

Appendix 2 and 5 U.S.C., 552b(c)(6), it has been determined 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 Gerald E. Calderone, Ph.D., Agency for Health Care Policy and Research, Suite 400, 2101 East Jefferson Street, Rockville, Maryland 20852, Telephone (301) 594-2462.

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

Dated: September 14, 1995.

Clifton R. Gaus,

Administrator.

[FR Doc. 95-23604 Filed 9-22-95; 8:45 am]

BILLING CODE 4160-90-M

Food and Drug Administration

[Docket No. 95N-0297]

Animal Drug Export; Syntex® Plus™ Implant

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Syntex Animal Health has filed an application requesting approval for export of the animal drug Syntex® Plus™ (trenbolone acetate and estradiol benzoate) Implant to Canada.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., 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: Benjamin A. Puyot, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1646.

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 Syntex Animal Health, Division of Syntex Agribusiness, Inc., 3401 Hillview Ave., Palo Alto, CA 94304, has filed application number 6242 requesting approval for export of the animal drug Syntex® Plus™ (trenbolone acetate and estradiol benzoate) Implant to Canada. The drug is an implant consisting of 8 pellets and it contains 200 milligrams (mg) of trenbolone acetate plus 28 mg of estradiol benzoate. The implant is to be used to increase weight gain and improve feed efficiency in feedlot steers and heifers. The application was received and filed in the Center for Veterinary Medicine on August 30, 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 October 5, 1995, 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: September 8, 1995.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 95-23685 Filed 9-22-95; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 95F-0255]

GE Silicones; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that GE Silicones has filed a petition proposing that the food additive regulations be amended to provide for the safe use of vinyl-containing siloxanes as a coating on paper and paperboard in contact with food and to provide for the safe use of 1-ethynyl-1-cyclohexanol as an optional inhibitor for the additive. It is also proposed that the regulations be amended to increase the level of platinum catalyst used in the manufacture of vinyl-containing siloxanes to 200 parts per million (ppm).

DATES: Written comments on the petitioner's environmental assessment by October 25, 1995

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3086.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 5B4475) has been filed by GE Silicones, c/o 700 13th St., NW., Washington, DC 20005. The petition proposes to amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the safe use of vinyl-containing siloxanes as a component of coatings for paper and paperboard in contact with food and to provide for the safe use of 1-ethynyl-1-cyclohexanol as an optional inhibitor for the additive. It is also proposed that the regulations be amended to increase the level of platinum catalyst used in the manufacture of vinyl-containing siloxane to 200 ppm.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4 (b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on

public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before (*insert date 30 days after date of publication in the Federal Register*), submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: September 13, 1995.

Alan M. Rulis,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 95-23596 Filed 9-22-95; 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:

Science Board to the Food and Drug Administration

Date, time, and place. November 6, 1995, 8:30 a.m., DoubleTree Hotel—National Airport, Washington Room, 300 Army Navy Dr., Arlington, VA.

Type of meeting and contact person. Open committee discussion, 8:30 a.m. to 2:30 p.m.; open public hearing, 2:30 p.m. to 3:30 p.m., unless public participation does not last that long; open committee discussion, 3:30 p.m. to 5 p.m.; Susan A. Homire, Office of Science (HF-33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3340, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Science Board to the Food and Drug Administration, code 12603.

General function of the board. The board shall provide advice primarily to the agency's Senior Science Advisor and, as needed, to the Commissioner and other appropriate officials on specific complex and technical issues as well as emerging issues within the scientific community in industry and academia. Additionally, the board will provide advice to the agency on keeping pace with technical and scientific evolutions in the fields of regulatory science; on formulating an appropriate research agenda; and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of agency sponsored intramural and extramural scientific research programs.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the board. Those desiring to make formal presentations must notify the contact person before October 23, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, and the names and addresses of proposed participants. Each presenter will be limited in time and not all requests to speak may be able to be accommodated. All written statements submitted in a timely fashion will be provided to the board.

Open committee discussion. The board will discuss issues related to the safety testing of biomaterials used in

products regulated by FDA. The discussion is designed to give the agency direction for future program development.

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