Dated: December 23, 2004.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 04–28661 Filed 12–30–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Funding Opportunity Number: CE05–029]

Dissemination Research on Fall Prevention: Development and Testing of an Exercise Program Package To Prevent Older Adult Falls; Notice of Availability of Funds—Amendment

A notice announcing the availability of fiscal year (FY) 2005 funds for cooperative agreements to conduct a research program on translating an exercise intervention that rigorous research has shown is effective in reducing falls among older adults into a program; testing implementation of the program in a community setting; and conducting dissemination research focusing on reach, uptake, feasibility, fidelity of the implementation, and acceptability was published in the **Federal Register** on November 8, 2004, Vol. 69, No. 215, pages 64762–64769. The notice is amended as follows to remove the requirement for submission of Letters of Intent (LOI):

On page 64764, column 3, section III.3. Other, Special Requirements, in the second bullet change the first sentence to read ''In order to plan the application review more effectively and efficiently, CDC requests that you submit a Letter of Intent (LOI) to apply for this program.''

On page 64765, column 3, section IV.3. Submission Dates and Times, remove the one-sentence paragraph under Letter of Intent (LOI): December 8, 2004.

Dated: December 23, 2004.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 04–28660 Filed 12–30–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10112, CMS–R–218]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1.*Type of Information Collection Request:* New collection; *Title of Information Collection:* Phone Surveys of Product/Service for Medicare Payment Validation and Supporting Regulations in 42 CFR 405.502; *Form No.:* CMS–10112 (OMB# 0938–NEW); *Use:* This collection will be used to identify specific Medicare Part B products/services provided to Medicare beneficiaries and the costs associated with the provision of those products/services. The information collected will be used to validate the Medicare payment amounts for those products/services and institute revisions of payment amounts where necessary. The respondents will be the companies that have provided the product/service under review to Medicare beneficiaries.; *Frequency:* On occasion; *Affected Public:* Business or other for-profit; *Number of Respondents:* 2,000; *Total Annual Responses:* 2,000; *Total Annual Hours:* 16,000.

2.*Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* ICRS Contained in 45 CFR Part 162; HIPAA Standards for Electronic Transactions; *Use:* This submission contains information collection requirements in HCFA–0149–F, CMS–0003–P, CMS–0005–P, and CMS–003/005–F. This collection establishes standards for electronic transactions and for code sets to be used in those transactions. The collection standardizes the approximately 400 formats of electronic health care claims used in the United States. The use of these standards significantly reduces the administrative burden associated with paper documents, lowers operating costs, and improves data quality for health care providers and health plans; *Form Number:* CMS–R–218 (OMB# 0938–0866); *Frequency:* On occasion; *Affected Public:* Business or other for-profit; *Number of Respondents:* 3.4 million; *Total Annual Responses:* 3.4 million; *Total Annual Hours:* 1 hour.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/regulations/pra/*, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Christopher Martin, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: December 23, 2004.

John P. Burke, III,

CMS Paperwork Reduction Act Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group.

[FR Doc. 04–28649 Filed 12–30–04; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0539]

Establishing a Docket for the Development of Plasma Standards Public Workshop; Notice

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 August 31 and September 1, 2004,

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–