

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 <sup>1</sup> ..... | 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 <sup>1</sup>                             | 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) (polytetrafluoroethylene 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 ..... | Methyl Dopate HCl Injection USP, 50 mg/mL .....   | Baxter Healthcare Corp.   |
| ANDA 070617 ..... | Verapamil HCl Injection USP, 2.5 mg/mL .....  | Luitpold Pharmaceuticals, Inc.  |
| ANDA 070891 ..... | Bretylum 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. |

<sup>1</sup> 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.