

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹—Continued

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
314.80(i)	665	601.5	399,998	16	6,399,968
Total	6,400,368

¹ There are no capital costs or operating costs associated with this collection of information. There are maintenance costs of \$22,000 annually.

These estimates are based on FDA's knowledge of adverse drug experience reporting, including the time needed to prepare the reports, and the number of reports submitted to the Agency.

Dated: June 22, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-15708 Filed 6-26-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0640]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Data To Support Food and Nutrition Product Communications as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Data to Support Food and Nutrition Product Communications as Used by the Food and Drug Administration" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley II, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

SUPPLEMENTARY INFORMATION: On May 27, 2011, the Agency submitted a proposed collection of information entitled "Data to Support Food and Nutrition Product Communications as Used by the Food and Drug Administration" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the

information collection and has assigned OMB control number 0910-0710. The approval expires on June 30, 2014. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: June 18, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-15714 Filed 6-26-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0535]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; "Real Time" Surveys of Consumers' Knowledge, Perceptions and Reported Behavior Concerning Foodborne Illness Outbreaks or Food Recalls

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Real Time" Surveys of Consumers' Knowledge, Perceptions and Reported Behavior Concerning Foodborne Illness Outbreaks or Food Recalls" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley II, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

SUPPLEMENTARY INFORMATION: On June 27, 2011, the Agency submitted a proposed collection of information entitled "Real Time" Surveys of Consumers' Knowledge, Perceptions and Reported Behavior Concerning Foodborne Illness Outbreaks or Food Recalls" to OMB for review and clearance under 44 U.S.C. 3507. An

Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0711. The approval expires on October 31, 2013. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: June 20, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-15696 Filed 6-26-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0249]

Guidance for Industry on Lupus Nephritis Caused by Systemic Lupus Erythematosus—Developing Medical Products for Treatment; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a guidance published in the *Federal Register* of June 22, 2010.

DATES: June 27, 2012.

FOR FURTHER INFORMATION CONTACT: Leila P. Hann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 22, rm. 3143, Silver Spring, MD 20993-0002, 301-796-3367;

or
Philip Desjardins, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, rm. 5437, Silver Spring, MD 20993-0002, 301-796-5678;
or
Stephen 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: In a notice published in the **Federal Register** of June 22, 2010 (75 FR 35492), FDA announced the availability of a guidance entitled “Lupus Nephritis Caused By Systemic Lupus Erythematosus—Developing Medical Products for Treatment.” This guidance is being withdrawn because it does not reflect FDA’s current thinking on the development of medical products for the treatment of lupus nephritis.

Dated: June 22, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-15716 Filed 6-26-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2011-0116]

GFIRST Conference Stakeholder Evaluation

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: 30-Day Notice and request for comments; New Information Collection Request: 1670-NEW.

SUMMARY: The Department of Homeland Security (DHS), National Protection and Programs Directorate (NPPD), Office of Cybersecurity and Communications (CS&C), National Cyber Security Division (NCSD), United States Computer Emergency Readiness Team (US-CERT) will submit the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chapter 35). NPPD is soliciting comments concerning new Information Collection Request—GFIRST Conference Stakeholder Evaluation. DHS previously published this ICR in the **Federal Register** on February 29, 2012, for a 60-day public comment period. DHS received two comments. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until July 27, 2012. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory

Affairs, OMB. Comments should be addressed to OMB Desk Officer, DHS, Office of Civil Rights and Civil Liberties. Comments must be identified by “DHS-2011-0116” and may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>.

- *Email:* oir_submission@omb.eop.gov. Include the docket number in the subject line of the message.

- *Fax:* (202) 395-5806.

Instructions: All submissions received must include the words “Department of Homeland Security” and the docket number for this action. Comments received will be posted without alteration at <http://www.regulations.gov>, including any personal information provided.

OMB is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions 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 through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

FOR FURTHER INFORMATION CONTACT: Corliss McCain, DHS/NPPD/CS&C/NCSD/US-CERT, Corliss.McCain@dhs.gov.

SUPPLEMENTARY INFORMATION: GFIRST is DHS’s premier cyber conference and continually seeks to enhance collaborative efforts among cyber constituencies, partners, and stakeholders. The data provided will assist GFIRST planners in areas of improvement and efficiency. With the survey responses, we can better tailor our events, materials, and activities to improve efforts to protect our Nation’s cybersecurity. As part of the National Strategy for a Secure Cyberspace, US-CERT is required to assist in the fight against the disruption of the operation of critical information systems.

The National Strategy for a Secure Cyberspace requires US-CERT to assist

in the continuous assessment of threats and vulnerabilities to Federal cyber systems. As part of our mission, US-CERT is required to assist and urge state and local governments to consider establishing information technology security programs and participate in information sharing and analysis centers with similar governments. The GFIRST conference provides an annual forum to network with public and private stakeholders, while also acting as a conduit for state and local government information sharing critical to securing our Nation’s cyberspace.

US-CERT received two comments from the 60-day comment window:

- *Public Comment DHS-2011-0116-002*—Summary: The comment referenced an issue with completing the new I-9 Form and instructions.
 - Action by Agency: NPPD will take no action to update the GFIRST Conference Stakeholder Evaluation Forms. There is no reference to the I-9 Form on the GFIRST Conference Stakeholder Evaluation Forms (DHS Form 9050 and DHS Form 9051).
- *Public Comment DHS-2011-0116-003*—Summary: The comment referenced the total burden cost. A suggestion was made to evaluate the accuracy of the estimated burden cost. There was also a question as to whether the benefit of the survey would outweigh the costs.
 - Action by Agency: NPPD will take no action to update the GFIRST Conference Stakeholder Evaluation Forms. The Total Burden Cost is the total annual costs for operating/maintaining costs for the 1,000 (approximate number) respondents.

Analysis

Agency: The Department of Homeland Security, National Protection and Programs Directorate, Office of Cybersecurity and Communications, United States Computer Emergency Readiness Team.

Title: GFIRST Conference Stakeholder Evaluation.

OMB Number: 1670-NEW.

Frequency: Annually.

Affected Public: Conference attendees, comprising the general public.

Number of Respondents: 1,000 respondents.

Estimated Time Per Respondent: 2 minutes.

Total Burden Hours: 16.6 annual burden hours.

Total Burden Cost (capital/startup): \$0.

Total Recordkeeping Burden: \$0.

Total Burden Cost (operating/maintaining): \$675.95.