

NDA No.	Drug	Applicant
50-192	Tegopen Powder for Oral Solution	Do.
50-194	Prostaphlin Powder for Oral Solution	Do.
50-195	Prostaphlin (Oxacillin Sodium) for Injection	Apothecon.
50-308	Polycillin (Ampicillin) Powder for Oral Solution	Do.
50-337	Dynapen for Oral Suspension	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 of the Center for Drug Evaluation and Research (21 CFR 5.82), approval of the NDA's listed above, and all amendments and supplements thereto, is hereby withdrawn, effective September 29, 1995.

Dated: September 21, 1995.
 Janet Woodcock,
 Director, Center for Drug Evaluation and Research.
 [FR Doc. 95-24156 Filed 9-28-95; 8:45 am]
 BILLING CODE 4160-01-P

[Docket No. 95N-0318]

Searle, et al.; Withdrawal of Approval of 17 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 17 new drug applications (NDA's). The holders of the NDA's notified the agency in writing that the drug products were no longer being marketed under the NDA and requested that the approval of the applications be withdrawn.

EFFECTIVE DATE: September 29, 1995.

FOR FURTHER INFORMATION CONTACT: Nancy G. Maizel, Center for Drug Evaluation and Research (HFD-53), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2623.

SUPPLEMENTARY INFORMATION: The holders of the NDA's listed below have informed FDA that these drug products are no longer being marketed under the NDA and have requested that FDA withdraw approval of the applications. The applicants have also, by request, waived their opportunity for a hearing.

NDA No.	Drug	Applicant
2-386	Aminophyllin Tablets	Searle, 4901 Searle Pkwy., Skokie, IL 60077
3-205	Pantholin Tablets	Lilly Research Laboratories, Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285.
6-917	Gantrisin Injection	Hoffmann-La Roche Inc., Roche Pharmaceuticals, 340 Kingsland St., Nutley, NJ 07110-1199.
8-867	Rauwiloid Tablets	3M Pharmaceuticals, 3M Center, St. Paul, MN 55144-1000.
9-078	Parsidol Tablets	Parke-Davis Pharmaceutical Research, 2800 Plymouth Rd., Ann Arbor, MI 48105.
9-299	Hyperloid Tablets	Person & Covey Inc., P.O. Box 25018, 616 Allen Ave., Glendale, CA 91221-5018.
11-045	Milprem Tablets	Wallace Laboratories, Division of Carter-Wallace Inc., 301B College Rd. East, Princeton, NJ 08540.
11-110	Actidil Tablets	Burroughs Wellcome Co., 3030 Cornwallis Rd., P.O. Box 12700, Research Triangle Park, NC 27709-2700.
11-496	Actidil Syrup	Do.
11-535	Equanil Meprobamate Suspension	Wyeth-Ayerst Laboratories, P.O. Box 8299, Philadelphia, PA 19101-8299.
11-876	Fedrazil Tablets	Burroughs Wellcome Co.
17-528	Uticort Lotion	Parke-Davis Pharmaceutical Research.
17-917	Duraquin Tablets	Warner Chilcott Laboratories, 201 Tabor Rd., Morris Plains, NJ 07950.
18-375	Turgex Bacteriostatic Skin Cleanser (Aerosol)	Xitrium Laboratories Inc., 415 West Pershing Rd., Chicago, IL 60609.
19-055	Turgex Bacteriostatic Skin Cleanser (Emulsion)	Do.
50-019	Penbritin Ampicillin Drops	Wyeth-Ayerst Laboratories.
50-355	Coly-Mycin S Oral Suspension	Parke-Davis Pharmaceutical Research.

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 NDA's listed above, and all amendments and supplements thereto, is hereby withdrawn, effective September 29, 1995.

Dated: September 2, 1995.
 Janet Woodcock,
 Director, Center for Drug Evaluation and Research.
 [FR Doc. 95-24157 Filed 9-28-95; 8:45 am]
 BILLING CODE 4160-01-P

Dated: September 2, 1995.

Janet Woodcock,
 Director, Center for Drug Evaluation and Research.
 [FR Doc. 95-24157 Filed 9-28-95; 8:45 am]
 BILLING CODE 4160-01-P

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone

system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1-800-741-8138 or 301-443-0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

National Task Force on Aids Drug Development

Date, time, and place. October 12, 1995, 8:30 a.m., Hubert H. Humphrey Bldg., rm. 800, 200 Independence Ave. SW., Washington, DC.

Type of meeting and contact person. Open task force discussion, 8:30 a.m. to 4:30 p.m.; open public hearing, 4:30 p.m. to 5:30 p.m., unless public participation does not last that long; Heidi C. Marchand or Kimberley M. Miles, Office of AIDS and Special Health Issues (HF-12), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-0104, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), National Task Force on AIDS Drug Development, code 12602.

General function of the task force. The task force shall identify any barriers and provide creative options for the rapid development and evaluation of treatments for human immunodeficiency virus (HIV) infection and its sequelae. It also advises on issues related to such barriers, and provides options for the elimination of these barriers.

Open task force discussion. The task force will present, hear, and discuss recommendations made at previous meetings and discuss the future of the task force.

FDA is giving less than 15 days public notice of the advisory committee meeting because of the urgent need to address the potential risk of this disease to public health safety. The agency decided that it was in the public interest to hold this scientific discussion on October 12, 1995, even if there was not sufficient time for the customary 15-day public notice.

Agenda—Open public hearing. Interested persons may present information or views, orally or in writing, on issues pending before the task force. Those desiring to make formal presentations should notify the contact person before October 10, 1995, 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 required to make their comments.

National Mammography Quality Assurance Advisory Committee

Date, time, and place. October 16, 1995, 10 a.m., and October 17 and 18, 1995, 9 a.m., Dupont Plaza Hotel, 1500 New Hampshire Ave. NW., Washington, DC. A limited number of overnight accommodations have been reserved at the Dupont Plaza Hotel. Attendees requiring overnight accommodations may contact the hotel at 202-483-6000 and reference the FDA Committee meeting block. Reservations will be confirmed at the group rate based on availability.

Type of meeting and contact person. Open committee discussion, October 16, 1995, 10 a.m. to 12 m.; open subcommittee discussions, 12 m. to 5 p.m.; open public hearing, October 17, 1995, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 5 p.m.; open subcommittee discussions, October 18, 1995, 9 a.m. to 1 p.m.; open committee discussion, 1 p.m. to 3 p.m.; Charles K. Showalter, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3332, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), National Mammography Quality Assurance Advisory Committee, code 12397.

General function of the committee. The committee advises on developing appropriate quality standards and regulations for the use of mammography facilities.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before October 10, 1995, 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 required to make their comments.

Open committee discussion. On October 16, 1995, the committee will discuss a methodology of assessing the costs and benefits of the Mammography Quality Standards Act (the MQSA). On October 17, 1995, the committee will discuss facility inspection procedures and have a briefing by FDA on facility inspections to date. Copies of the "MQSA Facility Inspection Procedures" may be obtained by submitting a written request to John L. McCrohan at the address given above for the FDA contact person. On October 18, 1995, the committee will discuss the ongoing work of the three subcommittees: Access to Mammography Services, Physicists Availability, and Cost Benefit of Compliance.

Open subcommittee discussions. On October 16 and 18, 1995, the three subcommittees will meet concurrently. The subcommittees will discuss information that is necessary to make the determinations and subsequently prepare the reports mandated by the MQSA. Upon completion, the subcommittee reports will be reviewed by the committee prior to submission to the Secretary of Health and Human Services and Congress.

Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee)

Date, time, and place. October 25, 1995, 8:30 a.m., Hubert H. Humphrey Bldg., rm. 405-A, 200 Independence Ave. SW., Washington, DC.

Type of meeting and contact person. Open committee discussion, 8:30 a.m. to 10:30 a.m.; open public hearing, 10:30 a.m. to 11:30 a.m., unless public participation does not last that long; open committee discussion, 11:30 a.m. to 5 p.m.; Ronald F. Coene, National Center for Toxicological Research (HFT-10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3155, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Ranch Hand Advisory Committee, code 12560.

General function of the committee. The committee shall advise the Secretary and the Assistant Secretary for Health concerning its oversight of the conduct of the Ranch Hand Study by the Air Force and other studies in which the Secretary or the Assistant Secretary for Health believes involvement by the advisory committee is desirable.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before October 16, 1995, 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 comments.

Open committee discussion. The committee will review and provide comments on the draft protocol and questionnaire for the Department of Veterans Affairs, Army Chemical Corps Vietnam Veterans Health Study, developed by the Environmental and Epidemiology Service, Department of Veterans Affairs, Veterans Administration.

A final agenda will be available October 18, 1995, from the contact person.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: September 25, 1995.
David A. Kessler,
Commissioner of Food and Drugs.
[FR Doc. 95-24219 Filed 9-28-95; 8:45 am]
BILLING CODE 4160-01-F

Health Care Financing Administration

Public Information Collection Requirements Submitted for Public Comment and Recommendations

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the

Health Care Financing Administration (HCFA), Department of Health and Human Services (HHS), is publishing the following summaries of proposed collections for public comment.

Type of Information Collection
Request: Extension; *Title of Information Collection:* Sole Community Home Health Agencies (HHA) at 42 CFR 424.22(b)(2),(f) and (g); *Form No.:* HCFA R-85; *Use:* These regulations implement the rules for participation of HHAs in Medicare and the establishment and review of plans of care for home health services. These regulations make it easier for certain HHAs to meet certification and plan of care requirements. *Frequency:* Annually; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 20; *Total Annual Hours:* 40.

To request copies of the proposed paperwork collections referenced above, call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections should be sent within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attention: Louis Blank, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: September 21, 1995.
Carl Bordone,
Acting Director, Management Planning and Analysis Staff, Office of Financial and Human Resources.
[FR Doc. 95-24133 Filed 9-28-95; 8:45 am]
BILLING CODE 4120-03-P

Indian Health Service

Availability of Funds for Loan Repayment Program for Repayment of Health Professions Educational Loans

AGENCY: Indian Health Service, HHS.
ACTION: Notice.

SUMMARY: The Administration's budget request for fiscal year (FY) 1996 includes \$11,000,000 for the Indian Health Service Loan Repayment Program for health professions educational loans (undergraduate and graduate) in return for full-time clinical service in Indian health programs. It is anticipated that \$11,000,000 will be available to support approximately 250 competing awards averaging \$50,000 per award.

This program announcement is subject to the appropriation of funds.