

will not send application kits by facsimile or express mail.

Please refer to Announcement Number 613 when requesting information and submitting an application.

Technical assistance on prevention activities may be obtained from David L. Forney, Chief, Program Services Section, Lead Poisoning Prevention Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway NE., Mailstop F-42, Atlanta, GA 30341-3724, telephone (770) 488-7330.

Technical assistance on surveillance activities may be obtained from Carol Pertowski, M.D., Medical Epidemiologist, Surveillance and Programs Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop F-42, Atlanta, GA 30341-3724, telephone (770) 488-7330.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017-001-00474-0) or Healthy People 2000 (Summary Report, Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

Dated: January 31, 1996.

Joseph R. Carter

Acting Associate Director for Management and Operations,
Centers for Disease Control and Prevention (CDC).

[FR Doc. 96-2587 Filed 2-6-96; 8:45 am]

BILLING CODE 4163-18-P

Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Savannah River Site Health Effects Subcommittee; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC) announce the following meeting.

Name: Citizens Advisory Committee on Public Health Service Activities and Research at DOE Sites: Savannah River Site Health Effects Subcommittee (SRS).

Times and Dates: 9 a.m.-5 p.m., February 29, 1996; 9 a.m.-12 noon, March 1, 1996.

Place: Holiday Inn—Savannah—Midtown, 7100 Abercorn Street, Savannah, Georgia 31406, telephone 912/352-7100, FAX 912/355-6408.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 60 people.

Background: Under a Memorandum of Understanding (MOU) signed in December 1990 with DOE, the Department of Health and Human Services (HHS) has been given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production use. HHS delegated program responsibility to CDC.

In addition, an MOU was signed in October 1990 and renewed in November 1992 between ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or "Superfund"). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

Purpose: This subcommittee is charged with providing advice and recommendations to the Director, CDC and the Administrator, 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: This subcommittee will listen to presentations from the Radiological Assessments Corporation, Medical University of South Carolina Cancer Registry, as well as updates on the Savannah River Site Phase II Dose Reconstruction Project findings and implications. Additional agenda items will include: the National Center for Environmental Health (NCEH) activities, the National Institute for Occupational Safety and Health and ATSDR presentations on the progress of current studies, and issues regarding the Committee selection process.

Agenda items are subject to change as priorities dictate.

Contact Persons for More Information: Paul G. Renard or Nadine Dickerson, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, (F-35), Atlanta, Georgia 30341-3724, telephone 770/488-7040, FAX 770/488-7044.

Dated: January 31, 1996.

Carolyn J. Russell,

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

[FR Doc. 96-2591 Filed 2-6-96; 8:45 am]

BILLING CODE 4163-18-M

Food and Drug Administration

[Docket No. 96N-0020]

Animal Drug Export; RALGRO® (Zeranol)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Mallinckrodt Veterinary, Inc., has filed an application requesting approval for export of the animal drug RALGRO® (zeranol) implant for cattle to Canada.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of food animal drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0213.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the Federal Register within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Mallinckrodt Veterinary, Inc., 421 East Hawley St., Mundelein, IL 60060, has filed application number 0082 requesting approval for export of the animal drug RALGRO® (zeranol)

implant to Canada. The product is intended for implanting in the ear of cattle for increased rate of weight gain and improved feed conversion of weaned beef calves, growing beef cattle, feedlot steers, and feedlot heifers, and increased rate of weight gain in suckling beef calves. The application was received and filed in the Center for Veterinary Medicine on December 7, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by February 20, 1996, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.44).

Dated: January 26, 1996.

Robert C. Livingston,
Director, Office of New Animal Drug
Evaluation, Center for Veterinary Medicine.
[FR Doc. 96-2596 Filed 2-6-96; 8:45 am]

BILLING CODE 4160-01-F

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting 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.

MEETING: The following advisory committee meeting is announced:

Dental Products Panel of the Medical Devices Advisory Committee

Date, time, and place. February 27, 28, and 29, 1996, 8 a.m., Bethesda Marriott Hotel, Grand Ballroom, 5151 Pooks Hill Rd., Bethesda, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301-897-9400 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Sociometrics, Inc., 301-608-2151. The availability of appropriate accommodations cannot be assured unless prior written notification is received.

Type of meeting and contact person. Open public hearing, February 27, 1996, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; closed committee deliberations, 5 p.m. to 6 p.m.; open public hearing, February 28, 1996, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 6 p.m.; open public hearing, February 29, 1996, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 6 p.m.; Carolyn A. Tylenda, Center for Devices and Radiological Health (HFZ-420), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8879, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Dental Products Panel, code 12518.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

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 February 20, 1996, 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 February 27, 1996, the committee will discuss and vote on a premarket approval application (PMA) for a bone filling device for periodontal use. On February 28, 1996, the committee will: (1) Discuss and vote on a PMA for a dental laser for hard tissue use, and (2) discuss the reliability and accuracy of digital subtraction radiography and its use in the clinical design of trials evaluating treatment and/or progression of periodontitis. On February 29, 1996, the committee, with representation from the Dental Drug Products Plaque Subcommittee, will discuss public health issues relevant to a new drug application (NDA) 20-231, a triclosan/fluoride dentifrice, sponsored by Colgate-Palmolive, for use in the prevention of caries, plaque, and gingivitis.

Closed committee deliberations. On February 27, 1996, FDA staff will present to the committee trade secret and/or confidential commercial information regarding dental device issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above 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. The dates and times reserved for the separate 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.