

concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices" (12 U.S.C. 1843). Any request for a hearing must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal. Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 16, 1996.

A. Federal Reserve Bank of Minneapolis (Karen L. Grandstrand, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. *Walker Ban Co.*, Walker, Minnesota; to merge with Pequot Area Bancorporation, Inc., Pequot Lakes, Minnesota, and thereby indirectly acquire Lakes State Bank, Pequot Lakes, Minnesota.

Board of Governors of the Federal Reserve System, November 18, 1996.

William W. Wiles,

Secretary of the Board.

[FR Doc. 96-29807 Filed 11-20-96; 8:45 am]

BILLING CODE 6210-01-F

Closed for remainder of meeting.

Purpose: This Panel is charged with conducting the initial review of grant applications proposing analytical and theoretical research on costs, quality, access, and efficiency of the delivery of health services for the research grant program administered by the Agency for Health Care Policy and Research (AHCPR).

Agenda: The open session of the meeting on December 3, from 3:00 p.m. to 3:15 p.m., will be devoted to a business meeting covering administrative matters. During the closed session, the panel will be reviewing and discussing grant applications dealing with health services research issues. In accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C., 552b(c)(6), the Administrator, AHCPR, has made a formal determination that this latter session will be closed because the discussions are likely to reveal personal information concerning individuals associated with the grant applications. This information is exempt from mandatory disclosure.

Anyone wishing to obtain a roster of members or other relevant information should contact Carmen Johnson, Agency for Health Care Policy and Research, Suite 400, 2101 East Jefferson Street, Rockville, Maryland 20852, Telephone (301) 594-1449 x1613.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: November 14, 1996.

Clifton R. Gaus,

Administrator.

[FR Doc. 96-29693 Filed 11-20-96; 8:45 am]

BILLING CODE 4160-90-M

whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Wilma Johnson, CDC Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Projects

1. **Evaluation of the Field Epidemiology Training Program—New**—A questionnaire has been designed to collect information for the "Evaluation of the Field Epidemiology Training Program" project. The purpose of the project is to develop and implement a comprehensive evaluation strategy which will provide the International Branch, Division of Field Epidemiology, Epidemiology Program Office, with the capacity to assess the degree to which CDC's Field Epidemiology Training Program (FETP) has achieved its objectives: (1) To train public health professionals in applied epidemiological skills; (2) to promote the sustainability of autonomous FETPs; and (3) to develop a global network of national programs. The information gathered will be analyzed, in conjunction with data collected from other sources, to address these questions. The results of the project will assist the International Branch, Division of Field Epidemiology, Epidemiology Program Office, in accomplishing the part of its mission related to protecting the health of the public of the United States, through maintaining a strong international presence and an international network of public health professionals and officials. In order to focus its support to international training efforts and resource allocation, a representative view of the overall Field Epidemiology Training Program (FETP), which includes assessing the recruitment of countries, the sustainability of autonomous FETPs, the quality of training, the public health usefulness of FETP, and the international linkages of FETP is needed. The total estimated cost to the in-country respondents is \$8,380.00.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Health Care Policy and Research

Notice of Health Care Policy and Research; Special Emphasis Panel Meeting

In accordance with section 10(a) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), announcement is made of the following special emphasis panel scheduled to meet during the month of December 1996:

Name: Health Care Policy and Research Special Emphasis Panel.

Date and Time: December 3, 1996, 3:00 p.m.

Place: Agency for Health Care Policy and Research, 2101 E. Jefferson Street, Suite 400, Rockville, MD 20852.

Open December 3, 1996, 3:00 p.m. to 3:15 p.m.

Centers for Disease Control and Prevention

[INFO-97-29]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639-7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including

Respondents	No. of respondents	No. of responses/respondent	Average burden/response (in hrs.)	Total burden (in hrs.)
FETP trainees from selected countries	150	45	0.08333	562
FETP trainers from selected countries	60	59	0.08333	295
Government officials and others who employ FETP trainees in selected countries	60	38	0.08333	190
CDC staff involved with FETP activities	24	27	0.08333	54
Total	1,101

Dated: November 15, 1996.

Wilma G. Johnson,

Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96-29760 Filed 11-20-96; 8:45 am]

BILLING CODE 4163-18-P

Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Idaho National Engineering Laboratory Health Effects Subcommittee

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Center for Disease Control and Prevention (CDC) announces the following meeting.

Name: Citizens Advisory Committee on Public Health Service Activities and Research at DOE Sites: Idaho National Engineering Laboratory (INEL) Health Effects Subcommittee.

Times and Dates:

8 a.m.-5 p.m., December 10, 1996

7 p.m.-9 p.m., December 10, 1996

8 a.m.-4:30 p.m., December 11, 1996

Place: Holiday Inn Westbank, 475 River Parkway, Idaho Falls, Idaho 83402, telephone 208/523-8000, FAX 208/529-9610.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: The Subcommittee is charged with providing advice and recommendations to the Director, CDC, and the Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), regarding community, American Indian Tribes, and labor concerns pertaining to CDC's and ATSDR's public health activities and research at respective DOE sites. Activities shall focus on providing a forum for community, American Indian Tribal, and labor interaction and serve as a vehicle for community concern to be expressed as advice and recommendations to CDC and ATSDR.

Matters To Be Discussed: Agenda items include presentations from the National Center for Environmental Health (NCEH), the National Institute for Occupational Safety and Health, and ATSDR, on the progress of current studies. On December 10, at 7 p.m., the meeting will continue in order to allow more time for public input and comment.

Agenda items are subject to change as priorities dictate.

Contact Persons for More Information:

Arthur J. Robinson, Jr., or Nadine Dickerson, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, M/S F-35, Atlanta, Georgia 30341-3724, telephone 770/488-7040, FAX 770/488-7044.

Dated: November 15, 1996.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96-29759 Filed 11-20-96; 8:45 am]

BILLING CODE 4163-18-M

Food and Drug Administration

[Docket No. 96P-0090]

Determination That Testosterone Propionate 2% Ointment Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that testosterone propionate 2% ointment (Perandren Ointment) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for testosterone propionate 2% ointment.

FOR FURTHER INFORMATION CONTACT:

Mary E. Catchings, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301-594-2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress passed into law the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength

and dosage form as the listed drug, which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDA's do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments included what is now section 505(j)(6) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(6)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

On March 19, 1996, Richard Hamer Associates, Inc., submitted a citizen petition (Docket No. 96P-0090/CP1) under 21 CFR 10.25(a), 10.30, and § 314.161(b), requesting that the agency determine whether testosterone propionate 2% ointment was withdrawn from sale for reasons of safety or effectiveness and, if the agency determines that the drug was not withdrawn from sale for reasons of safety or effectiveness, to relist the drug in the Orange Book. Testosterone propionate 2% ointment (Perandren Ointment) was the subject of approved NDA 0-0499 held by Ciba Pharmaceutical Co. In the Federal Register of September 23, 1971 (36 FR