public workshop entitled ''Development of Plasma Standards'' (the workshop). We are opening the docket to gather additional information from interested parties on the subjects of plasma collection, freezing, and storage, and for interested parties to provide comments on the presentations and discussions that took place during the workshop.

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 parties by July 5, 2004.

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 and transcripts from the workshop.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, 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 August 9, 2004 (69 FR 48250), we published a notice to announce a public workshop entitled ''Development of Plasma Standards.'' On August 31 and September 1, 2004, we held the workshop to address regulatory and scientific issues about currently licensed plasma products and unlicensed recovered plasma that is fractionated into both injectable and non-injectable products. The workshop covered a broad range of topics. A major objective of the workshop was to assist FDA in the development of plasma standards that would address concerns encountered over the years with regard to the preparation, storage, shipment, and use of plasma for both transfusion and the manufacture of plasma derived blood products such as Factor VIII and Immune Globulin Intravenous. Another objective was to gather information on current industry practices that are in place for the manufacture of plasma. At the end of the workshop, we invited written comments from workshop participants to gather additional public information on the subject of plasma freezing and storage.

We have established this docket to encourage interested parties to continue to provide information about suggested plasma standards, comments on the workshop, and comments on information submitted to the docket by other interested parties. We also request that those who have already submitted written comments and information to FDA resubmit the same comments to the docket to ensure their adequate consideration since this information was not previously submitted to the docket. This notice will also be posted at *http://www.fda.gov/cber/minutes/workshop-min.htm*.

Comments submitted to the docket will assist us in determining the need for and feasibility of establishing new standards for currently licensed plasma products, including time to freezing, freezing and storage temperatures, and shipping temperatures, among other issues. We may also consider this information in preparing any future additional standards for recovered plasma.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the workshop. 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 and transcripts 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* and the transcripts of the workshop at *http://www.fda.gov/cber/minutes/workshop-min.htm*.

Dated: December 15, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–28655 Filed 12–30–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2001D–0059 (formerly 01D–0059)]

Guidance for Industry on Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees.'' The guidance describes the agency's current policy on what should be contained in separate marketing applications and what should be combined into one application for purposes of assessing user fees and a definition of ''clinical data'' for user fee purposes.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Beverly Friedman, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, or Rockville, MD 20857, 301–594–2041, FAX: 301–827–5562, or

Carla A. Vincent, Center for Biologics Evaluation and Research (HFM–110), 1401 Rockville Pike, Rockville, MD 20852, 301–827–

3503, FAX: 301–827–2875.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees.'' The guidance document describes FDA's thinking on what will be considered separate marketing applications and what will constitute clinical data for purposes of assessing user fees under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g and 379h).

This guidance was issued in draft on February 22, 2001 (66 FR 11175) with comments due by March 26, 2001. No comments were received. In the meantime, Congress considered reauthorization of the user fee program. As a result, FDA delayed issuance of the guidance. Now that the program has been reauthorized without change to the relevant language, FDA is issuing the guidance. Other than minor editorial changes, only two changes of note have been made to the guidance. We have reevaluated our policy on pharmacy bulk packages and products for prescription compounding and determined that a separate application is no longer needed for these products unless otherwise noted in the guidance document. Therefore, the subsection entitled ''Pharmacy Bulk Packages and Products for Prescription Compounding'' has been removed. In addition, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173) may require a new application to be submitted because of a change to the reference listed drug. Therefore, a new subsection was added to clarify the user fee liability.

The guidance represents the agency's current thinking on this topic. 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 statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance 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 document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: December 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–28654 Filed 12–30–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; comment request; California Health Interview Survey 2005

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute, the National Institutes of Health has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on August 5, 2004, p. 47450 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: California Health Interview Survey 2005. *Type of Information Collection Request:* New. *Need and Use of Information Collection.* The NCI has sponsored two Cancer Control Modules to the California Health Interview Survey (CHIS), and will be sponsoring a third to be admitted in 2005. The CHIS is a telephone survey designed to provide population-based, standardized health-related data to assess California's progress in meeting Healthy People 2010 objectives for the nation and the state. The CHIS sample is designed to provide statistically reliable estimates statewide, for California counties, and for California's ethnically and racially diverse population. Initiated by the UCLA Center for Health Policy Research, the California Department of Health Services, and the California Public Health Institute, the survey is funded by a number of public and private sources. It was first administered in 2001 to 55,428 adults and subsequently in 2003 to 42,043 adults. These adults are a representative sample of California's non-institutionalized population living in households. CHIS 2005, the third bi-annual survey, is planned for administration to 55,000 adult Californians. The cancer control module, which is similar to that administered in CHIS 2001 and CHIS 2003, will allow NCI to examine trends in breast cancer screening and diagnosis, as well as to study other cancer-related topics, such as diet, physical activity and obesity.

Because California is the most populous and the most racially and ethnically diverse state in the nation, the CHIS 2005 sample will yield adequate numbers of respondents in key ethnic and racial groups, including African Americans, Latinos, Asians, and American Indian/Alaska Natives. The Latino group will include large numbers of Mexican-origin, Central Americans, South Americans, and other Latino subgroups; the Asian group will include large numbers of respondents in the Chinese, Filipino, Japanese, Vietnamese, and Korean subgroups. NCI will compare the CHIS and National Health Interview Survey (NHIS) data in order to conduct comparative analyses and better estimate cancer risk factors and screening among racial/ethnic minority populations. The CHIS sample size also permits NCI to create estimates for ethnic subdomains of the population, for which NHIS has insufficient numbers for analysis. *Frequency of Response:* One-time. *Affected Public:* Individuals. *Type of Respondents:* Adults (persons 18 years of age and older). The annual reporting burden is as follows: