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 (ANDA's) 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

18885), FDA withdrew approval of NDA 0–0499 for Perandren Ointment based on the applicant's failure to submit required annual reports (section 505(e) of the act (21 U.S.C. 355(e)) and 21 CFR 314.80 and 314.81).

FDA has reviewed its records and, under §§ 314.161 and 314.162(c), has determined that testosterone propionate 2% ointment was not withdrawn from sale for reasons of safety or effectiveness and will relist testosterone propionate 2% ointment in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDA's that refer to testosterone propionate 2% ointment may be approved by the agency.

Dated: October 27, 1996.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 96–29766 Filed 11–20–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96M–0482]

Biora US, Inc.; Premarket Approval of EMDOGAIN®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Biora US, Inc., West Chester, OH, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of EMDOGAIN®. After reviewing the recommendation of the Dental Products Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 30, 1996, of the approval of the application.

DATES: Petitions for administrative review by December 23, 1996.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Pamela D. Scott, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8879.

SUPPLEMENTARY INFORMATION: On July 19, 1993, Biora US, Inc., West Chester, OH 45069, submitted to CDRH an application for premarket approval of EMDOGAIN®. The device is a bone filling and augmentation device and is indicated for use as an adjunct to periodontal surgery for topical application onto exposed root surfaces to treat intrabony defects without furcations resulting from loss of tooth support due to moderate or severe periodontitis. EMDOGAIN® is to be used with the supplied vehicle solution of propylene glycol alginate.

On February 27, 1996, the Dental Products Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On September 30, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before December 23, 1996, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: October 24, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–29765 Filed 11–20–96; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

Notice of Meeting of the Advisory Committee to the Director, NIH

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Advisory Committee to the Director, NIH, December 12, 1996, Conference Room 10, Building 31, National Institutes of Health, Bethesda, Maryland 20892.

The entire meeting will be open to the public from 9:00 a.m. to adjournment. The topics proposed for discussion include (1) Clinical Center Update; (2) Report from the Clinical Research Panel; (3) Discussion of Small Business Innovation Research and Small Business Technology Transfer Grants; and (4) Report from the Research Integrity Panel. Attendance by the public will be limited to space available.

Ms. Janice Ramsden, Program Assistant, Office of the Deputy Director, National Institutes of Health, 1 Center Drive MSC 0159, Bethesda, Maryland 20892–0159, telephone (301) 496–0959, fax (301) 496–7451, will furnish the meeting agenda, roster of committee members, and substantive program information upon request. Any individual who requires special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Ramsden no later than December 9, 1996.

Dated: November 18, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–29813 Filed 11–20–96; 8:45 am]

BILLING CODE 4140–01–M