incorporate this donor deferral recommendation and reissue the revised CJD/vCJD Guidance as a level II guidance document in accordance with § 10.115(g)(4)(i) (21 CFR 10.115(g)(4)(i)).

Since the original publication of the CJD/vCJD Guidance, we have learned of additional information warranting revision to the CJD/vCJD Guidance to address a possible increased risk of vCJD transmission from individuals who have received a transfusion of blood or blood components in France. This revision is based on:

- The likelihood of exposure to the Bovine Spongiform Encephalopathy (BSE) agent in that country and
- The recent documentation of three presumptive cases of transfusion-transmitted vCJD infection in the United Kingdom (U.K.).

Because an unknown but possibly significant number of blood donors might have already been infected in France during peak significant years of the BSE outbreak in Europe, FDA believes that it would be a prudent preventive measure to indefinitely defer all donors (including Source Plasma donors) who received transfusions of blood or blood components in France since 1980.

The Draft Guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The Draft Guidance, when finalized, will represent FDA's current thinking on this topic.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 requirement of the applicable statutes and regulations.

II. Comments

The Draft Guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the Draft Guidance. 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 the brackets in the heading of this document. A copy of the Draft Guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.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Persons with access to the Internet may obtain the Draft Guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: August 1, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–13234 Filed 8–11–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0362]

Guidance for Industry on Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin G (IgG) Antibodies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin G (IgG) Antibodies,'' dated August 2006. The guidance document is intended to assist Source Plasma manufacturers in submitting to FDA the appropriate information when implementing an IgG antibody collection program or when adding a new IgG antibody collection to an existing program. This guidance finalizes the draft guidance entitled ''Guidance for Industry: Recommendations for Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin (IgG) Antibodies,'' dated October 2005, and supersedes the draft reviewers' guide entitled ''Disease Associated Antibody Collection Program,'' dated October 1, 1995.

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

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 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. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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*.

FOR FURTHER INFORMATION CONTACT: Brenda R. Friend, 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

FDA is announcing the availability of a document entitled ''Guidance for Industry: Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin G (IgG) Antibodies'' dated August 2006. The document supersedes the draft reviewers' guide, ''Disease Associated Antibody Collection Program,'' dated October 1, 1995. The document provides guidance to Source Plasma manufacturers in submitting the appropriate information to FDA when implementing an IgG antibody collection program or when adding a new IgG antibody collection to an existing program. The guidance identifies changes in collection programs that must be documented as minor changes in an annual report to FDA under § 601.12(d)(21 CFR 601.12(d)). These collection programs include disease-associated IgG antibodies and other existing IgG antibodies. The guidance also identifies labeling changes to be submitted as a supplement for changes being effected under § 601.12(f)(2)(i)(E). The guidance neither includes recommendations related to implementing Immunoglobulin M antibody collection programs, nor does it include recommendations for donors who do not meet all donor suitability requirements under 21 CFR 640.63.

In the **Federal Register** of October 20, 2005 (70 FR 61135), FDA announced the availability of the draft guidance entitled ''Guidance for Industry: Recommendations for Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin (IgG) Antibodies'' dated October 2005. FDA received one comment on the draft guidance. However, this comment related to the guidance process itself, not to the draft guidance. No changes other than editorial for clarification

have been made to the guidance. The guidance announced in this notice finalizes the draft guidance dated October 2005.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA'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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in § 601.12(d) and (f)(2) have been approved under OMB control number 0910–0338.

III. Comments

Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance. 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 the brackets in the heading of this document. A copy of 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.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: August 1, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–13233 Filed 8–11–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection: Comment Request; National Institute of Diabetes and Digestive and Kidney Diseases Information Clearinghouses Customer Satisfaction Survey

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institutes of Health (NIH), is giving public notice that the agency proposes to request reinstatement of an information collection activity for which approval has expired.

Proposed Collection: Title: NIDDK Information Clearinghouses Customer Satisfaction Survey. *Type of Information Requested:* Reinstatement, with change, of a previously approved collection for which approval has expired. The OMB control number 0925–0480 expired on July 31, 2003. *Need and Use of Information Collection:* NIDDK is conducting a survey to access the efficiency and effectiveness of services provided by NIDDK's three clearinghouses: the National Diabetes Information Clearinghouse (NDIC); the National Digestive Diseases Information Clearinghouse (NDDIC); and the National Kidney and Urologic Diseases Information Clearinghouse (NKUDRIC). The survey responds to Executive Order 12821, ''Setting Customer Service Standards,'' which requires agencies and departments to identify and survey their ''customers to determine the kind and quality of service they want and their level of satisfaction with existing services.'' *Frequency of Response:* On occasion. *Affected Public:* Individuals or households; business and for profit organizations; not-for-profit agencies, *Type of Respondents:* Physicians, healthcare professionals, patients, family and friends of patients.

The annual reporting burden is as follows: estimated number of respondents: 5,112; estimated number of responses per respondent: 1; estimated average burden hours per response: 0.025; and estimated total annual burden hours requested: 128. The annualized costs to respondents are estimated at $6,400. There are no capital costs to report. There are no operating or maintenance costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of the information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection reports and instrument, contact Kathy Kranzfelder, Project Officer, NIDDK Information Clearinghouses, NIH, Building 31, Room 9A06, MSC2560, Behtesda, MD 20892. You may also submit comment and data by electronic mail (e-mail) at *KranzfelderK@mail.nih.gov*.

Dated: July 11, 2006.

Barbara Merchant,

NIDDK Project Clearance Liaison, National Institutes of Health.

[FR Doc. 06–6878 Filed 8–11–06; 8:45am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Pre-Testing of NCI Communication Messages

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Pretesting of NCI Communication Messages. *Type of Information Collection Request:* EXTENSION (OMB# 0925–0046, expires 10/31/06). *Need and Use of Information Collection:* In order to carry out NCI's legislative mandate to educate and disseminate information about cancer prevention, detection, diagnosis, and treatment to a wide variety of audiences