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),