1987. The amendment has been placed on display at the Dockets Management Branch (address above).

Any petition that meets the requirements outlined in 21 CFR 170.30 and § 170.35 is filed by the agency. There is no prefiling review of the adequacy of data to support a GRAS conclusion. Thus, the filing of a petition for GRAS affirmation should not be interpreted as a preliminary indication of suitability for GRAS affirmation.

The agency has determined under 21 CFR 25.24(b)(7) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before October 21, 1996, review the amendment and file comments with the Dockets Management Branch (address above). Two copies of any comments should be filed and should be identified with the docket number found in brackets in the heading of this document. Comments should include any available information that would be helpful in determining whether the substance is, or is not, GRAS for the proposed use. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 2, 1996.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–19743 Filed 8–2–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0257]

Hoffmann-La Roche, Inc., et al.; Withdrawal of Approval of 87 New Drug Applications, 18 Abbreviated Antibiotic Drug Applications, and 103 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 87 new drug applications (NDA's), 18 abbreviated antibiotic applications (AADA's), and 103 abbreviated new drug applications (ANDA's). 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agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

EFFECTIVE DATE: September 4, 1996.

FOR FURTHER INFORMATION CONTACT: Lola E. Batson, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1038.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their request, waived their opportunity for a hearing.

Application no.	Drug	Applicant
NDA 6–54	Progstigmin (neostigmine bromide solution) Opthalmic Solution, 5%.	Hoffmann-La Roche, Inc., 340 Kingsland St., Nutley, NJ 07110–1199.
NDA 5–319	Pantopaque (iophendylate) Injection	Alcon Laboratories, Inc., 6201 South Freeway, Fort Worth, TX 76134–2099.
NDA 6–135	Folic Acid	Lilly Research Laboratories, Lilly Corporate Center, Indianopolis, IN 46285.
NDA 6–213	Propylthiouracil Tablets	Do.
NDA 6–215	Delphicol Tablets and Solution	Lederle Laboratories, Pearle River, NY 10965.
NDA 6–333	Synophylate (theophylline sodium glycinate) Elixir	Central Pharmaceuticals, Inc., 120 East Third St., Seymour, IN 47274.
NDA 6–386	Mol-Iron Liquid	Schering-Plough Corp., 110 Allen Rd., P.O. Box 276, Liberty Corner, NJ 07938–0276.
NDA 6–686	Dramamine Liquid	Richardson-Vicks, Inc., One Far Mill Crossing, Shelton, CT 06484.
NDA 6–911	Sulfisoxazole Syrup/Pediatric Suspension	Roche Pharmaceuticals, 340 Kingsland St., Nutley, NJ 07110–1199.
NDA 8–082	Propion Gel	Wyeth-Ayerst Laboratories, P.O. Box 8299, Philadelphia, PA 19101–8299.
NDA 8–855	Milontin 500 milligram (mg) Kapseals	Parke-Davis Pharmaceutical Research, 2800 Plymouth Rd., Ann Arbor, MI 48105.
NDA 8–951	Pagitane HCl Tablets	Lilly Research Laboratories.
NDA 9–008	Salpix Contrast Medium	The R. W. Johnson Pharmaceutical Research Institute, Rt. 202, Box 300, Raritan, NJ 08869–0602.
NDA 9–115	Serpasil Tablets and Elixir	Ciba-Geigy Corp., 556 Morris Ave., Summit, NJ 07901.
NDA 9–220	Di-Isopacin	Consolidated Midland Corp., 16–20 Main St., Brewster, NY 10509.
NDA 9–268	Choledyl Tablets, Pediatric Syrup, and Elixir,	Parke-Davis Pharmaceutical Research.
NDA 9–296	Serpasil Apresoline	Ciba-Geigy Corp.
NDA 9–309	Dionosil Oily	Glaxo, Inc., Five Moore Dr., P.O. Box 13358, Research Triangle Park, NC 27709.
NDA 9–434	Serpasil Parenteral Solution	Ciba-Geigy Corp.
NDA 9–750	Valmid Capsules, 500 mg	Lilly Research Laboratories.
NDA 10–291	Cortril Soluble Parenteral	Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755.
NDA 10–599	Tral Filmtab	Pharmaceutical Products Division, Abbott Laboratories, One Abbott Park Rd., Abbott Park, IL 60064–3500.
NDA 10–670	ORINASE Tablets	The Upjohn Co., 700 Portage Rd., Kalamazoo, MI 49001–0199.
NDA 10–710	Toleron Tablets and Suspension	Wallace Laboratories, Cranbury, NJ 08512.
NDA 10–776	DELTA-CORTEF Eye Drops, S.S.	The Upjohn Co.
NDA 10–911	BUCLADIN-S Tablets	Zeneca, 1800 Concord Pike, Wilmington, DE 19897.

Application no.	Drug	Applicant
NDA 11–078	Theruhistin Syrup	Wyeth-Ayerst Laboratories.
NDA 11–837	Alpha Chymar	Sola/Barnes-Hind, 810 Kifer Rd., Sunnyvale, CA 94086–5200.
NDA 11–878	Serpasil Esidrix	Ciba-Geigy Corp.
NDA 13–157	Anhydron Tablets	Lilly Research Laboratories.
NDA 13–621	Pertofrane Capsules	Rhone-Poulence Rorer Pharmaceuticals, Inc., 500 Arcola Rd., P.O. Box 1200, Collegeville, PA 19426–0107.
NDA 14–173	Proketazine Oral Suspension	Wyeth-Ayerst Laboratories.
NDA 15–148	Colgate MFP Flouride Toothpaste	Colgate-Palmolive Co., P.O. Box 1343, 909 River Rd., Piscataway, NJ 08855–1343.
NDA 16–001	BENZTHIAZIDE Tablets, 25 mg and 50 mg	Solvay Pharmaceuticals, 901 Sawyer Rd., Marietta, GA 30062.
NDA 16–144	Ethamide Tablets	Allergan, 2525 Dupont Dr., P.O. Box 19534, Irvine, CA 92713–9534.
NDA 16–287	Kaon Sugar Coated Tablets	Savage Laboratories, Division of Altana, Inc., 60 Baylis Rd., Melville, NY 11747.
NDA 16–749	Norlestrin 21 1/50 Tablets	Parke-Davis Pharmaceutical Research.
NDA 16–764	Stemex Oral Tablets	Hoffman-LaRoche, Inc.
NDA 16–852	Norlestrin 21 2.5/50 Tablets	Parke-Davis Pharmaceutical Research.
NDA 16–854	Norlestrin FE 2.5/50 Tablets	Do.
NDA 16–998	Uticort Cream	Do.
NDA 17–226	SORBITRATE SA Tablets, 40 mg	Zeneca.
NDA 17–421	Armohex Hexachlorophene Liquid Soap Ready to Use	The Dial Corp., 15191 North Scottsdale Rd., Scottsdale, AZ 85260.
NDA 17–508	Lidocaine Hydrochloride Injection	Fujisawa USA, Inc., Parkway North Center, Three Parkway North, Deerfield, IL 60015–2548.
NDA 17–546	Nipride Vials	Hoffmann-La Roche, Inc.
NDA 17–675	Bethanidine Sulfate Tablets	Medco Research, Inc., P.O. Box 13886, Research Triangle Park, NC 27709.
NDA 17–701	Lidocaine Hydrochloride Injection	International Medication Systems, Ltd., 1886 Santa Anita Ave., South El Monte, CA 91733.
NDA 17–780	Heparin Sodium Injection	Pharmaceutical Specialist Associates, 9852 Cowden St., Philadelphia, PA 19115.
NDA 17–927	Globin Zinc Insulin Injection	Novo Nordisk Pharmaceuticals, Inc., 100 Overlook Center, suite 200, Princeton, NJ 08540–7810.
NDA 17–928	Protamine Zinc Insulin Suspension	Do.
NDA 18–370	Furosemide Tablets, 20 mg and 40 mg	Superharm Corp., 600 Corporate Dr., suite 520, Fort Lauderdale, FL 33334.
NDA 18–382	Semilente Purified Pork Prompt Insulin Zinc Suspension	Novo Nordisk Pharmaceuticals, Inc.
NDA 18–385	Ultralente Purified Beef Extended Insulin Zinc Suspension	Do.
NDA 18–456	MICATIN Antifungal Spray Powder	Advanced Care Products, Ortho Pharmaceutical Corp., Raritan, NJ 08869.
NDA 18–457	MICATIN Antifungal Shaker Powder	Do.
NDA 18–524	Purified Insulin Semilente	Bristol-Myers Squibb, P.O. Box 4500, Princeton, NJ 08543–4500.
NDA 18–527	Purified Insulin Ultralente	Do.
NDA 18–539	Regular Iletin II	Lilly Research Laboratories.
NDA 18–540	Lente Iletin II	Do.
NDA 18–541	NPH Iletin II	Do.
NDA 18–542	Protamine, Zinc, and Ilentin	Do.
NDA 18–605	Azulfidine Oral Suspension	Kabi Pharmacia, c/o Adria Laboratories, P.O. Box 16529, Columbus, OH 43216–6529.
NDA 18–633	Fibocil Pulvules	Lilly Research Laboratories.
NDA 18–666	Fibocil Injection	Do.
NDA 18–747	Isoclor Timesule Capsules	CIBA, Mack Woodbridge II, 581 Main St., Woodbridge, NJ 07095.
NDA 18–777	Novolin L	Novo Nordisk Pharmaceuticals, Inc.
NDA 18–778	Novolin R	Do.
NDA 18–928	Pentuss Controlled Release Suspension	Fisons Corp., P.O. Box 1710, Rochester, NY 14603.
NDA 18–954	0.2% Lidocaine Hydrochloride in 5% Dextrose Injection	Abbott Laboratories.
NDA 19–005	Bretylium Tosylate in 5% Dextrose Injection	Do.
NDA 19–046	Normozide Labetalol	Schering Corp., Galloping Hill Rd., Kenilworth, NJ 07033.
NDA 19–441	Novolin 70/30	Novo Nordisk Pharmaceuticals, Inc.
NDA 19–443	Sodium Bicardonate Injection	Abbott Laboratories.
NDA 19–456	Pindac Pulvules	Leo Pharmaceutical Products, Ltd. A/S, 55 Industriparken, DK–2750 Ballerup Denmark.
NDA 19–564	Aminosyn II with Electrolytes in Dextrose Injection	Abbott Laboratories.
NDA 19–565	Aminosyn II 5% in 25% Dextrose	Do.
NDA 19–693	Decabid	Lilly Research Laboratories.
NDA 50–003	Erythrocin Stearate-Sulfas Filmtab/Erythromid Filmtab	Abbott Laboratories.
NDA 50–069	TAO Chewable Tablets	Pfizer, Inc.
NDA 50–072	Penbritin Injection	Wyeth-Ayerst Laboratories.

Application no.	Drug	Applicant
NDA 50–126	Bicillin Oral Suspension	Do.
NDA 50–198	Erythrocin Ethyl Succinate-Sulfas Chewable Tablets	Abbott Laboratories.
NDA 50–301	Veracillin Injection	Wyeth-Ayerst Laboratories.
NDA 50–371	Ilotycin Sulfa	Lilly Research Laboratories.
NDA 50–481	Velosef for Injection	Apothecon, P.O. Box 4500, Princeton, NJ 08543–4500.
NDA 50–523	Vira-A 200 mg/milliliter (mL) Intravenous Infusion	Parke-Davis Pharmaceutical Research.
NDA 50–699	SUPRAX Chewable Tablet	Lederle Laboratories.
AADA 60–075	Penicillin G Potassium Tablets, 200,000 Units, 250,000 Units, 400,000 Units, and 800,000 Units.	Pfizer, Inc.
AADA 60–097	Bacitracin Ointment, 500 Units/Gram	Do.
AADA 60–281	Neomycin and Polymyxin B Sulfates and Bacitracin Ophthalmic Ointment.	Do.
AADA 60–282	Sterile Bacitracin	Do.
AADA 60–576	Mycolog II Cream	Apothecon.
AADA 60–587	Penicillin G Potassium for Oral Solution	Pfizer, Inc.
AADA 60–726	Bacitracin Ophthalmic Ointment	Do.
AADA 60–728	Neomycin Sulfate and Bacitracin Ointment	Do.
AADA 60–877	Gentamicin Sulfate	Shering Corp.
AADA 61–815	Penicillin V Potassium for Oral Solution	Pfizer, Inc.
AADA 61–836	Penicillin V Potassium Tablets, 250 mg	Do.
AADA 61–898	Ampicillin and Probenecid for Oral Suspension	Apothecon.
AADA 62–049	Ampicillin for Oral Suspension	Pfizer, Inc.
AADA 62–050	Ampicillin Capsules	Do.
AADA 62–422	Cephalothin Sodium Injection	Baxter Healthcare Corp., Rt. 120 and Wilson Rd., Round Lake, IL 60073–0490.
AADA 62–494	Doxycycline Hyclate Tablets	Superpharm Corp.
AADA 62–540	Tetracycline Hydrochloride Capsules	Do.
AADA 62–730	Cephalothin Sodium Injection	Baxter Healthcare Corp.
ANDA 70–065	Sulfamethoxazole and Trimethoprim Tablets, 400 mg/80 mg.	Superpharm Corp.
ANDA 70–066	Sulfamethoxazole and Trimethoprim Tablets, 800 mg/160 mg.	Superpharm Corp.
ANDA 70–162	Tolazamide Tablets, 100 mg	Barr Laboratories, Inc., Two Quaker Rd., P.O. Box 2900, Pomona, NY 10970–0519.
ANDA 70–163	Tolazamide Tablets, 250 mg	Do.
ANDA 70–164	Tolazamide Tablets, 500 mg	Do.
ANDA 70–709	Ibuprofen Tablets, 600 mg	Superpharm Corp.
ANDA 70–926	Metoclopramide Hydrochloride Tablets, 10 mg	Do.
ANDA 71–245	Lorazepam Tablets, 0.5 mg	Do.
ANDA 71–246	Lorazepam Tablets, 1 mg	Do.
ANDA 71–247	Lorazepam Tablets, 2 mg	Do.
ANDA 71–319	Propoxyphene Napsylate and Acetaminophen Tablets, 100 mg/650 mg.	Do.
ANDA 71–659	Flurazepam Hydrochloride Capsules, 15 mg	Do.
ANDA 71–660	Flurazepam Hydrochloride Capsules, 30 mg	Do.
ANDA 71–771	Propranolol Hydrochloride and Hydrochlorothiazide Tablets, 40 mg/25 mg.	Warner Chilcott Laboratories, 182 Tabor Rd., Morris Plains, NJ 07950.
ANDA 72–809	Meclofenamate Sodium Capsules, 100 mg	Barr Laboratories, Inc.
ANDA 72–848	Meclofenamate Sodium Capsules, 50 mg	Do.
ANDA 80–457	Reserpine Tablets, 0.1 mg and 0.25 mg	Halsey Drug Co., Inc., 1827 Pacific St., Brooklyn, NY 11233.
ANDA 80–721	Reserpine Tablets, 0.25 mg	Do.
ANDA 80–744	Tripelennamine Hydrochloride Tablets, 50 mg	Do.
ANDA 80–854	Pyridoxone Hydrochloride Injection	Lilly Research Laboratories.
ANDA 80–855	Cyanocobalamin Injection	Do.
ANDA 80–884	Ergocalciferol (Vitamin D) Capsules, 1.25 mg	Do.
ANDA 83–130	Ammonium Chloride Injection	Abbott Laboratories.
ANDA 83–154	Lidocaine and Epinephrine Injection	Do.
ANDA 83–370	Dramamine Tablets	Richardson-Vicks, Inc.
ANDA 83–393	Quinidine Sulfate Tablets, 200 mg	ICN Pharmaceuticals, Inc., ICN Plaza, 3300 Hyland Ave., Costa Mesa, CA 92626.
ANDA 83–471	Cortisone Acetate Tablets, 25 mg	Barr Laboratories, Inc.
ANDA 83–644	Phendimetrazine Tartrate Tablets, 35 mg (yellow)	Do.
ANDA 83–684	Phendimetrazine Tartrate Tablets, 35 mg (white)	Do.
ANDA 83–686	Phendimetrazine Tartrate Tablets, 35 mg (gray)	Do.
ANDA 83–687	Phendimetrazine Tartrate Tablets, 35 mg (pink)	Do.
ANDA 83–944	Triamcinolone Acetonide Ointment, 0.5%	Apothecon.
ANDA 83–999	Hydrocortisone Tablets, 20 mg	Barr Laboratories, Inc.
ANDA 84–031	Sulfisoxazole Tablets, 500 mg	Do.
ANDA 84–177	Quinidine Sulfate Tablets, 200 mg	Do.
ANDA 84–225	Secobarbital Sodium Capsules, 100 mg	Do.
ANDA 84–230	Meprobamate Tablets, 600 mg	Do.

Application no.	Drug	Applicant
ANDA 84–267	Triamcinolone Tablets, 4 mg	Do.
ANDA 84–268	Triamcinolone Tablets, 8 mg	Do.
ANDA 84–286	Triamcinolone Tablets, 2 mg	Do.
ANDA 84–318	Triamcinolone Tablets, 2 mg	Do.
ANDA 84–319	Triamcinolone Tablets, 4 mg	Do.
ANDA 84–320	Triamcinolone Tablets, 8 mg	Do.
ANDA 84–426	Prednisolone Tablets, 5 mg	Do.
ANDA 84–468	Brompheniramine Maleate Tablets, 4 mg	Do.
ANDA 84–579	Reserpine and Hydrochlorothiazide Tablets, 0.125 mg/50 mg.	Do.
ANDA 84–580	Reserpine and Hydrochlorothiazide Tablets, 0.125 mg/25 mg.	Do.
ANDA 84–721	Lidocaine Hydrochloride Injection, 2%	Carlisle Laboratories, Inc., 865 Merrick Ave., Westbury, NY 11590.
ANDA 84–731	Theophylline Capsules, 100 mg, 200 mg, and 250 mg	R. P. Scherer North America, 2725 Scherer Dr., St. Petersburg, FL 33176–1016.
ANDA 84–771	Hydrochlorothiazide Tablets, 50 mg (yellow)	Barr Laboratories, Inc.
ANDA 84–831	Phendimetrazine Tartrate Tablets, 35 mg (green-speckled)	Do.
ANDA 84–834	Phendimetrazine Tartrate Tablets, 35 mg (green)	Do.
ANDA 84–835	Phendimetrazine Tartrate Tablets, 35 mg (pink)	Do.
ANDA 84–944	Lidocaine Ointment, 5% (spearmint)	Carlisle Laboratories, Inc.
ANDA 84–946	Lidocaine Ointment, 5% (mixed fruit)	Do.
ANDA 85–038	Quinidine Sulfate Tablets, 200 mg	Eli Lilly and Co.
ANDA 85–068	Quinidine Sulfate Tablets, 200 mg	Scherer Laboratories, Inc., 2301 Ohio Dr., suite 234, Plano, TX 75093.
ANDA 85–103	Quinidine Sulfate Capsules, 200 mg	Eli Lilly and Co.
ANDA 85–291	Acetaminophen and Codeine Phosphate Tablets, 300 mg/ 30 mg.	Geneva Pharmaceuticals, Inc., 2555 West Midway Blvd., P.O. Box 446, Broomfield, CO 80038–0446.
ANDA 85–353	Theophylline Tablets, 100 mg and 200 mg	Central Pharmaceuticals, Inc.
ANDA 85–928	Hydrocortisone Sodium Succinate for Injection	Abbott Laboratories.
ANDA 85–964	Acetaminophen and Codeine Phosphate Tablets, 300 mg/ 60 mg.	Geneva Pharmaceuticals, Inc.
ANDA 86–586	Diphenhydramine Hydrochloride Elixir, 12.5 mg/5 mL	Halsey Drug Co., Inc.
ANDA 87–121	Tolbutamide Tablets, 500 mg	Barr Laboratories, Inc.
ANDA 87–189	Sulfamethoxazole Tablets, 500 mg	Do.
ANDA 87–247	Chlorthalidone Tablets, 50 mg	Superpharm Corp.
ANDA 87–982	Nitroglycerin Extended-Release Capsules, 2.5 mg	Zenith Laboratories, Inc., 140 Legrand Ave., Northvale, NJ 07647.
ANDA 87–983	Nitroglycerin Extended-Release Capsules, 6.5 mg	Do.
ANDA 88–213	Triprolidine and Pseudoephedrine Hydrochlorides Syrup, 1.25 mg/ 30 mg per 5 mL.	Halsey Drug Co., Inc.
ANDA 88–297	Aminophylline Tablets, 100 mg	Barr Laboratories, Inc.
ANDA 88–298	Aminophylline Tablets, 200 mg	Do.
ANDA 88–416	Dipyridamole Tablets, 25 mg	Do.
ANDA 88–417	Dipyridamole Tablets, 50 mg	Do.
ANDA 88–418	Dipyridamole Tablets, 75 mg	Do.
ANDA 88–503	Theophylline Controlled-Release Tablets, 100 mg	Forest Pharmaceuticals, Inc., 909 Third Ave., New York, NY 10022–4731.
ANDA 88–504	Theophylline Controlled-Release Tablets, 200 mg	Do.
ANDA 88–505	Theophylline Controlled-Release Tablets, 300 mg	Do.
ANDA 88–695	Chlorpropamide Tablets, 250 mg	Superpharm Corp.
ANDA 88–735	Triprolidine Hydrochloride Syrup, 1.25 mg/ 5 mL	Halsey Drug Co., Inc.
ANDA 88–794	Hydroxyzine Hydrochloride Tablets, 10 mg	Superpharm Corp.
ANDA 88–795	Hydroxyzine Hydrochloride Tablets, 25 mg	Do.
ANDA 88–796	Hydroxzine Hydrochloride Tablets, 50 mg	Do.
ANDA 88–812	Chlorpropamide Tablets, 100 mg (white)	Barr Laboratories, Inc.
ANDA 88–813	Chlorpropamide Tablets, 250 mg (white)	Do.
ANDA 88–827	Hydrochlorothiazide Tablets, 25 mg	Superpharm Corp.
ANDA 88–828	Hydrochlorothiazide Tablets, 50 mg	Do.
ANDA 88–829	Hydrochlorothiazide Tablets, 100 mg	Do.
NADA 88–865	Prednisone Tablets, 5 mg	Do.
ANDA 88–866	Prednisone Tablets, 10 mg	Do.
ANDA 88–867	Prednisone Tablets, 20 mg	Do.
ANDA 88–893	Tolbutamide Tablets, 500 mg	Do.
ANDA 88–962	Diphenoxylate Hydrochloride and Atropine Sulfate Tablets, 2.5 mg/ 0.025 mg.	Do.
ANDA 89–103	Thioridazine Hydrochloride Tablets, 10 mg	Do.
ANDA 89–104	Thioridazine Hydrochloride Tablets, 25 mg	Do.
ANDA 89–105	Thioridazine Hydrochloride Tablets, 50 mg	Do.
ANDA 89–177	Folic Acid Tablets, 1 mg	Barr Laboratories, Inc.
ANDA 89–179	Diphenhydramine Hydrochloride Syrup, 12.5 mg/ 5 mL	Halsey Drug Co., Inc.

Application no.	Drug	Applicant
ANDA 89–184	Acetaminophen and Codeine Phosphate Tablets, 300 mg/ 30 mg.	Superpharm Corp.
ANDA 89–185	Acetaminophen and Codeine Phosphate Tablets, 300 mg/ 60 mg.	Do.
ANDA 89–199	Cyproheptadine Hydrochloride Syrup, 2 mg/ 5 mL	Halsey Drug Co., Inc.
ANDA 89–362	Lidocaine Hydrochloride Injection, 20%	Abbott Laboratories.
ANDA 89–446	Chlorpropamide Tablets, 100 mg (blue)	Barr Laboratories, Inc.
ANDA 89–447	Chlorpropamide Tablets, 250 mg (blue)	Do.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed above, and all amendments and supplements thereto, is hereby withdrawn, effective September 4, 1996.

Dated: July 9, 1996.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 96–19804 Filed 8–02–96; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Cancer Institute (NCI); Developmental Therapeutics Program (DTP); Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Identification, Characterization, and Development of Antibiotics From NCI's Natural Products Repository and Database of Open Compounds

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (DHHS) seeks a company that can effectively pursue the preclinical identification, characterization, and development of antibiotic treatments from NCI/DTP's Natural Products Repository and Database of Open Compounds. The selected sponsor will be awarded a CRADA to establish antibiotic activity associated with such compounds.

ADDRESSES: Questions about this opportunity may be addressed to Gary Colby, or Vasiliana Moussatos, Office of Technology Development, NCI, (301) 496–0477, from whom further information may be obtained:

Address for delivery by U.S. Postal Service: Executive Plaza South, Suite 450; 6120 Executive Blvd. MSC 7182; Bethesda MD 20892–7182.

Address for delivery by messenger or overnight delivery services: 6120 Executive Blvd; Suite 450; Rockville, MD 20852.

DATES: In view of the important priority of developing new drugs for the treatment of antibiotic resistant bacteria, proposals must be received at the above address by 5:00 p.m. September 4, 1996.

TERM: The term of the CRADA will be 3 to 5 years.

SUPPLEMENTARY INFORMATION: Cooperative Research and Development Agreement or ''CRADA'' means the anticipated joint agreement to be entered into by NCI pursuant to the Federal Technology Transfer Act of 1986 and Executive Order 12591 of October 10, 1987 to collaborate on the specific research project described below. Under the present proposal, the Government is seeking a company which will perform the requirements set forth in the CRADA in accordance with the regulations governing the transfer of technology in which the Government has taken an active role in developing (37 CFR 404.8).

The general scope of this CRADA includes:

1. Characterizations of compounds or natural product extracts with activity against bacterial strains provided by Collaborator, including but not limited to antibiotic-resistant variants of common nosocomial infections, emerging organisms of public interest (e.g., flesh-eating bacteria), and organisms responsible for opportunistic infections (e.g., Mycobacterium spp.); (This characterization will include screening of compounds provided by NCI for this application (including previously characterized compounds in the public domain), isolation, extraction, and purification of the compound(s) present in natural product extracts, chemical characterization, and demonstration that isolation and production of the active chemical are reproducible.)

2. Using the structure(s) identified in (1), computer analyses by NCI of previously screened open NCI compounds to identify or suggest compounds that also may inhibit bacteria in (1), followed by the use of Collaborator's assays to screen and profile the NCI compounds' activity against different strains of such bacteria;

3. Modification or improvement of assays for activity against such bacterial strains in (1) based directly upon the findings in (1) and (2);

4. Addition of related bacterial strains supplied by Collaborator to this collaboration based upon this experience;

5. Synthesis of analogues of the lead structures based directly upon information gained in this collaboration; and

6. Where appropriate and under a mutually agreeable amendment, preclinical development of compounds to support clinical trials using agents for which the compelling rationale for development was identified in this collaboration.

The principal goal of the CRADA in the first year is to generate sufficient data to prove the concept that compounds exist in the NCI Natural Products Repository of crude extracts and purified chemicals which may possess activity against such bacteria listed above in (1) as provided by the Collaborator. The Collaborator will test a variety of extracts, e.g., fungal, higher plant, marine organisms, etc. selected for this purpose and provided by NCI, against said bacteria utilizing a screening and testing program which may or may not be proprietary to Collaborator such as a standard plate assay of bacterial growth or an enzyme-based screening system capable of high throughput and automation. It is further hoped that long-term results may also lead to new and novel molecular structures.

In view of the intellectual contributions of NCI, such as the creation of the ranked lists of compounds with potential to interact with such bacterial strains of interest as provided by the Collaborator, the results of this collaboration, in the form of agents with clinical potential or tools for