Dated: March 20, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–7542 Filed 3–27–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1198]

John J. Ferrante et al.; Proposal to Withdraw Approval of 158 Abbreviated New Drug Applications; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for a hearing on the agency's proposal to withdraw approval of 158 abbreviated new drug applications (ANDA's). The basis for the proposal is that the sponsors have repeatedly failed to file required annual reports for these applications.

DATES: Submit written requests for a hearing by April 27, 2000; submit data and information in support of the hearing request by May 30, 2000.

ADDRESSES: Requests for a hearing, supporting data, and other comments are to be identified with Docket No. 00N–1198 and submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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). The holders of the applications listed in the following table have failed to submit the required annual reports and have not responded to the agency's request by certified mail for submission of the reports.

ANDA No.	Drug	Applicant
60–058	Chloramphenicol Capsules, 250 milligrams (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 Hydrochloride (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	Neomycin Sulfate and Hydrocortisone Actetate 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 Ointment 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.
60–453	Neomycin and Polymyxin B Sulfate and Bacitracin Ointment with Diperodon HCl.	Ambix Laboratories.
60–464	Neomycin Sulfate and Prednisolone.	The Upjohn Co.
60–647	Neo-Polycin Opthalmic 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.
61–396	Hetacillin Capsules.	Bristol-Myers, U.S. Pharmaceutical Group, Evansville, IN 47721–0001.
61–523	Tetracycline HCl Susceptibility Power, 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	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.

ANDA No.	Drug	Applicant
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	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	Bacitracin USP, 50,000 and 10,000 units/vial.	Alpharma A.S., c/o Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024.
62–042	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.
62–538	Doxycycline Hyclate Tablets USP, 100 mg.	Vintage Pharmaceuticals, Inc., 3241 Woodpark Blvd., Charlotte, NC 28206.
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.
71–419	Chlorhexidine Gluconate Topical Solution 4%.	Hygenics Pharmaceuticals, Inc., 26941 Cabot Rd., suite 128, Laguna Hills, CA 92653.
71–639	Ibuprofen Tablets USP, 200 mg.	Vintage Pharmaceuticals, Inc.
71–644	Ibuprofen Tablets USP, 400 mg.	Do.
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, and 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.
81–008	Chlorzoxazone Tablets USP, 500 mg.	Ferndale Laboratories, Inc., 780 West Eight Mile Rd., Ferndale, MI 48220.
83–102	Vitamin D Capsules, 50,000 units.	West-Ward, Inc.
83–156	Hydrocortisone Acetate Cream, 1.0%.	Parke-Davis, Div. of Warner-Lambert Co., 201 Tabor Rd., Morris Plains, NJ 07950.
83–161	Dexamethasone Sodium Phosphate Injection.	Dell Laboratories, Inc., 668 Front St., Teaneck, NJ 07666.
83–358	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.
83–682	Phendimetrazine Tartrate Tablets USP, 35 mg (yellow).	Zenith Laboratories, Inc., 140 Legrand Ave., Northvale, NJ 07647.
83–787	Chlorpheniramine Maleate Tablets, 4 mg.	West-Ward, Inc.

ANDA No.	Drug	Applicant
83–790	Phendimetrazine Tartrate Tablets USP, 35 mg.	Numark Laboratories, Inc., 75 Mayfield Ave., Edison, NJ 08837.
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.
84–185	Bethanechol Chloride Tablets, 10 mg.	Wendt Laboratories, Inc., 100 Nancy Dr., P.O. Box 128, Belle Plaine, MN 56011.
84–186	Bethanechol Chloride Tablets, 25 mg.	Do.
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	Prednisone Capsules, 50 mg.	R. P. Scherer Corp., 2725 Scherer Dr., St. Petersburg, FL 33702.
84–492	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	Dexamethasone Sodium Phosphate Ophthalmic Solution USP, 0.1%.	Akorn, Inc.
85–039	Folic Acid Tablets USP, 1 mg.	Wendt Laboratories, Inc.
85–040	Isoniazed Tablets USP, 100 mg.	Do.
85–041	Meclizine HCl Tablets, 25 mg.	Do.
85–042	Methocarbamol Tablets USP, 500 mg.	Do.
85–044	Reserpine Tablets USP, 0.25 mg.	Do.
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.
85–539	Triamcinolone Acetonide Cream USP, 0.1%, 0.5%, and 0.025%.	Zenith Goldline Pharmaceuticals, Inc.,
85–630	Trichlormethiazide Tablets, 4 mg.	Lannett Co., Inc., 9000 State Rd., Philadelphia, PA 19136.
85–733	Hydrocortisone Cream USP, 1%.	Zenith Goldine Pharmaceuticals, Inc.
85–777	Selenium Sulfide USP.	Do.
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.
86–766	Nitrofurazone Ointment 0.2%.	Wendt Laboratories, Inc.
87–081	Nitrofurazone Solution 0.2%.	Do.
87–328	Trifluoperazine HCl Tablets USP, 5 mg.	Zenith Goldline Pharmaceuticals, Inc.
87–375	Triamcinolone Acetonide Ointment USP, 0.025%.	Do.
87–376	Triamcinolone Acetonide Ointment USP, 0.5%.	Do.
87–377	Triamcinolone Acetonide Ointment USP, 0.1%.	Do.
87–427	Hydrocortisone Cream USP, 1%.	Do.
87–428	Triamcinolone Acetonide Cream USP, 0.5%.	Do.
87–429	Triamcinolone Acetonide Cream USP, 0.1%.	Do.
87–430	Triamcinolone Acetonide Cream USP, 0.025%.	Do.
87–489	Hydrocortisone Lotion USP, 1%.	Heran Pharmaceutical, Inc., 7215 Eckhert Rd., San Antonio, TX 78238.
87–612	Trifluoperazine HCl Tablets USP, 1 mg.	Zenith Goldline Pharmaceuticals, Inc.
87–613	Trifluoperazine HCl Tablets USP, 2 mg.	Do.
87–614	Trifluoperazine HCl Tablets USP, 10 mg.	Do.

ANDA No.	Drug	Applicant
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., 75 Mayfield Ave., Edison, NJ 08837.
88–059	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	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	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 Antonio, TX 78238.
89–805	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg.	Vintage Pharmaceuticals, Inc.
89–828	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/60 mg.	Do.
89–990	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/15 mg.	Do.

Therefore, notice is given to the holders of the applications listed in the table and to all other interested persons that the Director of the Center for Drug Evaluation and Research proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) withdrawing approval of the applications and all amendments and supplements thereto on the ground that the applicants have failed to submit reports required under § 314.81.

In accordance with section 505 of the act and 21 CFR part 314, the applicants are hereby provided an opportunity for a hearing to show why the applications listed previously should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by these applications.

An applicant who decides to seek a hearing shall file: (1) On or before April 27, 2000, a written notice of participation and request for a hearing, and (2) on or before May 30, 2000, the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation and request for a hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 and in 21 CFR part 12.

The failure of an applicant to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that applicant not to avail itself of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the applications and the drug products may not thereafter lawfully be marketed, and FDA will begin appropriate regulatory action to remove the products from the market. Any new drug product marketed without an approved new drug application is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. Reports submitted to remedy the deficiencies must be complete in all respects in accordance with § 314.81. If the submission is not complete or if a request for a hearing is not made in the required format or with the required reports, 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.

All submissions under this notice of opportunity for a hearing must be filed in four copies. Except for data and information prohibited from public disclosure under section 301 of the act (21 U.S.C. 331(j)) or 18 U.S.C. 1905, the submissions 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. 505 (21 U.S.C. 355)) and under authority delegated to the Director,

Center for Drug Evaluation and Research (21 CFR 5.82).

Dated: March 13, 2000.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 00–7589 Filed 3–27–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System Devices Panel of the Medical Devices 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: Circulatory System Devices Panel of the Medical Devices 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 April 4, 2000, 8 a.m. to 6 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: John E. Stuhlmuller, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8243, ext. 157, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12625. Please call the Information Line for up-to-date information on this meeting.

Agenda: There will be a brief FDA presentation on the least burdensome provisions of the FDA Modernization Act of 1997. Subsequently, the committee is being asked to provide input to the agency regarding the design of clinical trials for the following: (1) Devices using spinal cord stimulation in the treatment of angina pectoris; (2) rate-responsive pacemakers, specifically, the evaluation of rate-adaptive features; and (3) devices used in the treatment of atrial fibrillation. Background information, questions for the panel, and a bibliography for each topic to be discussed by the committee are available to the public on the Internet at http://www.fda.gov/cdrh/upadvmtg.html.

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 March 28, 2000. Oral presentations from the public will be scheduled between approximately 8 a.m. and 9 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 28, 2000, 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.

FDA regrets that it was unable to publish this notice 15 days prior to the April 4, 2000, Circulatory System Devices Panel of the Medical Device Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Circulatory System Devices Panel were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: March 20, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–7543 Filed 3–27–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2000 Funding Opportunities

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of funding availability.

SUMMARY: The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Treatment (CSAT) announces the availability of FY 2000 funds for grants for the following activity. This activity is discussed in more detail under Section 3 of this notice. This notice is not a complete description of the activity; potential applicants must obtain a copy of the Program Announcement, including Part I, Programmatic Guidance for Grants to Expand Substance Abuse Treatment Capacity in Targeted Areas of Need, and Part II, General Policies and Procedures Applicable to all SAMHSA Applications for Discretionary Grants and Cooperative Agreements, before preparing an application.

Activity	Application deadline	Estimated funds available, FY 2000	Estimated No. of Awards	Project period
PRC Implementation Program	June 13, 2000	$3,000,000	8–10	Up to 3 years.

The actual amount available for awards and their allocation may vary, depending on unanticipated program requirements and the number and quality of applications received. FY 2000 funds for the activity discussed in this announcement were appropriated by the Congress under Public Law No. 106–113. SAMHSA's policies and procedures for peer review and Advisory Council review of grant and cooperative agreement applications were published in the **Federal Register** (Vol. 58, No. 126) on July 2, 1993.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. The SAMHSA Centers' substance abuse and mental health services activities address issues related to Healthy People 2000 objectives of Mental Health and Mental Disorders; Alcohol and Other Drugs; Clinical Preventive Services; HIV Infection; and Surveillance and Data Systems. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017–001–00474–0) or Summary Report: Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325 (Telephone: 202–512–1800).