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]

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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

Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul Loebach, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2262, Silver Spring, MD 20993–0002, email: *edrls@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration.'' In July 2012, FDASIA was signed into law (Pub. L. 112–144). Sections 701 and 702 of FDASIA direct the Secretary to specify the UFI system for registration of domestic and foreign drug establishments. Once the UFI system is specified, section 510 of the FD&C Act, as amended, requires that each initial and annual drug establishment registration include a UFI (21 U.S.C. 360(b), (c), and (i)). This draft guidance reflects the Agency's current thinking in light of data standards, information technology, and information management resources. As these variables change over time, FDA may revisit this guidance.

This draft guidance is intended solely to address the provisions in sections 701 and 702 of FDASIA. Although section 703 of FDASIA mandates the use of the same UFI system (specified for drug establishment registration) to identify excipient manufacturers in product listings, this guidance does not address implementation of section 703 of FDASIA.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on specification of the UFI system for drug establishment registration. 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. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal Agencies to provide a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this draft guidance, FDA invites comments on the following topics: (1) Whether the proposed information collected is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimated burden of the proposed information collected, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Sections 701 and 702 of FDASIA direct the Secretary to specify the UFI system for registration of domestic and foreign drug establishments. Once the UFI system is specified, section 510 of the FD&C Act, as amended, requires that each initial and annual drug establishment registration include a UFI. The draft guidance specifies the UFI system as follows. At this time, FDA's preferred UFI for a drug establishment is the Data Universal Numbering System D–U–N–S (DUNS) number, assigned and managed by Dun and Bradstreet. The DUNS number is available free of charge to all drug establishments and may be obtained by visiting the Web site for Dun and Bradstreet. As explained in the guidance, however, if a company wants to use an alternative UFI for its drug establishment, it may contact FDA via email at *edrls@fda.hhs.gov.*

OMB has previously approved existing information collections associated with the electronic submission of initial and annual registration of domestic and foreign drug establishments, as described in part 207 (21 CFR part 207) and the guidance document ''Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing'' (the 2009 Guidance) (available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072339.pdf*), under OMB control number 0910–0045. The Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85) required that drug establishment registration and drug listing information must be submitted electronically unless a waiver is granted. As part of its recommendations to facilitate electronic submission of drug establishment registration information, as required by statute, the 2009 guidance explained that FDA is adopting the use of extensible markup language (XML) files in a standard structured product labeling (SPL) format for the electronic submission of drug establishment registration and drug listing information. The 2009 guidance also explained that the automated submission process functions most efficiently and effectively when the information is provided in a standardized format with defined code sets and codes. In addition, the 2009 guidance requested, among other things, the electronic submission of a site-specific DUNS number for each entity as part of the registration information submitted electronically. In FDA's experience, all firms currently registered with FDA under section 510 of the FD&C Act and part 207 have submitted their DUNS number as requested in the 2009 guidance.

The draft guidance addressed in this notice, ''Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration,'' when finalized, would modify the currently approved information collections associated with drug establishment registration, consistent with subsequent statutory enactment. In July 2012, Congress enacted FDASIA, sections 701 and 702 of which direct the Secretary to specify the UFI system for registration of domestic and foreign drug establishments. Once the UFI system is specified, section 510 of the FD&C Act, as amended, requires that each initial and annual drug establishment registration include a UFI. Because drug firms generally possess, and for those already registered, have previously provided, a DUNS number for each facility, FDA expects that consistent with the proposed UFI system, they will submit DUNS numbers as the UFIs for drug establishments. Although the change in statutory authority described in this document will alter the legal basis for submission of the DUNS number, it is not expected to have any other impact on the previously approved collection of information.

FDA expects that the DUNS number will continue to be submitted by the same respondents, with the same frequency, as part of the same electronic registration submission previously approved under the PRA, and the Agency will continue to use the information for the same purposes, in furtherance of its mission to protect the public health.

While FDA anticipates that firms will submit DUNS as UFI, the draft guidance also instructs firms who want to submit an alternative identifier to contact FDA. FDA estimates that no more than one respondent per year will invoke this option. FDA estimates that it would require on average 1 hour for a company to contact FDA and identify its proposed alternative UFI. If FDA determines that the alternative is one the Agency's systems can accommodate, and that satisfies the statutory goal of uniquely identifying the firm's facilities, FDA anticipates that the firm would include that alternative UFI in place of the DUNS, with no net change in the burden of a registration submission. We invite comment on these estimates.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, or http://www.regulations.gov.*

Dated: August 29, 2013.

Leslie Kux,

Commissioner for Policy.

[FR Doc. 2013–21630 Filed 9–5–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Food and Drug Administration/American Academy of Ophthalmology Workshop on Developing Novel Endpoints for Premium Intraocular Lenses; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''FDA/American Academy of Ophthalmology (AAO) Workshop on Developing Novel Endpoints for Premium Intraocular Lenses.'' The main topic of this workshop is the current challenges in the assessment of innovative intraocular lens (IOL) designs with a focus on endpoint methodologies used in evaluating IOL safety and effectiveness. Experts in subjects ranging from patient reported outcomes to objective measures of accommodation will give talks on the latest developments in the field. Participants will then engage in indepth discussions of the pros and cons of various methods used to assess premium IOLs and work to devise a plan to further promote innovation in this device area. The primary goal of the workshop is to improve the regulatory science for evaluating premium IOLs, which in turn may enhance the efficiency with which safe and effective premium IOLs get to the market.

Date and Time: The public workshop will be held on October 11, 2013, from 8:30 a.m. to 5:30 p.m. Materials may be picked up starting at 7:30 a.m.

Location: The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact: Michelle Tarver, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2504, Silver Spring, MD 20993, 301–796–5620, FAX: 301–847–8126, email: *michelle.tarver@fda.hhs.gov.*

Registration: AAO will charge a registration fee to cover its share of the expenses associated with the workshop. The registration fee is $250 for Academy members and $400 for non-members. Registration is available on a first-come, first-served basis. Persons interested in attending this public workshop must register online. The deadline for online registration is October 10, 2013, at 5 p.m. EDT. There will be no onsite registration on the day of the public workshop. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization.

To register for the public workshop, please visit the AAO Web site (www.aao.org/IOLworkshop). Those interested in attending but unable to access the electronic registration site should fax the PDF form on the AAO Web site (*http://www.aao.org/meetings/upload/FDA_iol_workshop_reg.pdf*) to 415–561–8575. Those without Internet access should contact AAO Customer Service to register at 451–561–8540 or 866–561–8558 (toll free). Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. If there are any questions with registration, please contact the AAO administrative offices at 415–561–8540. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Food and beverages will be available for purchase by participants during the workshop breaks.

If you need special accommodations due to a disability, please contact Ms. Susan Monahan at *susan.monahan@fda.hhs.gov* or 301–796–5661 no later than September 30, 2013.

For more information on the workshop, please see the FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.)

Streaming Webcast of the Public Workshop: The morning session but not the afternoon session of this public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by 5 p.m. EDT, September 27, 2013. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection