related to future user fee legislation. Send suggestions or recommendations to the Division of Dockets Management (see **ADDRESSES**).

FDA will place an additional copy of any material it receives on the docket for this document (2005N–0364). Suggestions, recommendations, and materials may be seen at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday (see **ADDRESSES**).

V. Transcripts

Following the meeting, transcripts will be available for review at the Division of Dockets Management (see **ADDRESSES**).

Dated: September 22, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–19864 Filed 9–29–05; 3:11 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0342]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: AFP-L3% Immunological Test Systems; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: AFP-L3% Immunological Test Systems.'' This guidance document describes a means by which AFP-L3% (alpha-fetoprotein L3 subfraction percent) immunological test systems may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify AFP-L3% immunological test systems into class II (special controls). This guidance document is immediately in effect as the special control for AFP-L3% immunological test systems, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Class II Special Controls Guidance Document: AFP-L3% Immunological Test Systems'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Maria Chan, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0493

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying AFP-L3% immunological test systems into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This document announces the guidance document that will serve as the special control for AFP-L3% immunological test systems. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act (21 U.S.C. 360c(a)(1)). FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the agency's current thinking on AFP-L3% immunological test systems. 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 requirements of the applicable statute and regulations.

III. Electronic Access

To receive ''Class II Special Controls Guidance Document: AFP-L3% Immunological Test Systems'' by fax, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1570) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork

Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120), and the quality system regulation (21 CFR part 820, OMB control number 0910–0073). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 9, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 05–19853 Filed 10–3–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0347]

Establishing a Docket for the Biological Products for Treatment of Rare Plasma Protein Disorders Public Workshop; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the opening of a docket to receive information and comments on the June 13 and 14, 2005, public workshop entitled ''Biological Products for Treatment of Rare Plasma Protein Disorders'' (the workshop). We are opening the docket to gather additional information from interested persons on the challenges in the development of products to treat rare plasma protein disorders and on current and future opportunities to facilitate development of such products. Interested persons may also submit comments on the workshop presentations and discussions, which we are also making available.

DATES: Submit written or electronic comments on the workshop, related regulatory and scientific issues, and comments on information submitted to the docket by other interested persons by April 4, 2006.

ADDRESSES: Submit written comments and information regarding the workshop to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852–1448. Submit electronic comments or information to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic and other access to the slide presentations from the workshop.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 6, 2005 (70 FR 24079), we published a notice to announce a public workshop entitled ''Biological Products for Treatment of Rare Plasma Protein Disorders.'' On June 13 and 14, 2005, we, in cosponsorship with the Office of Public Health and Science in the Department of Health and Human Services, held the workshop to facilitate the development of biological products used to treat patients with rare plasma protein disorders and to discuss related scientific and regulatory challenges. The following topics were discussed at the workshop:

- Patients' and physicians' perspective on the need for products to treat rare plasma protein disorders;
- The availability of registries and databases to identify patients for clinical trials;
- Differences between international and FDA regulatory approaches to the licensure of products for treating rare plasma protein diseases;
- Case studies describing the application of current FDA regulatory pathways to product development;
- Issues of product reimbursement; and
- Incentives for product development, such as the availability of small business and research grants, and orphan drug provisions.

The meeting concluded with proposals for advancing product development, and suggestions for future discussions on this topic. At the end of the workshop, we invited written comments to provide an opportunity for additional information and discussion of the issues.

We encourage interested persons to continue to provide information to this docket regarding:

- How to facilitate development of products used to treat rare plasma protein disorders,
- Comments on the workshop, and
- Comments on information submitted to the docket by other interested persons.

Information and comments submitted to the docket will assist us in determining the need for, and feasibility of, establishing new regulatory pathways and incentives for developing products to treat rare plasma protein disorders, among other issues.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the workshop and any additional information on the development of biological products for treatment of rare plasma protein disorders. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of this notice, the slide presentations from the workshop, and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the slide presentations at *http://www.fda.gov/cber/summaries.htm#biother*.

Dated: September 12, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–19852 Filed 10–3–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Migrant Health; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act