applicant's ability to commit appropriate staff time needed to carry out the study.

3. Project Management (35 Points)

The applicant's ability to implement and monitor the proposed study to include specific, attainable, and realistic goals and objectives, and an evaluation plan.

4. Budget Justification (Not Scored)

The extent to which the budget is reasonable, clearly justified, and consistent with the intended use of cooperative agreement funds.

5. Human Subjects (Not Scored)

The extent to which the applicant complies with the Department of Health and Human Services regulations (45 CFR part 46) on the protection of human subjects.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with the original plus two copies of:

1. Quarterly progress reports, which are required of all grantees. The quarterly report narrative should not exceed 15 pages. Time lines for the quarterly reports will be established at the time of award, but are typically due 30 days after the end of each quarter.

2. Calendar-year surveillance data must be submitted annually to CDC in the approved OMB format between March–June. In addition to CDC, a written surveillance summary must be disseminated to State and local public health officials, policy makers, and others.

3. Financial Status Reports are due within 90 days of the end of the budget period.

4. Final financial reports and performance reports are due within 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Note: Data collection initiated under this cooperative agreement program has been approved by the Office of Management and Budget under OMB number (0920–0337), ''National Childhood Blood Lead Surveillance System'', Expiration Date: March 31, 2001.

The following additional requirements are applicable to this program. For a complete description of each, see Addendum 1 in the application package.

AR–1 Human Subjects Requirement
AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–7 Executive Order 12372 Review
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a), 317A and 317B of the Public Health Service Act (42 U.S.C. 241(a), 247b–1, and 247b–3), as amended by the Children's Health Act of 2000. Program regulations are set forth in Title 42, Code of Federal Regulations, Part 51b to State and local health departments. The Catalog of Federal Domestic Assistance number is 93.197.

J. Pre-Application Workshop for New and Competing Continuation Applicants

For interested applicants, a telephone conference call for pre-application technical assistance will be held on Wednesday, February 14, 2001, from 1:30 p.m. to 3:30 p.m. Eastern Standard Time. The bridge number for the conference call is 1–800–311–3437, and the pass code is 907844. For further information about all workshops, please contact Claudette Grant-Joseph at 404–639–2510.

K. Where to Obtain Additional Information

This and other CDC announcements may be downloaded through the CDC homepage on the Internet at http://www.cdc.gov. Please refer to program announcement number 01020 when requesting information. To receive additional written information and to request an application kit, call 1–888–GRANTS4 (1–888–472–6874). You will be asked to leave your name, address, and phone number and will need to refer to Announcement 01020. You will receive a complete program description, information on application procedures, and application forms. CDC will not send application kits by facsimile or express mail. If you have questions after reviewing the contents of all documents, business management technical assistance may be obtained from: Lisa T. Garbarino, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, telephone (770) 488–2710.

For programmatic technical assistance, contact: Claudette A. Grant-Joseph, Chief, Program Services Section, Lead Poisoning Prevention Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE, Mailstop E–25, Atlanta, GA 30333, telephone (404) 639–2510, Internet address cag4@cdc.gov.

Dated: January 29, 2001.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–2828 Filed 2–1–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1198]

John J. Ferrante et al; Withdrawal of Approval of 125 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 125 abbreviated new drug applications (ANDA's). The basis for the withdrawals is that the holders of the applications have repeatedly failed to file required annual reports for these applications.

DATES: Effective February 2, 2001.

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The holders of approved applications to market new drugs for human use are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 314.81 (21 CFR 314.81).

In the **Federal Register** of March 28, 2000 (65 FR 16397), FDA offered an opportunity for a hearing on a proposal to withdraw approval of 158 ANDA's because the firms had failed to submit the required annual reports for these applications.

I. Annual Reports Submitted

In response to the notice of opportunity for a hearing (NOOH), 5

firms requested hearings and submitted an annual report for each of 18 ANDA's. Therefore, FDA rescinds its proposal to withdraw approval of the following 18 ANDA's:

1. Ambix Laboratories, 210 Orchard St., East Rutherford, NJ 07073; ANDA 60–453, Neomycin and Polymyxin B Sulfate and Bacitracin Ointment with Diperodon Hydrochloride (HCl).

2. Ferndale Laboratories, Inc., 780 West Eight Mile Rd., Ferndale, MI 48220; ANDA 81–008, Chlorzoxazone Tablets USP, 500 milligrams (mg).

3. Hygenics Pharmaceuticals, Inc., 26941 Cabot Rd., suite 128, Laguna Hills, CA 92653; ANDA 71–419, Chlorhexidine Gluconate Topical Solution, 4%.

4. Vintage Pharmaceuticals, Inc., 3241 Woodpark Blvd., Charlotte, NC 28206; ANDA 62–538, Doxycycline Hyclate Tablets USP, 100 mg; ANDA 71–639, Ibuprofen Tablets USP, 200 mg; ANDA 71–644, Ibuprofen Tablets USP, 400 mg; ANDA 89–805, Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg; ANDA 89–828, Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/60 mg; and ANDA 89–990, Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/15 mg.

5. Wendt Laboratories, Inc., 100 Nancy Dr., P.O. Box 128, Belle Plaine, MN 56011; ANDA 84–185, Bethanechol Chloride Tablets, 10 mg; ANDA 84–186, Bethanechol Chloride Tablets, 25 mg; ANDA 85–039, Folic Acid Tablets USP, 1 mg; ANDA 85–040, Isoniazed Tablets USP, 100 mg; ANDA 85–041, Meclizine HCL Tablets, 25 mg; ANDA 85–042, Methocarbamol Tablets USP, 500 mg; ANDA 85–044, Reserpine Tablets USP, 0.25 mg; ANDA 86–766, Nitrofurazone Ointment, 0.2%; and ANDA 87–081, Nitrofurazone Solution, 0.2%.

II. Requests to Withdraw Approval

In response to the NOOH, Zenith Goldline Pharmaceuticals, Inc., 140 Legrand Ave., Northvale, NJ 07647 notified the agency that they no longer market the products for ANDA's 83–682, 85–539, 85–733, 85–777, 87–328, 87–375, 87–376, 87–377, 87–427, 87–428, 87–429, 87–430, 87–612, 87–613, and 87–614. In the **Federal Register** of October 2, 2000 (65 FR 58775), the agency withdrew approval of these 15 ANDA's under the written request of the applicant.

Another 7 firms notified the agency that they no longer market the products for 14 of the ANDA's listed in the NOOH. The firms did not request hearings and submitted formal requests for the agency to withdraw approval of the ANDA's for these products. These 14 ANDA's are included in the table in this notice and are marked with a footnote.

III. No Response to NOOH Received

The holders of the other 111 applications did not respond to the NOOH. Failure to file a written notice of participation and request for hearing as required by 21 CFR 314.200 constitutes an election by the applicant not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and a waiver of any contentions concerning the legal status of the drug products.

Therefore, the Director, Center for Drug Evaluation and Research, is withdrawing approval of the applications listed in the table of this document.

ANDA No.	Drug	Applicant
60–058	Chloramphenicol Capsules, 250 mg.	John J. Ferrante, c/o Operations Management Consulting, 11 Fairway Lane, Trumbull, CT 06611.
60–062	Penicillin G Potassium.	The Upjohn Co., 700 Portage Rd., Kalamazoo, MI 49001.
60–094	Sterile Penicillin G Procaine Suspension USP.	Do.
60–110	Sterile Dihydrostreptomycin Sulfate USP.	Pfizer Central Research, Pfizer, Inc., Eastern Point Rd., Groton, CT 06340.
60–170	Penicillin G Potassium Tablets, 200,000, 250,000, and 400,000 units.	John J. Ferrante.
60–173	Tetracycline HCl Capsules, 250 mg.	Do.
60–174	Tetracycline Oral Suspension, 125 mg/5 milliliters (ml).	Do.
60–177	Bacitracin-Neomycin Sulfate Polymyxin B Sulfate Ointment.	Do.
60–178	Bacitracin-Neomycin Sulfate Ointment.	Do.
60–179	Oxytetracycline HCl Capsules, 250 mg.	Do.
60–188[1]	Neomycin Sulfate and Hydrocortisone Acetate Ophthalmic Suspension USP.	Akorn, Inc., c/o Walnut Pharmaceuticals, Inc., 1340 North Jefferson St., Anaheim, CA 92807.
60–360	Neomycin and Polymyxin B Sulfate and Bacitracin with Benzocaine.	Ambix Laboratories, 210 Orchard St., East Rutherford, NJ 07073.
60–435	Tetracycline HCl Tablets USP, 250 mg.	Farmitalia Carlo Erba S.p.A., c/o Montedison, USA, Inc., 1114 Avenue of the Americas, New York, NY 10036.
60–464	Neomycin Sulfate and Prednisolone.	The Upjohn Co.
60–647	Neo-Polycin Ophthalmic Ointment.	Merrell Dow Pharmaceuticals, Inc., P.O. Box 68511, Indianapolis, IN 46268.
60–666	Ampicillin Tihydrate for Oral Suspension.	Beecham Laboratories, 501 Fifth St., Bristol, TN 37620.
60–690	Oxytetracycline HCl.	Pierrel America, Inc., 576 Fifth Ave., New York, NY 10036.
60–720	Tetracycline HCl Capsules, 250 mg.	Towne Paulsen & Co., Inc., 140 East Duarte Rd., Monrovia, CA 91016.
60–757	Polymyxin B Sulfate, 500,000 units.	Burroughs Wellcome Co., 3030 Cornwallis Rd., Research Triangle Park, NC 27709.
60–774	Griseofulvin Tablets, 500 mg.	McNeil Consumer, Inc., Camp Hill Rd., Fort Washington, PA 19034.
60–809	Penicillin G Potassium Tablets USP, 100,000, 200,000, 250,000, 400,000, and 500,000 units.	Consolidated Pharmaceutical Group, 6110 Robinwood Rd., Baltimore, MD 21225.
60–855	Oxytetracycline HCl Capsules, 250 mg.	Rachelle Laboratories, Inc., 700 Henry Ford Ave., P.O. Box 2029, Long Beach, CA 90801.
60–869	Oxytetracycline HCl Capsule, 250 mg.	Proter S.p.A., c/o Arnold Buhl Christen, 1000 Connecticut Ave., Washington, DC 20086.
61–174	Candicidin.	Penick Corp., 1050 Wall St. West, Lyndhurst, NJ 07071.

ANDA No.	Drug	Applicant
61–396	Hetacillin Capsules.	Bristol-Myers, U.S. Pharmaceutical Group, Evansville, IN 47721–0001.
61–523[1]	Tetracycline HCl Susceptibility Powder, 20 mg.	Lederle Laboratories, Division of American Cyanamid Co., Pearl River, NY 10965.
61–676	Ampicillin Trihydrate Capsules, 250 mg and 500 mg.	Public Health Service, Health Service Administration, Perry Point, MD 21902.
61–700[1]	Bacitracin Zinc USP for Compounding.	Alpharma A. S., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024.
61–718	Nystatin Vaginal Tablets USP, 100,000 units.	Holland-Rantos Co., Inc., 310 Enterprise Ave., Trenton, NJ 08638.
61–720	Doxycycline Oral Suspension USP.	Rachelle Laboratories, Inc.
61–933	Penicillin G Potassium for Injection USP.	E. R. Squibb & Sons, P.O. Box 191, New Brunswick, NJ 08903–0191.
61–953	Doxycycline Hyclate Injection.	Rachelle Laboratories, Inc., P.O. Box 187, Culver, IN 46511.
61–957	Benzylpenicilloyl Polylysine Injection.	Kremers-Urban Co., 5600 West County Line Rd., P.O. Box 2038, Milwaukee, WI 53201.
61–961[1]	Bacitracin Ointment USP.	Clay-Park Labs, Inc., 1700 Bathgate Ave., Bronx, NY 10457.
61–994	Kanamycin Sulfate Injection USP.	Bristol Laboratories, Division of Bristol-Myers Co., P.O. Box 657, Syracuse, NY 13201.
62–007[1]	Bacitracin USP, 50,000 and 10,000 units/vial.	Alpharma A. S.
62–042[1]	Chloramphenicol Ophthalmic Solution, 0.5%.	Akorn, Inc.
62–138	Cefoxitin Solution.	Pfizer Pharmaceuticals, Inc., 235 East 42d St., New York, NY 10017.
62–224	Neomycin Sulfate Ointment.	Clay-Park Labs, Inc.
62–236	Bacitracin Ointment USP.	Denison Laboratories, Inc., 60 Dunnell Lane, P.O. Box 1305, Pawtucket, RI 02862.
62–248	Gentamicin Sulfate Injection USP.	The Upjohn Co.
62–345	Tetracycline HCl Capsules, 250 mg.	Public Health Service, HAS Supply Service Center, Perry Point, MD 21902.
62–354	Gentamicin Sulfate Injection USP.	Kalapharm, Inc., 145 East 27th St., New York, NY 10016.
62–357	Amoxicillin Trihydrate Capsules, 250 mg and 500 mg.	Public Health Service, HAS Supply Service Center.
62–359	Bacitracin Topical Ointment, 500 units/gram.	NMC Laboratories, Inc., 70–36 83d St., Glendale, NY 11385.
62–361	Bacitracin-Neomycin-Polymyxin B Sulfate.	Do.
62–528	Amoxicillin Capsules USP, 250 mg and 500 mg.	Laboratories Atral, S.A., c/o Louie F. Turner, P.O. Box 331044, Fort Worth, TX 76133–2924.
71–278	PEG 3350 and Electrolytes for Oral Solution USP.	E-Z-EM, Inc., 717 Main St., Westbury, NY 11590.
71–320	PEG 3350 and Electrolytes for Oral Solution USP.	DynaPharm, Inc., P.O. Box 2141, Del Mar, CA 92014.
71–777	Clorazepate Dipotassium Capsules, 3.75 mg.	Able Laboratories, 333 Cassell Dr., suite 3500, Baltimore, MD 21224.
71–778	Clorazepate Dipotassium Capsules, 7.5 mg.	Do.
71–779	Clorazepate Dipotassium Capsules, 15 mg.	Do.
72–319	Glycoprep (PEG 3350 and Electrolytes for Oral Solution).	Goldline Laboratories, 1900 West Commerical Blvd., Ft. Lauderdale, FL 33309.
72–399	Sulfamethoxazole and Trimethorprim Oral Suspension USP.	NASKA Pharmacal Co., Inc., P.O. Box 898 Riverview Rd., Lincolnton, NC 28093.
72–409	Nifedipine Capsules USP, 10 mg.	Chase Laboratories, Inc., 280 Chestnut St., Newark, NJ 07105.
73–421	Nifedipine Capsules USP, 20 mg.	Do.
74–080	Carbidopa and Levodopa Tablets USP, 10 mg/100 mg, 25 mg/100 mg, 25 mg/250 mg.	SCS Pharmaceuticals, 4901 Searle Pkwy., Skokie, IL 60077.
80–094	Triple Sulfoid Tablets.	Pal-Pak, Inc., 1201 Liberty St., Allentown, PA 18102.
80–117	Nitrofurantoin Tablets, 50 mg.	Rachelle Laboratories, Inc., 700 Henry Ford Ave., P.O. Box 2029, Long Beach, CA 90801.
80–118	Nitrofurantoin Tablets, 100 mg.	Do.
80–335	Prednisolone Tablets, 5 mg.	Central Pharmaceutical, Inc., 110–128 East Third St., Seymour, IN 47274.
80–375	Lidocaine HCl Injection USP, 2%.	Rachelle Laboratories, Inc.
80–376	Lidocaine HCl Injection USP, 1%.	Do.
80–481	Hydrocortisone Ointment USP.	C & M Pharmacal, Inc., 1721 Maple Lane, Hazel Park, MI 48030–1215.
80–482	Hydrocortisone Cream USP.	Do.
80–562	Prednisolone Tablets, 2.5 mg and 5 mg.	John J. Ferrante.
80–568	Hydrocortisone Tablets, 10 mg and 20 mg.	Do.
80–967	Vitamin A Capsules USP.	West-Ward, Inc., 465 Industrial Lane, Eatontown, NJ 07724.
83–102	Vitamin D Capsules, 50,000 units.	Do.
83–156	Hydrocortisone Acetate Cream, 1.0%.	Parke-Davis, Div. of Warner-Lambert Co., 201 Tabor Rd., Morris Plains, NJ 07950.
83–161[1]	Dexamethasone Sodium Phosphate Injection.	Dell Laboratories, Inc., 668 Front St., Teaneck, NJ 07666.
83–358[1]	Prednisolone Sodium Phosphate Ophthalmic Solution USP.	Akorn, Inc.
83–400	Propoxyphene HCl Capsules USP, 65 mg.	Rachelle Laboratories, Inc.
83–643	Acetaminophen and Codeine Phosphate Tablets, 325 mg/30 mg.	Carnrick Laboratories, Inc., 65 Horse Hill Rd., Cedar Knolls, NJ 07927.
83–787	Chlorpheniramine Maleate Tablets, 4 mg.	West-Ward, Inc.
83–790	Phendimetrazine Tartrate Tablets USP, 35 mg.	Numark Laboratories, Inc., 75 Mayfield Ave., Edison, NJ 08837.

ANDA No.	Drug	Applicant
83–791	Nitrofurazone Powder.	Roberts Laboratories, Inc., 4 Industrial Way West, Eatontown, NJ 07724.
83–829	Chlorpromazine HCl Tablets USP.	Rachelle Laboratories, Inc.
83–977	Selenium Sulfide.	USV Pharmaceutical Corp., One Scarsdale Rd., Tuckahoe, NY 10707.
84–030	Meprobamate Tablets, 400 mg.	Ferndale Laboratories, Inc.
84–255	Sulfasalazine Tablets, 500 mg.	William H. Rorer, Inc., 500 Virginia Dr., Fort Washington, PA 19034.
84–337	Sulfisoxasole Tablets, 500 mg.	Rachelle Laboratories, Inc.
84–377[1]	Prednisone Capsules, 50 mg.	R. P. Scherer Corp., 2725 Scherer Dr., St. Petersburg, FL 33702.
84–492[1]	Prednisolone Acetate Injection.	Akorn, Inc.
84–563	Aminophylline Tablets, 200 mg.	ICN Pharmaceuticals, Inc., 5040 Lester Rd., Cincinnati, OH 45213.
84–639	Chlordiazepoxide HCl Capsules USP, 10 mg.	Rachelle Laboratories, Inc.
84–727	Lidocaine HCl Injection, 2%.	Pharmaton, Inc., 150 East 58th St., New York, NY 19155.
84–728	Lidocaine HCl Injection, 2% with Epinephrine 1:50,000.	Pharmaton, Inc., c/o Bass, Ullman & Lustrigman, 747 Third Ave., New York, NY 10017.
84–855[1]	Dexamethasone Sodium Phosphate Ophthalmic Solution USP, 0.1%.	Akorn, Inc.
85–086	Chlordiazepoxide HCl Capsules, 5 mg.	Rachelle Laboratories, Inc.
85–087	Chlordiazepoxide HCl Capsules USP, 25 mg.	Do.
85–091	Isoniazid Tablets USP, 100 mg.	Pharmavite Corp., 15451 San Fernando Mission Blvd., P.O. Box 9606, Mission Hills, CA 91346–9606.
85–104	Chlorpheniramine Maleate Tablets USP, 4 mg.	Do.
85–118	Chlordiazepoxide HCl Capsules, 5 mg.	John J. Ferrante.
85–119	Chlordiazepoxide HCl Capsules, 10 mg.	Do.
85–120	Chlordiazepoxide HCl Capsules, 25 mg.	Do.
85–341	Butabartital Sodium Tablets USP, 30 mg.	Vale Chemical Co., Inc., 1201 Liberty St., Allentown, PA 18102.
85–345	Butabartital Sodium Tablets USP, 15 mg.	Do.
85–477	Secobarbital Sodium Capsules, 100 mg.	ICN Pharmaceuticals, Inc., 222 North Vincent Ave., Covina, CA 91722.
85–509	Diphenoxylate HCl and Atropine Sulfate Tablets USP, 2.5 mg/0.025 mg.	Inwood Laboratories, Inc., Subsidiary of Forest Labs, Inc., 150 East 58th St., New York, NY 10155.
85–630	Trichlormethiazide Tablets, 4 mg.	Lannett Co., Inc., 9000 State Rd., Philadelphia, PA 19136.
85–851	Imipramine HCl Tablets USP, 25 mg.	A. H. Robins Co., 1407 Cummings Dr., P.O. Box 26609, Richmond, VA 23261–6609.
86–116	Phendimetrazine Tartrate Tablets, 17.5 mg.	Camall Co., P.O. Box 218, Washington, MI 48094.
86–129	Heparin Sodium Injection USP, 1,000 units/ml.	Pharma-Serve, Inc., 218–20 98th Ave., Queens Village, NY 11429.
86–543	Diphenhydramine HCl Capsules, 25 mg.	Newtron Pharmaceuticals, Inc., 155 Knickerbocker Ave., Bohemia, NY 11716.
86–544	Diphenhydramine HCl Capsules, 50 mg.	Do.
87–489	Hydrocortisone Lotion USP, 1%.	Heran Pharmaceutical, Inc., 7215 Eckhert Rd., San Antonio, TX 78238.
87–628	Butalbital, Acetaminophen, and Caffeine Capsules, 50 mg/325 mg/40 mg.	Roberts/Hauck Pharmaceuticals, Inc., Six Industrial Way West, Eatontown, NJ 07724.
87–818	Sulfacetamide Sodium Ophthalmic Solution, 10%.	Bausch & Lomb Pharmaceuticals, 8500 Hidden River Pkwy., Tampa, FL 33637.
87–834	Hydrocortisone USP (micronized powder).	Torch Laboratories, Inc., P.O. Box 248, Reisterstown, MD 21136.
87–865	Chlorpromazine HCl Tablets, 25 mg.	West-Ward, Inc.
88–024	Phendimetrazine Tartrate Extended-Release Capsules, 105 mg.	Numark Laboratories, Inc.
88–059[1]	Sulfacetamide Sodium and Prednisolone Acetate Ophthalmic Suspension USP, 10%/0.5%.	Akorn, Inc.
88–089	Sulfacetamide Sodium and Prednisolone Acetate Ophthalmic Suspension USP, 10%/0.5%.	Bausch & Lomb Pharmaceuticals.
88–189	Reserpine and Hydrochlorthiazide Tablets USP, 0.125 mg/50 mg.	West-Ward, Inc.
88–255[1]	Theophylline Sustained-Release Capsules, 300 mg.	R. P. Scherer North America, P.O. Box 5600, Clearwater, FL 33518.
88–393	Hydroxyzine Pamoate Capsules, 50 mg.	Vanguard Labs, Packaging Div. of MWM Corp., 101–107 Samson St., P.O. Box K, Glasgow, KY 42141.
88–447[1]	Tropicamide Ophthalmic Solution USP, 1%.	Akorn, Inc.
88–474	Triprolidine HCl and Pseudoephedrine HCl, 1.25 mg/5 ml and 30 mg/5 ml.	Newtron Pharmaceuticals, Inc.
89–268	Butalbital and Acetaminophen Capsules, 50 mg/325 mg.	Dunhall Pharmaceuticals, Inc., P.O. Box 100, Gravette, AR 72736.
89–273	Hydrocortisone Cream USP, 1.0%.	Topiderm, Inc., 155 Knickerbocker Ave., Bohemia, NY 11716.
89–274	Triamcinolone Acetonide Cream USP, 0.025%.	Do.
89–275	Triamcinolone Acetonide Cream USP, 0.1%.	Do.
89–276	Triamcinolone Acetonide Cream USP, 0.5%.	Do.
89–495	Hydrocortisone Lotion USP, 1%.	Beta Dermaceuticals, Inc., 5419 Bandera Rd., suite 708, San Antonia, TX 78238.

[1]Applicant requested withdrawal.

The Director, Center for Drug Evaluation and Research, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), and under authority of 21 CFR 5.82, finds that the holders of the applications listed above have repeatedly failed to submit reports required by § 314.81. Therefore, under this finding, approval of the applications listed above, and all amendments and supplements thereto, is hereby withdrawn, effective February 2, 2001.

Dated: January 9, 2001.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 01–2790 Filed 2–1–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Antiviral Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Antiviral Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 27, 2001, 9 a.m. to 5:30 p.m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Tara P. Turner, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, e-mail: TurnerT@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12531. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug application (NDA) 21–304, valganciclovir hydrochloride tablets, 450mg, Syntex (U.S.A.) LLC, proposed for treatment of cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome (AIDS).

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 20, 2001. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 20, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 18, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–2788 Filed 2–1–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0027]

Guidance for Industry on Statistical Approaches to Establishing Bioequivalence; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Statistical Approaches to Establishing Bioequivalence.'' This guidance provides recommendations to sponsors and/or applicants who intend to use equivalence criteria in analyzing in vivo or in vitro bioequivalence (BE) studies for investigational new drug applications (IND's), new drug applications (NDA's), abbreviated new drug applications (ANDA's) and supplements to these applications. The guidance discusses the use of average, population, and individual BE approaches to compare in vivo and in vitro bioavailability (BA) measures. (This guidance replaces the draft guidance that was issued in 1999 entitled ''Average, Population, and Individual Approaches to Establishing Bioequivalence.'')

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of this guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mei-Ling Chen, Center for Drug Evaluation and Research (HFD–350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5688.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Statistical Approaches to Establishing Bioequivalence.'' This guidance provides information on statistical approaches for sponsors and/or applicants intending to provide BA and BE information to the agency in IND's, NDA's, ANDA's, and their supplements.

Over the years, BA/BE data have been analyzed using an average BE approach. This statistical guidance describes two new approaches for analysis, population and individual BE. This guidance does not provide information about when an approach should be used; that information is provided in other FDA BA/BE guidances. Instead, the guidance provides recommendations on how to use each of these approaches once one has been selected.

This guidance is a final revision of a document that began with the publication of a preliminary draft guidance on this subject entitled ''In Vivo Bioequivalence Studies Based on Population and Individual Bioequivalence Approaches'' in 1997 (62 FR 67880, December 30, 1997), and was followed by a draft guidance entitled ''Average, Population, and Individual Approaches to Establishing Bioequivalence,'' published in 1999 (64 FR 48842, September 8, 1999). This final guidance replaces both of these draft guidances and a 1992 FDA guidance entitled ''Statistical Procedure for Bioequivalence Studies Using a Standard Two-Treatment Crossover Design.''

In September 1999, FDA announced the availability of a draft guidance entitled ''BA and BE Studies for Orally Administered Drug Products—General Considerations'' (64 FR 48409, September 3, 1999). That draft guidance was intended to provide general information on how to comply with the BA and BE requirements in part 320 (21 CFR part 320) for orally administered dosage forms. When that draft guidance was published, FDA received a total of 16 public comments, a number of which