phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun*: April 18, 1986. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)) for human tests to begin became effective April 18, 1996, the date that the IDE for a similar, related product, LIPOSORBER® LA–40 System, was approved.

Although the device was subsequently modified, the results of the initial clinical investigations on the earlier model, LIPOSORBER® LA–40 System were included in FDA's analysis of the approved product's safety and effectiveness. The test on the earlier model is, therefore, part of the testing phase.

Additionally, the product is of a type which, under present regulations, would require IDE approval prior to the start of clinical investigations, and normally the initiation of the testing phase for a medical device is determined by reference to the approval phase of the relevant IDE.

2. *The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e)*: October 3, 1991. The applicant claims March 24, 1988, as the date the premarket approval application (PMA) for the LIPOSORBER® LA–40 System (PMA 880019) was initially submitted, which applicant argues should be used in place of the PMA for LIPOSORBER® LA–15 System (PMA 910018). FDA records indicate that PMA 880019 was received by the agnecy on March 25, 1998, but this PMA was never filed, and it was withdrawn by the applicant on April 3, 1996. The applicant claims that PMA 910018 was submitted on March 26, 1991, but FDA records indicate that it was submitted on October 3, 1991.

The applicant argues that the PMA for the LA–40 device should be used as the start of the approval phase for the LA–15 device, because its liposorber technology and adsorbent are identical to those described in the patent for which applicant is requesting extension, U.S. Patent No. 4,637,994. The LA–15 device contains additional components of a plasma separator, the tubing system for plasmaphereses and the apheresis unit.

However, the patent term restoration regulations define the approval phase of medical device in terms of the actual approved product, not an earlier tested product. For example, while the patent term restoration statute does define drug product as the active ingredient of a new drug, ''product'' for ''medical devices'' has been defined as ''[a]ny medical device * * * subject to regulation under the Federal Food, Drug, and Cosmetic Act'' (35 U.S.C. 156(f)). Given that the LA–40 device was withdrawn by applicant from further regulatory consideration, the LA–15 device is the only applicable medical device subject to FDA regulations.

Regarding the definition of regulatory review period for the start of the approval phase of a medical device, the regulations state ''* * * the period beginning on the date the application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act * * *'' 35 U.S.C. 156(g)(3)(B); see also 21 CFR 60.22(c)(2)(i). In this case, the only PMA which submitted, filed, and approved under section 515 of the Federal Food, Drug, and Cosmetic Act was PMA P910018, which was submitted on October 3, 1991, and is, therefore, the appropriate date the approval application was initially submitted for LIPOSORBER® LA–15 System.

3. *The date the application was approved*: February 21, 1996. FDA has verified the applicant's claim that PMA P9910018 was approved on February 21, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,825 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 6, 1998, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 2, 1998, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 31, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–11682 Filed 5–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Dental Plaque Subcommittee of the Nonprescription Drugs 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 of the Nonprescription Drugs Advisory Committee.

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

Date and Time: The meeting will be held on May 27, 28, and 29, 1998, 8:30 a.m. to 5 p.m.

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

Contact Person: Robert L. Sherman or Stephanie A. Mason, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, 301–827–5191, 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 May 27, 1998, the subcommittee will discuss: (1) The safety and effectiveness of the combination of stannous pyrophosphate and zinc citrate; (2) the effectiveness of the combination of hydrogen peroxide, sodium lauryl sulfate, sodium citrate and zinc chloride; (3) the safety and effectiveness of hexetidine, soluble pyrophosphate, nonsaponifiable fraction of corn oil, bromchlorophene and chlorhexidine digluconate; and (4) final formulation testing. On May 28, 1998, the subcommittee will discuss labeling

of over-the-counter antiplaque-antigingivitis drug products. On May 29, 1998, the subcommittee will discuss recommended therapeutic combinations for antiplaque-antigingivitis drug products.

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 May 20, 1998. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 12 m. on May 27, 28, and 29, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 20, 1998, 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: April 24, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–11742 Filed 5–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0191]

Testing for Skin Sensitization to Chemicals in Latex Products; Draft Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled ''Testing for Skin Sensitization to Chemicals in Latex Products.'' This draft guidance is intended to provide alternative claims for medical devices containing natural rubber latex to the ''hypoallergenic'' claim that no longer will be acceptable after September 30, 1998. The draft guidance, which is not in effect at this time, is being issued for comment. This draft guidance was reviewed by the General Hospital and Personal Use Devices Panel in September 1997, and it will be posted on the Internet.

DATES: Written comments concerning this guidance must be received by August 3, 1998.

ADDRESSES: Written comments concerning the draft guidance must be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document. Submit written requests for singles copies of the draft guidance to the Division of Small Manufacturers Assistance (DSMA), Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Chiu S. Lin, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913.

SUPPLEMENTARY INFORMATION:

I. Background

This is the second draft of the guidance entitled ''Testing for Skin Sensitization to Chemicals in Latex Products,'' and it replaces the July 28, 1997, version that was posted on the Internet and distributed by DSMA to manufacturers of medical devices made of natural rubber to consumer groups and other agencies of the Federal Government for comment. This draft guidance was also discussed during the General Hospital and Personal Use Devices Advisory Panel meeting on September 15, 1997. This second draft incorporates comments received from the General Hospital and Personal Use Devices Advisory Panel meeting, consumer groups, and medical device manufacturers. This draft guidance is intended to provide alternative claims for medical devices containing natural rubber latex to replace the ''hypoallergenic'' claim. The ''hypoallergenic'' claim will no longer be acceptable after September 30, 1998, which is the effective date of the final rule on medical devices containing natural-rubber that published in the **Federal Register** of September 30, 1997 (62 FR 51021). This draft guidance also includes test methods for supporting these claims. When this draft guidance becomes final, the manufacturers of latex containing medical devices may use it to address label options and what tests FDA regards as appropriate to support statements that replace the current ''hypoallergenic'' statement.

II. Significance of Guidance

The draft guidance represents the agency's recommended tests to support label claims for reduced chemical sensitivity during use of latex products and label options. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both. The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is being issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive the draft guidance entitled ''Testing for Skin Sensitization to Chemicals in Latex Products'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (944) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). The Center for Devices and Radiological Health (CDRH) maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes ''Testing for Skin Sensitization to Chemicals in Latex Products,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. The draft guidance entitled ''Testing for Skin Sensitization to Chemicals in Latex Products'' will be available at http://www.fda.gov/cdrh/ode/ed—rp.html.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 1–800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press