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 A product development protocol (PDP) based on the draft guidance document for monofocal IOL's will be discussed. On October 21, 1997, the committee will discuss proposed extensions to the draft guidance document for refractive surgical lasers, specifically, clinical criteria for the determination of safety and effectiveness for photorefractive keratectomy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,