirements of section 505(q) and has also made revisions to clarify aspects of the guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on citizen petitions and petitions for stay of action that are subject to section 505(q) of the FD&C Act. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (44 U.S.C. 3501–3520). The collections of information in this guidance were approved under OMB control number 0910–0679. This guidance also refers to previously approved collections of information found in FDA regulations and approved under OMB control number 0910–0183 (21 CFR 10.20, 10.30, and 10.35) and OMB control number 0910–0001 (21 CFR 314.54, 314.94, and 314.102).

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: *June 2, 2011.*

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–14058 Filed 6–7–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0411]

Bristol-Myers Squibb Co. et al.; Withdrawal of Approval of 70 New Drug Applications and 97 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 70 new drug applications (NDAs) and 97 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:* July 8, 2011.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6366, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in table 1 of 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 007289	Trigesic and Trigesic with Codeine Tablets	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543–4000.
NDA 008248	Wyamine (mephentermine sulfate) Sulfate Injection	Baxter Healthcare Corp., 2 Esterbrook Lane, Cherry Hill, NJ 08003–4099.
NDA 008834	Tronothane HCl (pramoxine hydrochloride (HCl))	Abbott Laboratories, Dept. PA76/Bldg. AP30–1E, 200 Abbott Park Rd., Abbott Park, IL 60064–6157.
NDA 009182	Gantrisin (sulfisoxazole acetyl)	Hoffman-La Roche, Inc., 340 Kingsland St., Nutley, NJ 07110–1199.
NDA 011835	Hydrodiuril (hydrochlorothiazide (HCTZ)) Tablets	Merck & Co., Inc., P.O. Box 1000, UG2C–50, North Wales, PA 19454.
NDA 011971	Oretic (HCTZ) Tablets, 25 milligrams (mg) and 50 mg	Abbott Laboratories.
NDA 012302	Choloxin (dextrothyroxine sodium) Tablets, 1 mg, 2 mg, 4 mg, and 6 mg.	Do.
NDA 013402	Aldoril (methyldopa/HCTZ) Tablets	Merck & Co., Inc.
NDA 015539	Serax (oxazepam) Capsules and Tablets	Alpharma U.S. Pharmaceuticals Division, c/o King Pharmaceuticals, Inc., 501 Fifth St., Bristol, TN 37620.
NDA 016118	Teslac (testolactone) Tablets	Bristol-Myers Squibb Co.
NDA 016402	Alupent (metaproterenol sulfate) Inhalation Aerosol [1]	Boehringer Ingelheim, 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877–0368.
NDA 016666	Hippuran (hippuran I–131) Injection	Mallinckrodt Medical Inc., c/o Covidien, 675 McDonnell Blvd., Hazelwood, MO 63042.
NDA 016979	Megace (megestrol acetate) Tablets, 20 mg and 40 mg	Bristol-Myers Squibb Co.
NDA 017015	Pavulon (pancuronium bromide) Injection	Organon USA Inc., c/o Schering-Plough Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033–0530.
NDA 017352	Fastin (phentermine HCl) Capsules	GlaxoSmithKline, P.O. Box 13398, Five Moore Dr., Research Triangle Park, NC 27709–3398.

TABLE 1—Continued

Application No.	Drug	Applicant
NDA 017628	Tolectin (tolmetin sodium) Tablets, 200 mg and 600 mg	Ortho-McNeil Pharmaceutical, Inc., c/o Johnson & Johnson Pharmaceutical Research & Development, LLC, 1125 Trenton-Harbourton Rd., Titusville, NJ 08560–0200.
NDA 017920	Tagamet (cimetidine) Tablets, 100 mg, 200 mg, 300 mg, 400 mg, and 800 mg.	GlaxoSmithKline.
NDA 017924	Tagamet (cimetidine) Oral Solution, 300 mg/5 milliliters (mL).	Do.
NDA 017933	Lente Iletin (insulin zinc suspension purified beef-pork)	Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285.
NDA 017934	Similente Iletin (insulin zinc suspension purified beef-pork).	Do.
NDA 017939	Tagamet (cimetidine) Injection, 150 mg/mL	GlaxoSmithKline.
NDA 018084	Tolectin DS (tolmetin sodium) Capsules	Ortho-McNeil Pharmaceutical, Inc., c/o Johnson & Johnson Pharmaceutical Research & Development, LLC.
NDA 018096	Dextrose and Sodium Chloride Injection USP	Hospira, Inc.
NDA 018118	Lanoxicaps (digoxin) Capsules	GlaxoSmithKline.
NDA 018201	Moduretic (amiloride HCl/HCTZ) Tablets	Merck & Co., Inc.
NDA 018380	Sodium Chloride Irrigation USP	Do.
NDA 018590	Aminocaproic Acid Injection USP, 250 mg/mL	Baxter Healthcare Corp.
NDA 018776	Norcuron (vecuronium bromide) Injection	Organon USA Inc., c/o Schering-Plough Corp.
NDA 018869	Nimotop (nimodipine) Capsules	Bayer Healthcare Pharmaceuticals, Inc., P.O. Box 1000, Montville, NJ 07045.
NDA 019008	Bretylium Tosylate in Dextrose Injection USP	Hospira, Inc., 275 North Field Dr., Bldg. H2, Lake Forest, IL 60045–5046.
NDA 019030	Bretylium Tosylate Injection USP, 50 mg/mL	Hospira, Inc.
NDA 019058	Tenormin (atenolol) Injection, 5 mg/10 mL	AstraZeneca Pharmaceuticals LP, 1800 Concord Pike, P.O. Box 8355, Wilmington, DE 19803–89355.
NDA 019091	Ismo (isosorbide mononitrate) Tablets, 20 mg	Promius Pharma, LLC, 200 Somerset Corporate Blvd., 7th Floor, Bridgewater, NJ 08807.
NDA 019165	Protamine Zinc (insulin zinc suspension beef)	Eli Lilly and Co.
NDA 019168	Lente Insulin (insulin zinc suspension beef)	Do.
NDA 019204	Cartrol (carteolol HCl) Tablets	Abbot Laboratories.
NDA 019377	Humulin L (insulin zinc suspension recombinant human) Injection.	Do.
NDA 019434	Tagamet (cimetidine HCl) in Sodium Chloride Injection, Equivalent to (EQ) 6 mg Base/mL.	GlaxoSmithKline.
NDA 019546	Dynacirc (isradipine) Capsules	SmithKline Beecham Corp., d/b/a GlaxoSmithKline, One Franklin Plaza, 200 North 16th St., Philadelphia, PA 19102.
NDA 019561	Micro-K LS (potassium chloride)	KV Pharmaceutical Co., One Corporate Woods Dr., Bridgeton, MO 63044.
NDA 019571	Humulin U (insulin zinc suspension extended recombinant human) Injection.	Eli Lilly and Co.
NDA 019583	Relafen (nabumetone) Tablets	SmithKline Beecham Corp., c/o GlaxoSmithKline, 2301 Renaissance Blvd., RN210, P.O. Box 61540, King of Prussia, PA 19406.
NDA 019591	Lariam (mefloquine HCl) Tablets, 250 mg	Hoffmann-La Roche Inc.
NDA 019638	Arduan (pipecuronium bromide) Injection	Organon USA Inc., c/o Schering-Plough Corp.
NDA 019735	Floxin (ofloxacin) Tablets	Ortho-McNeil-Janssen Pharmaceuticals, Inc., c/o Johnson & Johnson Pharmaceutical Research & Development, LLC, P.O. Box 300, 920 Route 202 South, Raritan, NJ 08869–0602.
NDA 019979	Ticlid (ticlopidine HCl) Tablets	Roche Palo Alto LLC, c/o Hoffmann-La Roche Inc., 340 Kingsland St., Nutley, NJ 07110–1199.
NDA 020027	Cardizen (diltiazem HCl) Injection	Biovail Technologies Ltd., On Behalf of Biovail Laboratories International SRL, 700 Route 202/206 North, Bridgewater, NJ 08807.
NDA 020100	Humulin 50/50 (insulin recombinant human and insulin suspension isophane recombinant human).	Eli Lilly and Co.
NDA 020269	Dobutamine HCl in 5% Dextrose Injection	Hospira, Inc.
NDA 020507	Teczem (enalapril maleate/diltiazem maleate) Extended-Release Tablets.	Biovail Technologies, Ltd.
NDA 020548	Flovent (fluticasone propionate) Inhalation Aerosol [1]	GlaxoSmithKline.
NDA 020549	Flovent (fluticasone propionate) Inhalation Powder	Do.
NDA 020668	Lexxel (enalapril maleate and felodipine) Extended-Release Tablets.	AstraZeneca Pharmaceuticals LP.
NDA 020792	Cardizem (diltiazem HCl) Injection	Biovail Technologies, Ltd.
NDA 020906	Etopophos (estoposide phosphate) Injection	Bristol-Myers Squibb Co.
NDA 020939	Diltiazem HCl Extended-Release Capsules, 120 mg, 180 mg, 240 mg, 300 mg, 360 mg, and 420 mg.	Biovail Technologies, Ltd.

TABLE 1—Continued

Application No.	Drug	Applicant
NDA 020961	Vitravene (fomivirsen sodium) Injection	Novartis Pharmaceuticals Corp., One Health Plaza, East Hanover, NJ 07936–1080.
NDA 020966	Sporanox (itraconazole) Injection	Ortho-McNeil-Janssen Pharmaceuticals, Inc., c/o Johnson & Johnson Pharmaceutical Research & Development, LLC.
NDA 021084	Skin Exposure Reduction Paste Against Chemical Warfare Agent (SERPACWA) (polyetrafluoroethylene and perfluoropolymethylisopropyl ether).	U.S. Army Medical Material Development Activity, c/o Office of Surgeon General, 1430 Veterans Dr., Fort Detrick, MD 21702–9234.
NDA 021088	Viadur (leuprolide acetate) Implant	Ortho-McNeil-Janssen Pharmaceutical, Inc., c/o Johnson & Johnson Pharmaceutical Research & Development, LLC.
NDA 021281	Prevacid (lansoprazole)	Takeda Global Research and Development Center, Inc., One Takeda Parkway, Deerfield, IL 60015.
NDA 021435	Amvaz (amlodipine maleate) Tablets, 2.5 mg, 5 mg, and 10 mg.	Dr. Reddy's Laboratories, Inc., 200 Somerset Corporate Blvd., Bldg. II, 7th Floor, Bridgewater, NJ 08807–2862.
NDA 021486	Lidopel (lidocaine HCl and epinephrine) Solution	Empi, Inc., P.O. Box 709, Highway 22 East, Clear Lake, SD 57226.
NDA 021507	Prevacid NapraPac 250, Prevacid NapraPac 375, and Prevacid NapraPac 500 (lansoprazole and naproxen) Tablets.	Takeda Global Research and Development Center, Inc.
NDA 021566	Prevacid I.V. (lansoprazole) Injection	Do.
NDA 021592	Foradil Certihaler (formoterol fumarate) Inhalation Powder.	Novartis Pharmaceuticals Corp.
NDA 021850	Zegerid (omeprazole/sodium bicarbonate/magnesium hydroxide).	Santarus, Inc., 3721 Valley Center Dr., suite 400, San Diego, CA 92130.
ANDA 040013	Lidocaine HCl Injection USP, 1%	Hospira, Inc.
ANDA 040073	Naphazoline HCl Ophthalmic Solution USP, 0.1%	Bausch & Lomb, Inc., 7 Giralda Farms, suite 1001, Madison, NJ 07940.
ANDA 040095	Heparin Sodium Injection USP, 10,000 Units/mL	Hospira, Inc.
ANDA 040224	Chlorpromazine HCl Oral Concentrate USP, 100 mg/mL.	Pharmaceutical Associates, Inc., 201 Delaware St., Greenville, SC 29605.
ANDA 040360	Perphenazine Oral Solution USP, 16 mg/5 mL	Do.
ANDA 040522	Norepinephrine Bitartrate Injection USP, EQ 1 mg (base)/1 mL.	Metrics Pharmaceuticals Ventures, LLC, c/o Pharmaforce Inc., 960 Crupper Ave., Columbus, OH 43229.
NDA 050521	Ceclor (cefaclor) Capsules, 250 mg and 500 mg	Eli Lilly and Co.
NDA 050522	Ceclor (cefaclor) Suspension	Do.
NDA 050560	Cefizox (ceftizoxime sodium) Powder for Injection	Astellas Pharma US, Inc., 3 Parkway North, Deerfield, IL 60015.
ANDA 061394	Principen (ampicillin for oral suspension USP)	Apothecon, Inc., c/o Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543–4000.
ANDA 061886	Trimox (amoxicillin for oral suspension USP), 50 mg/mL, 125 mg/5 mL, and 250 mg/5 mL.	Do.
ANDA 062336	Mutamycin (mitomycin for injection USP) 5 mg, 20 mg, and 40 mg Vials.	Bristol-Myers Squibb Co.
ANDA 062557	Kefzol (cefazolin sodium for injection USP)	Eli Lilly and Co.
ANDA 062563	Erythromycin Lactobionate for Injection USP	Elkins-Sinn, Inc., c/o Baxter Healthcare Corp., 2 Esterbrook Lane, Cherry Hill, NJ 08003–4002.
ANDA 062885	Trimox (amoxicillin for oral suspension USP), 125 mg/5 mL and 250 mg/5 mL.	Apothecon, Inc., c/o Bristol-Myers Squibb Co.
ANDA 062993	Erythromycin Lactobionate for Injection USP, EQ 500 mg (base) and 1 gram (g) (base) Vials.	Baxter Healthcare Corp.
ANDA 063294	Cefizox (ceftizoxime for injection USP), EQ 1 g (base) and 2 g (base) Vials.	Astellas Pharma US, Inc., Three Parkway North, Deerfield, IL 60015–2548.
ANDA 070225	Verapamil HCl Injection USP, 2.5 mg/mL	Luitpold Pharmaceuticals, Inc., One Luitpold Dr., P.O. Box 9001, Shirley, NY 11967.
ANDA 070231	Carbamazepine Tablets USP, 200 mg	Inwood Laboratories, Inc., Subsidiary of Forest Laboratories, Inc., Harborside Financial Center, Plaza Three, suite 602, Jersey City, NJ 07311.
ANDA 070291	Methyldopate HCl Injection USP, 50 mg/mL	Baxter Healthcare Corp.
ANDA 070617	Verapamil HCl Injection USP, 2.5 mg/mL	Luitpold Pharmaceuticals, Inc.
ANDA 070891	Bretylium Tosylate Injection USP, 50 mg/mL	Do.
ANDA 072058	Pancuronium Bromide Injection, 1 mg/mL	Elkins-Sinn, Inc., c/o Baxter Healthcare Corp.
ANDA 072059	Pancuronium Bromide Injection, 2 mg/mL	Do.
ANDA 072060	Pancuronium Bromide Injection, 2 mg/mL	Do.
ANDA 072272	Droperidol Injection USP, 2.5 mg/mL	Hospira, Inc.
ANDA 072335	Droperidol Injection USP, 2.5 mg/mL	Luitpold Pharmaceuticals, Inc.
ANDA 074188	Dipivefrin HCl Ophthalmic Solution USP, 0.1%	Bausch & Lomb, Inc.
ANDA 074320	Etoposide Injection, 20 mg/mL	Hospira, Inc.
ANDA 074351	Etoposide Injection, 20 mg/mL	Do.
ANDA 074353	Cimetidine HCl Injection USP	Luitpold Pharmaceuticals, Inc.

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 074381	Dobutamine Injection USP, 12.5 mg (base)/mL	Baxter Healthcare Corp.
ANDA 074545	Dobutamine Injection USP, 12.5 mg/mL	Luitpold Pharmaceuticals, Inc.
ANDA 074634	Dobutamine Injection USP, 12.5 mg/mL	Hospira, Inc.
ANDA 074643	Minoxidil Topical Solution, 2%	Bausch & Lomb, Inc.
ANDA 074743	Minoxidil Topical Solution, 2%	Sight Pharmaceuticals, Inc., 7 Giralda Farms, suite 1001, Madison, NJ 07940.
ANDA 074824	Atracurium Besylate Injection USP, 10 mg/mL	Baxter Healthcare Corp.
ANDA 074825	Atracurium Besylate Injection USP, 10 mg/mL	Do.
ANDA 075341	Ketoconazole Tablets USP, 200 mg	AAIPharma Service Corp., 2320 Scientific Park Dr., Wilmington, NC 28405.
ANDA 075456	Enalaprilat Injection, 1.25 mg/mL	Hospira, Inc.
ANDA 075542	Amrinone (inamrinone injection USP) EQ 5 mg/mL	Baxter Healthcare Corp.
ANDA 076617	Fluconazole in Sodium Chloride 0.9% Injection	Hospira, Inc.
ANDA 076656	Fenoldopam Mesylate Injection USP, EQ 10 mg (base)/mL.	Luitpold Pharmaceuticals, Inc.
ANDA 076695	Ondansetron Injection USP, EQ 2 mg (base)/mL	Hospira, Inc.
ANDA 076696	Ondansetron Injection USP, EQ 2 mg (base)/mL	Do.
ANDA 077065	Terbinafine HCl Tablets, EQ 250 mg (base)	Gedeon Richter PLC, c/o Gedeon Richter USA, Inc., 1200 East Ridgewood Ave., Ridgewood, NJ 07450.
ANDA 077333	Amlodipine Besylate Tablets, EQ 2.5 mg (base), 5 mg (base), and 10 mg (base).	Do.
ANDA 077389	Carboplatin Injection	Teva Parenteral Medicines, Inc., 19 Hughes, Irvine, CA 92618.
ANDA 077392	Lamotrigine Tablets, 25 mg, 100 mg, 150, mg, and 200 mg.	Roxane Laboratories, Inc., 1809 Wilson Rd., Columbus, OH 43228.
ANDA 077994	Ironotecan HCl Injection	Sandoz, Inc., 2555 West Midway Blvd., Broomfield, CO 80038–0446.
ANDA 080416	Procaine HCl Injection USP, 1% and 2%	Hospira, Inc.
ANDA 083346	Isoproterenol HCl Injection USP, 0.2 mg/mL	Do.
ANDA 084178	Methyltestosterone Tablets, 5 mg	KV Pharmaceutical Co., One Corporate Woods Dr., Bridgeton, MO 63044.
ANDA 084179	Methyltestosterone Tablets, 25 mg	Do.
ANDA 084312	Methyltestosterone Tablets, 10 mg	Do.
ANDA 084767	Dimenhydrinate Injection USP	Baxter Healthcare Corp.
ANDA 085284	Aminophylline Tablets, 100 mg	KV Pharmaceutical Co.
ANDA 085285	Secobarbital Sodium Capsules, 100 mg	Do.
ANDA 085289	Aminophylline Tablets, 200 mg	Do.
ANDA 085363	Acetaminophen and Codeine Phosphate Tablets, 325 mg/45 mg.	Do.
ANDA 085384	Triprolidine HCl Syrup, 1.25mg/5 mL	Do.
ANDA 085385	Promethazine HCl Syrup, 25 mg/5 mL	Do.
ANDA 085388	Promethazine HCl Syrup, 6.25 mg/5 mL	Do.
ANDA 085466	Brompheniramine Maleate Elixir, 2 mg/5 mL	Do.
ANDA 085492	Acetic Acid with Hydrocortisone Otic Solution, 2%/1%	Do.
ANDA 085493	Acetic Acid Otic Solution, 2%	Do.
ANDA 085551	Hydroxyzine HCl Injection USP, 25 mg/mL and 50 mg/mL.	Baxter Healthcare Corp.
ANDA 085621	Diphenhydramine HCl Elixir, 12.5 mg/5 mL	KV Pharmaceutical Co.
ANDA 085810	Prednisone Tablets, 5 mg	Do.
ANDA 086619	Hydrocortisone Sodium Succinate for Injection USP, EQ 100 mg (base)/Vial.	Baxter Healthcare Corp.
ANDA 086661	Donnatal (phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine (HBr)) Elixir.	A.H. Robins Co., c/o Wyeth Pharmaceuticals, Inc., P.O. Box 8299, Philadelphia, PA 19101–8299.
ANDA 086676	Donnatal (phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine (HBr)) Tablets.	Do.
ANDA 086677	Donnatal (phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine (HBr)) Capsules.	Do.
ANDA 086797	Novocain (procaine HCl injection USP) 10%	Hospira, Inc.
ANDA 086906	Methylprednisolone Sodium Succinate for Injection USP, EQ 40 mg (base), 125 mg (base), 500 mg (base), and 1 g (base) Vials.	Elkins-Sinn, Inc., c/o Baxter Healthcare Corp.
ANDA 087239	Aminophylline Injection USP, 25 mg/mL	Do.
ANDA 087240	Aminophylline Injection USP, 25 mg/mL	Luitpold Pharmaceuticals, Inc.
ANDA 087311	Chlorthalidone Tablets, 25 mg	KV Pharmaceutical Co.
ANDA 087312	Chlorthalidone Tablets, 50 mg	Do.
ANDA 087506	Muro Opcon (naphazoline HCl ophthalmic solution USP, 0.1%).	Bausch & Lomb, Inc.
ANDA 087567	Hydrocortisone Sodium Succinate for Injection USP, EQ 250 mg (base)/Vial.	Baxter Healthcare Corp.
ANDA 087568	Hydrocortisone Sodium Succinate for Injection USP, EQ 500 mg (base)/Vial.	Do.

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 087569	Hydrocortisone Sodium Succinate for Injection USP, EQ 1 g (base)/Vial.	Do.
ANDA 087584	Potassium Chloride for Injection Concentrate USP	Luitpold Pharmaceuticals, Inc.
ANDA 087601	Aminophylline Injection USP, 25 mg/mL	Hospira, Inc.
ANDA 087956	Vitamin K1 (phytonadione injection emulsion USP), 10 mg/mL.	Do.
ANDA 088279	Meperidine HCl Injection USP, 25 mg/mL	Baxter Healthcare Corp.
ANDA 088280	Meperidine HCl Injection USP, 50 mg/mL	Do.
ANDA 088281	Meperidine HCl Injection USP, 75 mg/mL	Do.
ANDA 088282	Meperidine HCl Injection USP, 100 mg/mL	Do.
ANDA 088326	Lidocaine HCl Injection USP, 1.5%	Hospira, Inc.
ANDA 088331	Lidocaine HCl Injection USP, 2%	Do.
ANDA 088368	Lidocaine HCl Injection USP, 20%	Do.
ANDA 088371	Cyclophosphamide for Injection USP, 100 mg/Vial	Baxter Healthcare Corp.
ANDA 088372	Cyclophosphamide for Injection USP, 200 mg/Vial	Do.
ANDA 088373	Cyclophosphamide for Injection USP, 500 mg/Vial	Do.
ANDA 088374	Cyclophosphamide for Injection USP, 1 g/Vial	Do.
ANDA 089649	Lidocaine HCl and Epinephrine Injection	Hospira, Inc.
ANDA 089703	Prochlorperazine Edisylate Injection USP, EQ 5 mg (base)/mL.	Do.
ANDA 089707	Perphenazine Tablets USP, 2 mg	Ivax Pharmaceuticals Inc., 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677.
ANDA 090954	Cromolyn Sodium Oral Solution Concentrate, 100 mg/5 mL.	Pack Pharmaceuticals, LLC, 1110 West Lake Cook Rd., suite 152, Buffalo Grove, IL 60089.

[1] This product was an oral pressurized metered-dose inhaler that contained chlorofluorocarbons (CFCs) as a propellant. CFCs may no longer be used as a propellant for any metaproterenol sulfate or fluticasone propionate metered-dose inhalers (see 75 FR 19213–19241, April 14, 2010; 71 FR 70870–70873, December 7, 2006).

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 of Food and Drugs, approval of the applications listed in table 1 of this document, and all amendments and supplements thereto, is hereby withdrawn, effective July 8, 2011. 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 of this document 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: May 31, 2011.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 2011–14164 Filed 6–7–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Epidemiology Program for American Indian/Alaska Native Tribes and Urban Indian Communities

Division of Epidemiology and Disease Prevention; Epidemiology Program for American Indian/Alaska Native Tribes and Urban Indian Communities

Announcement Type: New.

Funding Opportunity Number: HHS–2011–IHS–EPI–0001.

Catalog of Federal Domestic Assistance Number: 93.231

DATES: *Key Dates:*

Application Deadline Date: July 15, 2011;

≤*Review Date:* August 16–17, 2011;

Anticipated Start Date: September 16, 2011.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting competitive cooperative agreement applications to establish Tribal Epidemiology Centers serving American Indian/Alaska Native (AI/AN) Tribes and urban Indian communities. This program is managed by the IHS Division of Epidemiology and Disease Prevention (DEDP). This program is authorized under the Snyder Act, 25 U.S.C. 13, and 25 U.S.C. 1621m of the Indian Health Care Improvement Act. To obtain details regarding eligibility, please refer to Section III below.

Background

The Tribal Epidemiology Center (TEC) program was authorized by Congress in 1998 as a way to provide public health support to multiple Tribes and urban Indian communities in each of the IHS Areas. The funding opportunity announcement is open to eligible Tribes, Tribal organizations, intertribal consortia, and urban Indian organizations, including currently funded TECs.

TECs are uniquely positioned within Tribes, Tribal and urban Indian organizations to conduct disease surveillance, research, prevention and control of disease, injury, or disability, and to assess the effectiveness of AI/AN public health programs. In addition, they can fill gaps in data needed for Government Performance and Results Act (GPRA) and Healthy People 2020 measures. Some of the existing TECs have already developed innovative strategies to monitor the health status of Tribes and urban Indian communities, including development of Tribal health registries and use of sophisticated record linkage computer software to correct existing state data sets for racial misclassification. TECs work in partnership with IHS DEDP to provide a more accurate national picture of Indian health status.