genuine and substantial issue of fact that precludes the withdrawal of approval of the MFA's, or that the request for a hearing is not made in the required format or with the required analysis, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing. If a hearing is requested and is justified by the sponsor's response to this notice, the issues will be defined, an administrative law judge will be assigned, and a written notice of the time and place at which the hearing will begin will be issued as soon as practicable.

All submissions under this notice shall be filed in four copies and, except as provided in 21 CFR 10.20(j), may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 512 (21 U.S.C. 360b)) and under authority delegated to the Director, Center For Veterinary Medicine (21 CFR 5.84).

Dated: April 19, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–10274 Filed 4–25–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0101]

Warren Teed Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 107 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 107 abbreviated new drug applications (ANDA's). The holders of the ANDA's 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agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.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: May 26, 1995.

FOR FURTHER INFORMATION CONTACT: Carolyn C. Harris, Center for Drug Evaluation and Research (HFD–360), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1038.

SUPPLEMENTARY INFORMATION: The holders of the ANDA's 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.

ANDA No.	Drug	Applicant
83–076	Sulfasalazine, 500 milligrams (mg)	Warren Teed Pharmaceuticals, Inc., Columbus, OH 43215.
83–078	Chlorpheniramine Maleate Tablets, 4 mg	Anabolic, Inc., P.O. Box C–19508, Irvine, CA 92713.
83–135	Lidocaine Hydrochloride Injection, U.S.P., 1% and 2%	G. D. Searle and Co., P.O. Box 5110, Chicago, IL 60680.
83–168	Hydrocortisone Liquid, 1% and 2 1/2%	Dermik Laboratories, Inc., 500 Arcola Rd., P.O. Box 1200, Collegeville, PA 19426–0107.
83–169	Hydrocortisone Gel, 1% and 2 1/2%	Do.
83–184	Propoxyphene Hydrochloride Capsules, 65 mg	Smith, Kline & French, One Franklin Plaza, P.O. Box 7929, Philadelphia, PA 19101.
83–275	Diphenhydramine Hydrochloride Capsules, U.S.P., 50 mg	Anabolic, Inc.
83–301	Pentobarbital Sodium Capsules, 100 mg	Purepac Pharmaceutical, Co., 200 Elmora Ave., Elizabeth, NJ 07207.
83–313	Triamcinolone Acetonide Ointments, 0.025%, 0.1%, and 0.5%.	Dermik Laboratories, Inc.
83–314	Triamcinolone Acetonide Creams, 0.025%, 0.1%, and 0.5%.	Do.
83–363	Metaraminol Bitartrate Injection, U.S.P., 10 mg/milliliters (mL).	Elkins-Sinn, Inc., Two Esterbrook Lane, Cherry Hill, NJ 08003–4099.
83–554	Hydrochlorothiazide Tablets, 50 mg	Smith, Kline & French.
83–567	Diphenhydramine Hydrochloride Capsules, 50 mg	West-Ward Pharmaceutical Corp., 465 Industrial Way, West, Eatontown, NJ 07724.
83–625	Tripelennamine Hydrochloride Tablets, U.S.P., 25 mg	Warner-Lambert, 201 Tabor Rd., Morris Plains, NJ 07950.
83–626	Tripelennamine Hydrochloride Tablets, U.S.P., 50 mg	Do.
84–125	Dextroamphetamine Sulfate Tablets, 5 mg and 10 mg	Purepac Pharmaceutical, Co.
84–239	Hydrocortisone Tablets, 10 mg	Warner-Lambert.
84–240	Prednisone Tablets, 5 mg	Do.
84–242	Prednisolone Tablets, 5 mg	Do.
84–530	Aminophylline Tablets, 200 mg	The Vale Chemical Co., Inc., Allentown, PA 18102.
84–531	Aminophylline Tablets, 100 mg	Do.
84–601	Chlordiazepoxide Hydrochloride Capsules, 10 mg	Mylan Pharmaceuticals, Inc., P.O. Box 4310, 781 Chestnut Ridge Rd., Morgantown, WV 26505–4310.
84–699	Aminophylline Tablets, 100 mg	Purepac Pharmaceutical, Co.
84–739	Theophylline Elixir, 80 mg/15 mL	Roxane Laboratories, Inc., 1809 Wilson Rd., Columbus, OH 43228.
84–880	Hydrochlorothiazide Tablets, 25 mg and 50 mg	Mylan Pharmaceuticals, Inc.
85–112	Hydrochlorothiazide Tablets, 50 mg	Do.
85–195	Meclizine Hydrochloride Tablets, 12.5 mg	Circa Pharmaceuticals, 15 Grand Park Blvd., Athens, OH 45701.
85–375	Acetaminophen Capsules, 500 mg Oxycodone Hydrochloride Capsules, 4.5 mg Oxycodone Terephthalate Capsules, 0.38 mg.	McNeil Pharmaceutical, Welsh and Mckeon Rds., Spring House, PA 19477–0776.
85–534	Sulfisoxazole Tablets, 500 mg	Chelsea Laboratories, Inc., 896 Orlando Ave., West Hempstead, NY 11552.
85–564	Aminophylline Tablets, 200 mg	Do.
85–567	Aminophylline Tablets, 100 mg	Do.

ANDA No.	Drug	Applicant
85–667	Hydrocodone Bitartrate Tablets, 5 mg Acetaminophen Tablets, 500 mg.	Knoll Pharmaceutical, 30 North Jefferson Rd., Whippany, NJ 07981.
85–867	Secobarbital Sodium Capsules, U.S.P., 100 mg	Purepac Pharmaceutical, Co.
85–892	Dextroamphetamine Sulfate Tablets, 10 mg	Phoenix Pharmaceutical, Inc., 111 Leuning St., South Hackensack, NJ 07606.
86–044	Isosorbide Dinitrate Tablets, 10 mg	Circa Pharmaceuticals.
86–049	Brompheniramine Maleate Tablets, 4 mg	Purepac Pharmaceutical Co.
86–170	Hydrocortisone Cream,1%	Stiefel Laboratories, Inc., 2801 Ponce De Leon Blvd., Coral Gables, FL 33134.
86–202	Procaine Hydrochloride Injection, 1% and 2%	G. D. Searle and Co.
86–205	Ammonium Chloride Injection, 3 milliquivalent (meq)/mL	Do.
86–219	Potassium Chloride Injection, U.S.P., 10 meq/10 mL, 20 meq/10 mL, 30 meq/mL, and 40 meq/10 mL.	Do.
86–220	Potassium Chloride Injection	G. D. Searle and Co.
86–302	Isosorbide Dinitrate Tablets, 10 mg	Purepac Pharmaceutical, Co.
86–304	Isosorbide Dinitrate Tablets, 5 mg	Do.
86–369	Hydrochlorothiazide Tablets, 25 mg	Smith, Kline & French.
86–418	Metaraminol Bitartrate Injection, U.S.P.	McGaw Inc., P.O. Box 19791, Irvine, CA 92713–9791.
86–824	Hydrocortisone Lotion, 0.5%	Pharmaceutical Associates, Inc., P.O. Box 128, Conestee, SC 29636.
86–858	Isosorbide Dinitrate Tablets, U.S.P., 5 mg	Lederle Labs, One Cyanamid Co., Wayne, NJ 07470–8426.
86–862	Isosorbide Dinitrate Tablets, U.S.P., 10 mg	Do.
86–981	Dipyridamole Tablets, Coated, 25 mg	Circa Pharmaceuticals.
87–085	Hydralazine Hydrochloride Tablets, 25 mg Hydrochlorothiazide Tablets, 15 mg Reserpine Tablets, 0.1 mg.	Mylan Pharmaceuticals, Inc.
87–163	Isosorbide Dinitrate Chewable Tablets, 5 mg	D. M. Graham Laboratories, Inc., Hobart, NY 13788.
87–415	Isosorbide Dinitrate Capsules T.R., 40 mg, Green & Clear	Eon Labs Manufacturing, Inc., 227–15 North Conduit Ave., Laurelton, NY 11413.
87–474	Isosorbide Dinitrate Oral Tablets, 5 mg	Ascot Hospital Pharmaceuticals, Inc., 8055 North Ridgeway Ave., Skokie, IL 60076.
87–475	Isosorbide Dinitrate Oral Tablets, 10 mg	Do.
87–476	Isosorbide Dinitrate Oral Tablets, 20 mg	Do.
87–478	Isosorbide Dinitrate Sublinqual Tablets, 5 mg	Do.
87–484	Nitroglycerine TD Capsules, 2.5 mg	Do.
87–485	Nitroglycerine TD Capsules, 6.5 mg	Do.
87–486	Isosorbide Dinitrate SR Capsules, 40 mg	Do.
87–512	Chlordiazepoxide Hydrochloride Capsules, 25 mg	Do.
87–514	Triprolidine Hydrochloride Syrup, 1.25 mg/5 mL	Pharmaceutical Associates, Inc.
87–517	Brompheniramine Maleate Elixir, 2 mg/5 mL	Do.
87–518	Promethazine Hydrochloride Syrup, 6.25 mg/5 mL	Do.
87–520	Chlorpheniramine Maleate Syrup, 2 mg/5 mL	Do.
87–522	Aminophylline Tablets, 100 mg	Ascot Hospital Pharmaceuticals, Inc.
87–523	Aminophylline Tablets,200 mg	Do.
87–524	Chlordiazepoxide Hydrochloride Capsules, 10 mg	Do.
87–525	Chlordiazepoxide Hydrochloride Capsules, 5 mg	Do.
87–539	Hydrochlorothiazide Tablets, 25 mg	Do.
87–540	Hydrochlorothiazide Tablets, 50 mg	Do.
87–541	Tolbutamide Tablets, 500 mg	Do.
87–542	Procainamide Hydrochloride Capsules, 250 mg	Do.
87–543	Procainamide Hydrochloride Capsules, 500 mg	Do.
87–621	Aminophylline Injection, 25 mg/mL	G. D. Searle and Co.
87–660	Methocarbamol Tablets, 500 mg	Ascot Hospital Pharmaceuticals, Inc.
87–661	Methocarbamol Tablets,750 mg	Do.
87–662	Sulfamethoxazole Tablets, 500 mg	Do.
87–663	Propantheline Bromide Tablets, 15 mg	Do.
87–685	Cyproheptadine Hydrochloride Tablets, 4 mg	Do.
87–686	Acetazolamide Tablets, 250 mg	Do.
87–687	Spironolactone Tablets,25 mg	Do.
87–697	Procainamide Hydrochloride Capsules, 375 mg	Do.
87–698	Chlorthalidone Tablets, 25 mg	Do.
87–699	Chlorthalidone Tablets, 50 mg	Do.
87–734	Nitroglycerin Oral Transmucosal Long Acting Tablets, 1 mg.	Merrell Dow Pharmaceuticals, Inc., 2110 East Galbraith Rd., P.O. Box 156300, Cincinnati, OH 45215–6300.
87–778	Dimenhydrinate Tablets, 50 mg	Republic Drug Co., Inc., 175 Great Arrow Ave., Buffalo, NY 14207.
87–934	Diphenoxylate Hydrochloride Tablets, 2.5 mg Atropine Sulfate Tablets, 0.025 mg.	Ascot Hospital Pharmaceuticals, Inc.
88–005	Isosorbide Dinitrate Sublingual Tablets, 5 mg	Unit Dose Laboratories, 1718 Northrock Court, Rockford, IL 61103.
88–006	Isosorbide Dinitrate Tablets, Oral, 10 mg	Do.
88–025	Spironolactone with Hydrochlorothiazide Tablets, 25 mg/25 mg.	Ascot Hospital Pharmaceuticals, Inc.

ANDA No.	Drug	Applicant
88–067	Orphenadrine Citrate S. R. Tablets, 100 mg	Do.
88–117	Triprolidine Hydrochloride Tablets, 2.5 mg Pseudoephedrine Hydrochloride Tablets, 60 mg.	West-Ward Pharmaceutical Corp.
88–199	Folic Acid Tablets, 1 mg	Unit Dose Laboratories.
88–256	Meclizine Hydrochloride Tablets, 12.5 mg	Do.
88–257	Meclizine Hydrochloride Tablets, 25 mg	Do.
88–288	Bethanechol Chloride Tablets, 10 mg	Ascot Hospital Pharmaceuticals, Inc.
88–289	Bethanechol Chloride Tablets, 25 mg	Do.
88–307	Thioridazine Hydrochloride Oral Concentrate, 30 mg/milliliters (mL).	Geneva Pharmaceuticals, Inc., 2555 West Midway Blvd., Broomfield, CO 80038–0446.
88–308	Thioridazine Hydrochloride Oral Concentrate, 100 mg/mL	Do.
88–318	Triprolidine Hydrochloride Tablets, 2.5 mg Pseudoephedrine Hydrochloride Tablets, 60 mg.	Circa Pharmaceuticals.
88–332	Thioridazine Hydrochloride Tablets, 10 mg	Mylan Pharmaceuticals, Inc.
88–333	Thioridazine Hydrochloride Tablets, 25 mg	Do.
88–334	Thioridazine Hydrochloride Tablets, 50 mg	Do.
88–335	Thioridazine Hydrochloride Tablets, 100 mg	Do.
88–582	Quinidine Gluconate Sustained Release Tablets, 324 mg	Ascot Hospital Pharmaceuticals, Inc.
88–646	Methocarbamol Tablets, 500 mg	Roxane Laboratories, Inc.
89–079	Nitroglycerin Controlled Release Capsules, 9 mg	Ascot Hospital Pharmaceuticals, Inc.

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 ANDA's listed above, and all amendments and supplements thereto, is hereby withdrawn, effective on May 26, 1995.

Dated: April 10, 1995.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 95–10272 Filed 4–25–95; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Request for Nominations for Voting Members

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations to fill three vacancies on the Advisory Commission on Childhood Vaccines (ACCV). The ACCV was established by title XXI of the Public Health Service Act (the Act), as enacted by Public Law (Pub. L.) 99–660 and as subsequently amended, and advises the Secretary of Health and Human Services (the Secretary) on issues related to implementation of the National Vaccine Injury Compensation Program (VICP).

FOR FURTHER INFORMATION CONTACT: Mr. Jerry Anderson, Principal Staff Liaison, Policy and Commission Branch, Division of Vaccine Injury Compensation, at (301) 443–1533.

DATES: Nominations are to be submitted by May 26, 1995.

ADDRESSES: All nominations are to be submitted to the Director, Division of Vaccine Injury Compensation, Bureau of Health Professions, HRSA, Parklawn Building, Room 8A–35, 5600 Fishers Lane, Rockville, Maryland 20857.

SUPPLEMENTARY INFORMATION: Under the authorities that established the ACCV, viz., the Federal Advisory Committee Act of October 6, 1972 (P.L. 92–463) and section 2119 of the Act, 42 U.S.C. 300aa–19, as added by P.L. 99–660 and amended, HRSA is requesting nominations for three voting members of the ACCV.

The ACCV advises the Secretary on the implementation of the VICP; on its own initiative or as the result of the filing of a petition, recommends changes in the Vaccine Injury Table; advises the Secretary in implementing the Secretary's responsibilities under section 2127 regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions; surveys Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b); advises the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines; and recommends to the Director, National Vaccine Program, Office of the Assistant Secretary for Health, research related to vaccine injuries which should be conducted to carry out the VICP.

The ACCV consists of nine members appointed by the Secretary as follows: Three health professionals, of whom at least two are pediatricians, who are not employees of the United States, who have expertise in the health care of children, the epidemiology, etiology and prevention of childhood diseases, and the adverse reactions associated with vaccines; three members from the general public, of whom at least two are legal representatives of children who have suffered a vaccine-related injury or death; and three attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death and one shall be an attorney whose specialty includes representation of vaccine manufacturers. In addition, the Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of the Food and Drug Administration (or the designees of such officials) serve as nonvoting ex officio members.

Specifically, HRSA is requesting nominations for three voting members of the ACCV representing: (1) A health professional with special experience in childhood diseases; (2) a member from the general public who is a legal representative of a child who has suffered a vaccine-related injury or death; and (3) an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death. Nominees will be invited to serve 3-year terms beginning January 1, 1996, and ending December 31, 1998.

Interested persons may nominate one or more qualified persons for