DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0984]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Specification of the Unique Facility Identifier System for Drug Establishment Registration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 or email written comments on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

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 0910-0045. 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, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, 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.

Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution (OMB Control Number 0910-0045)

In the Federal Register of September 6, 2013 (78 FR 54899), FDA announced the availability of a draft guidance for industry entitled "Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration." Sections 701 and 702 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144) 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 Federal, Food, Drug, and Cosmetic Act (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 This draft guidance specifies the UFI system as follows.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 files in a standard structured product labeling 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 guidance modifies 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 guidance also suggests that firms who want to submit an alternative identifier 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.

In the Federal Register of September 6, 2013 (78 FR 54899), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received three comments that did not pertain to the information collection. Upon review of these comments FDA does not plan to revise the information collection.

Dated: June 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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