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