Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Requests and comments should be identified with the docket number found in brackets in the heading of this 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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Robert H. King, Sr., Center for Drug Evaluation and Research (HFD–003), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 3542,Silver Spring, MD 20993–0002, 301–796–1242;or

Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–20), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–435–5681.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of August 8, 2006 (71 FR 45058), FDA published a notice announcing the availability of a draft guidance entitled ''Q4B Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria; Annex 1: Residue on Ignition/Sulphated Ash General Chapter.'' The notice gave interested persons an opportunity to submit comments by October 10, 2006.

After consideration of the comments received and revisions to the guidance, a final draft guidance entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 1: Residue on Ignition/Sulphated Ash General Chapter'' was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in November 2007.

The guidance provides the specific evaluation outcome from the ICH Q4B process for the Residue on Ignition/Sulphated Ash General Chapter harmonization proposal originating from the three-party PDG. This guidance is in the form of an annex to the core ICH Q4B guidance. When implemented, the annex will provide guidance for industry and regulators on the use of the specific pharmacopeial texts evaluated by the ICH Q4B process. Following receipt of comments on the draft, no substantive changes were made to the annex. The title of the core Q4B guidance was changed to more closely reflect the actual workings and process of the Q4B EWG.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). 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, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written comments on the 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 brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

III. Electronic Access

Persons with access to the Internet may obtain the document at*http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: February 12, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–3187 Filed 2–20–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Process Evaluation of the Global Health Research Initiative Program for New Foreign Investigators (GRIP)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Fogarty International Center (FIC), the National Institutes of Health (NIH) 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 November 30, 2007, 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: Process evaluation of the Global Health Research Initiative Program for New Foreign Investigators (GRIP). *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* This study will assess the outputs of the Global Health Research Initiative Program for New Foreign Investigators (GRIP) to date, assess the program's alignment with new strategic goals of the FIC, and identify potential directions for program enhancement. The primary objectives of the study are to determine if GRIP awards (1) promote productive re-entry of NIH-trained foreign investigators into their home countries, (2) increase the research capacity of the international scientists and institutions, and (3) stimulate research on a wide variety of high priority health-related issues. The findings will provide valuable information concerning: (1) Specific research advances attributable to GRIP support; (2) specific capacity and career enhancing advances that are attributable to GRIP; (3) policy implications for GRIP at the program level based on survey responses, such as successes and challenges of the program's implementation, the GRIP support mechanism, etc. *Frequency of Response:* Once. *Affected Public:* None. *Type of Respondents:* Foreign researchers. The annual reporting burden is as follows: *Estimated Number of Respondents:* 101; *Estimated Number of Responses Per Respondent:* 1; *Average Burden Hours Per Response:* 0.50; and *Estimated Total Annual Burden Hours Requested:* 50.5. The annualized cost to respondents is estimated at: $656.50. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report. Table 1 and Table 2 respectively present data concerning the burden hours and cost burdens for this data collection.

TABLE 1.—ANNUALIZED ESTIMATE OF HOUR BURDEN

Type of respondents	Number of respondents	Frequency of response	Average time for response (hr)	Total hour burden*
GRIP Awardees	101	1	0.50	50.5
Total	101	1	0.50	50.5

Total Burden = N Respondents x Response Frequency x minutes to complete/60.

TABLE 2.—ANNUALIZED COST TO RESPONDENTS

Type of respondents	Number of respondents	Frequency of response	Approx. hourly wage rate	Total respondent cost*
GRIP Awardees	101	1	$13/hr	$656.50
Total	101	1	13/hr	656.50

Total Respondent Cost = N Respondents x Response Frequency x minutes to complete/60 x hourly rate.

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) Evaluate 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) Evaluate 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) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of 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.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget at *OIRA_submission@omb.eop.gov*, or by fax to 202–395–6974. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Linda Kupfer, Fogarty International Center, National Institutes of Health, 16 Center Drive, Bethesda, MD 20892, or call non-toll-free number 301–496–3288, or email your request, including your address to: *kupferl@mail.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: February 12, 2008.

Timothy Tosten,

Executive Officer, FIC, National Institutes of Health.

[FR Doc. E8–3166 Filed 2–20–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing