ACL estimates the burden of this collection of information as follows: *Frequency:* Based on the budget authorization for that Fiscal Year, ACL publishes, on average, 15 to 20 FOAs annually. *Respondents:* States, public agencies, private nonprofit agencies, institutions of higher education, and organizations including tribal organizations. *Estimated Number of Responses:* 350 annually. *Total Estimated Burden Hours:* 16,800.

Dated: August 29, 2013.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2013–21654 Filed 9–5–13; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0523]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Applications for Food and Drug Administration Approval To Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 7, 2013.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0646. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Applications for Food and Drug Administration Approval To Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs—(OMB Control Number 0910–0646)—Extension

In the **Federal Register** of July 28, 2009 (74 FR 37163), FDA published a final rule that required, under § 314.81(b)(2)(ii)(*b*) (21 CFR 314.81(b)(2)(ii)(*b*)), the holder of a new drug application (NDA) to notify the Agency if an authorized generic drug is marketed by clearly including this information in annual reports in an easily accessible place and by sending a copy of the relevant portion of the annual reports to a central contact point. We took this action as part of our implementation of the Food and Drug Administration Amendments Act (Pub. L. 110–85), which requires that FDA publish a list of all authorized generic drugs included in an annual report after January 1, 1999, and that the Agency update the list quarterly. We initially published this list on June 27, 2008, on the Internet and notified relevant Federal Agencies that the list was published, and we will continue to update it.

Based on the number of annual reports the Agency currently receives under § 314.81(b)(2) containing authorized generic drug information, we estimate that we will receive approximately 500 annual reports containing the required information on authorized generic drugs. Based on the number of sponsors that currently submit these annual reports, we estimate that approximately 70 sponsors will submit these 500 annual reports. We estimate that each sponsor will need approximately 30 minutes to include the required information on authorized generic drugs in each annual report.

We also estimate that we will receive authorized generic drug information on first marketed generics in approximately 20 annual reports from approximately 20 sponsors, and that each sponsor will need approximately 1 hour to include the required information in each annual report.

We also estimate that we will receive a copy of that portion of each annual report containing the authorized generic drug information for approximately 500 annual reports from approximately 70 sponsors, and that each sponsor will need approximately 3 minutes to submit a copy of that portion of each annual report containing the authorized generic drug information.

In the **Federal Register** of May 10, 2013 (78 FR 27404), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information is as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR 314.81(b)(2)(ii)(*b*)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of authorized generic drug information in each annual report.	70	7	490	0.50 (30 minutes)	245
Submission of authorized generic drug information on first marketed generics in an annual report.	20	1	20	1	20
Submission of a copy of that portion of each annual report containing authorized generic drug information.	70	7	490	0.05 (3 minutes)	25
Total	.....	.....	.....	.....	290

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: September 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–21681 Filed 9–5–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1181]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Recordkeeping Requirements for Medicated Feed Mill License Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, ''Medicated Feed Mill License Application,'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On May 15, 2013, the Agency submitted a proposed collection of information entitled ''Medicated Feed Mill License Application,'' 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 0910–0337. The approval expires on August 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: September 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–21679 Filed 9–5–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0297]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Prevention of Salmonella Enteritidis in Shell Eggs During Production—Recordkeeping and Registration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, ''Prevention of Salmonella Enteritidis in Shell Eggs During Production—Recordkeeping and Registration,'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On May 20, 2013, the Agency submitted a proposed collection of information entitled ''Prevention of Salmonella Enteritidis in Shell Eggs During Production—Recordkeeping and Registration,'' 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 0910–0660. The approval expires on August 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: September 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–21680 Filed 9–5–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0984]

Draft Guidance for Industry on Specification of the Unique Facility Identifier System for Drug Establishment Registration; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration.'' This draft guidance specifies the UFI system for registration of domestic and foreign drug establishments. The guidance addresses provisions set forth in the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA).

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 November 5, 2013. Submit either electronic or written comments concerning the proposed collection of information by November 5, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002; the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448; or Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. 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