www.fda.gov. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 20, 1997, the committee will discuss issues relating to a premarket approval application for a surface modified intraocular lens (IOL) in addition to a review of an update of the FDA ''grid'' of historical IOL data. A product development protocol (PDP) based on the draft guidance document for monofocal IOL's will be discussed. On October 21, 1997, the committee will discuss proposed extensions to the draft guidance document for refractive surgical lasers, specifically, clinical criteria for the determination of safety and effectiveness for photorefractive keratectomy (PRK) and laser in-situ keratomileusis (LASIK) for myopia, astigmatism, hyperopia, and other refractive indications. A PDP for excimer lasers for PRK will also be discussed. Single copies of the above-mentioned guidance documents are available to the public by contacting the Division of Small Manufacturers Assistance, 1350 Piccard Dr., Rockville, MD 20851, 1–800–638–2041, or from the Internet: http://www.fda.gov/cdrh/draftgui.html.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 10, 1997. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. on October 20 and 21, 1997. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 10, 1997, 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 requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 16, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–25265 Filed 9-23-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Dental Plaque Subcommittee Meeting of the Nonprescription Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on October 29 and 30, 1997, 8:30 a.m. to 5 p.m.

Location: Holiday Inn, The Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Andrea G. Neal, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12541. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 29, 1997, the subcommittee will continue discussion and/or possibly vote on the safety and effectiveness of: C–31G, xylitol, and zinc citrate, as well as the following combination ingredients: (1) Menthol, thymol, eucalyptol, and methyl salicylate; (2) hydrogen peroxide and povidone iodine; and (3) hydrogen peroxide, sodium citrate, zinc chloride, and sodium lauryl sulfate. The subcommittee will also continue discussion of the criteria for over-the-counter (OTC) antiplaque and antigingivitis combination drug products. On October 30, 1997, the subcommittee will discuss the final formulation testing for OTC antiplaque and antigingivitis drug products, and assignments will be made for the review of foreign marketing data supporting OTC antiplaque and antigingivitis ingredients.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by October 15, 1997. Oral presentations from the public will be scheduled on both days between approximately 9 a.m. and 10 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 15, 1997, 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 requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 15, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–25266 Filed 9-23-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Transmissible Spongiform Encephalopathies Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on October 6 and 7, 1997, 8:30 a.m. to 5:30 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: William Freas or Jane S. Brown, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12388. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 6, 1997, the committee will discuss FDA regulatory controls to address transmission of Creutzfeldt-Jakob Disease (CJD) by human dura mater products. On October 7, 1997, the committee will discuss appropriate FDA actions concerning CJD-implicated ''secondary'' products (i.e., products in which a CJD-implicated plasma derivative was either added as an excipient or used as a reagent in the manufacturing process).

Procedure: On October 6, 1997, from 8:30 a.m. to 5:30 p.m., and October 7,

1997, from 8:30 a.m. to 1:15 p.m., and 1:45 p.m. to 5:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 1, 1997. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:30 a.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 1, 1997, 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 requested to make their presentation.

Closed Committee Deliberations: On October 7, 1997, from 1:15 p.m. to 1:45 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial or financial information (5 U.S.C. 552b(c)(4)). The meeting will be closed to discuss trade secret and/or confidential information concerning the manufacture of the products under discussion.

FDA regrets that it was unable to publish this notice 15 days prior to the October 6 and 7, 1997, Transmissible Spongiform Encephalopathies Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Transmissible Spongiform Encephalopathies Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 16, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–25264 Filed 9-23-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on October 16, 1997, 12:30 p.m. to 3:15 p.m.

Location: Food and Drug Administration, Bldg. 29, conference room 121, 8800 Rockville Pike, Bethesda, MD. This meeting will be held by a telephone conference call. A speaker telephone will be provided in the conference room to allow public participation in the meeting.

Contact Person: Nancy T. Cherry or Denise H. Royster, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12388. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the intramural scientific program of the Laboratory of Pertussis.

Procedure: On October 16, 1997, from 12:30 p.m. to 1:15 p.m., and 2:15 p.m. to 3:15 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 9, 1997. Oral presentations from the public will be scheduled between approximately 2:15 p.m. and 3:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 9, 1997, 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 requested to make their presentation.

Closed Committee Deliberations: On October 16, 1997, from 1:15 p.m. to 2:15 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The meeting will be closed to discuss personal information concerning individuals associated with the research program.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 16, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–25267 Filed 9-23-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability of a Technical/ Agency Draft Recovery Plan for Gesneria Pauciflora for Review and Comment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of document availability.

SUMMARY: The U.S. Fish and Wildlife Service announces availability for public review of a technical/agency draft recovery plan for *Gesneria pauciflora* (no common name). This small shrub, designated as threatened, is endemic to Puerto Rico. Only three populations are known to occur in the western mountains of Puerto Rico. The species is threatened by natural disasters and the modification of its highly restricted habitat. The Service solicits review and comments from the public on this draft plan.

DATES: Comments on the draft recovery plan must be received on or before November 24, 1997 to receive consideration by the Service.

ADDRESSES: Persons wishing to review the draft recovery plan may obtain a copy by contacting Ms. Susan Silander, Boquerón Field Office, P.O. Box 491, Boquerón, Puerto Rico 00622. Comments and materials received are available upon request for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Ms. Susan Silander, Boquerón Field Office, P.O. Box 491, Boquerón, Puerto Rico 00622, Telephone: 809/851–7297.

SUPPLEMENTARY INFORMATION:

Background

Restoring an endangered or threatened species or plant to the point where it is again a secure, self-sustaining member of its ecosystem is a primary goal of the U.S. Fish and Wildlife Service's endangered species program. To help guide the recovery effort, the Service is working to prepare recovery plans for most of the listed species native to the United States.