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 The guidance announced in this notice finalizes the draft guidance dated October 2005.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