ANNUAL BURDEN ESTIMATES—Continued

Instrument	Affected public	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
(General Web and Conference versions).	State, Local, or Tribal Governments	66	1	0.014	1
Online Tool/Web Section Survey	Individuals/Households	229	1	0.052	12
	Private Sector	30	1	0.052	2
	State, Local, or Tribal Governments	28	1	0.052	1
Webinar Feedback Survey	Private Sector	597.5	1	0.052	31
	Federal Government	1,049.5	1	0.052	55
General Focus Group Guide	Private Sector	12	1	1.0	12
	State, Local, or Tribal Governments	12	1	1.0	12
User Needs Assessment Focus Group Guide.	Private Sector	12	1	1.0	12
	State, Local, or Tribal Governments	12	1	1.0	12
Customer Services Information Questions.	Individuals/Households	2,730	1	0.014	38
	Private Sector	608.4	1	0.014	9
	State, Local,or Tribal Governments	561.6	1	0.014	8

Total Estimated Annual Burden Hours: 311.

Additional Information:

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment:

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, E-mail: *OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.*

Dated: July 6, 2010.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2010–17293 Filed 7–16–10; 8:45 am]

BILLING CODE 4184–01–M

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 expired on February 28, 2010.

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 February 28, 2010. *Need and Use of Information Collection:* NIDDK is conducting a survey to assess 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 (NKUDIC). 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, health care professionals, patients, family and friends of patients.

The annual reporting burden is as follows: Estimated number of respondents: 7,079; *estimated number of responses per respondent:* 1; *estimated average burden hours per response:* 0.025; and *estimated total annual burden hours requested:* 177. The annualized cost to respondents is estimated at $3,793.00. 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 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, Director, NIDDK Office of Communications and Public Liaison, Building 31, Room 9A06, MSC2560, Bethesda, MD 20852 or e-mail your request, including your address to: *KranzfelderK@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: July 6, 2010.

Lynell Nelson, NIDDK,

Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2010–17581 Filed 7–16–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0343]

International Conference on Harmonisation; Draft Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 14 on Bacterial Endotoxins Test General Chapter; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 14: Bacterial Endotoxins Test General Chapter." The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance provides the results of the ICH Q4B evaluation of the Bacterial Endotoxins Test General Chapter harmonized text from each of the three pharmacopoeias (United States, European, and Japanese) represented by the Pharmacopoeial Discussion Group (PDG). The draft guidance conveys recognition of the three pharmacopoeial methods by the three ICH regulatory regions and provides specific information regarding the recognition. The draft guidance is intended to recognize the interchangeability between the local regional pharmacopoeias, thus avoiding redundant testing in favor of a common testing strategy in each regulatory region. This draft guidance is the 14th annex to the core guidance on the Q4B process entitled "Q4B Evaluation and Recommendation of Pharmaceutical Texts for Use in the ICH Regions" (the core ICH Q4B guidance).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 14, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft 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 draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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. 51, rm. 4150, Silver Spring, MD 20993–0002, 301–796–1242; or Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–0373.

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 June 2010, the ICH Steering Committee agreed that a draft guidance entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 14: Bacterial Endotoxins Test General Chapter" should be made available for public comment. The draft guidance is the product of the Q4B Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Q4B Expert Working Group.

The draft guidance provides the specific evaluation results from the ICH Q4B process for the Bacterial Endotoxins Test General Chapter harmonization proposal originating from the three-party PDG. This draft