

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]

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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]

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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