Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution
(Guidance for Industry on Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration)

0910-0045

SUPPORTING STATEMENT

Terms of Clearance – None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

In the Federal Register of September 6, 2013 (78 FR 54899), FDA announced the availability of a draft guidance for industry entitled "Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration."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 Food and Drug Administration Safety and Innovation Act (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 Federal, Food, Drug, and Cosmetic Act (the FD&C Act), as amended, requires that each initial and annual drug establishment registration include a UFI. The 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 (FDAAA) (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 "Guidance for Industry on Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration" 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.

2. Purpose and Use of the Information Collection

Sections 701 and 702 of FDASIA direct the Secretary to specify a UFI system for registration of domestic and foreign drug establishments, and that each initial and annual drug establishment registration include a UFI. The "Guidance for Industry on Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration" specifies that FDA's preferred UFI for a drug establishment is the DUNS number. The DUNS number is available free of charge to all drug establishments. As explained in the guidance, however, if a company wants to use an alternative UFI for its drug establishment, it may contact FDA.

3. Use of Improved Information Technology and Burden Reduction

As mandated by FDAAA and FDASIA and described in the 2009 guidance document,

all registration and listing information must be submitted electronically unless FDA grants a waiver request.

4. Efforts to Identify Duplication and Use of Similar Information

This information does not duplicate any other collection.

5. Impact on Small Businesses or Other Small Entities

Under the Regulatory Flexibility Act, FDA regularly analyzes regulatory options that would minimize any significant impact on small entities. FDA also assists small businesses in complying with regulatory requirements.

6. Consequences of Collecting the Information Less Frequently

FDA will be unable to comply with the statutory provisions of FDASIA and FDAAA if this information is not submitted as currently required with a drug manufacturer's registration information.

7. Special Circumstances Relating to the Guidelines in 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of September 6, 2013 (78 FR 54899). FDA received three comments not related to the information collection.

9. Explanation of Any Payment or Gift to Respondents

FDA has not provided and has no intention to provide any payment or gift to respondents under these requirements.

10. Assurance of Confidentiality Provided to Respondents

Public disclosure of information submitted under this information collection, and drug establishment registration information generally, is currently governed by section 510(f) of the FD&C Act and 21 CFR § 207.37. Under these provisions, it is FDA's current policy to disclose the UFIs associated with individual establishments.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Estimates of Annualized Hour Burden

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 2009 Guidance under OMB control number 0910-0045. The approved burdens are listed in the table below. The Food and Drug Administration Amendments Act of 2007 (FDAAA) (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. Under FDASIA, the currently approved information collections associated with drug establishment registration has been modified to require the use of a UFI system for drug registration. In the "Guidance for Industry on Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration," FDA has specified the DUNS number as the UFI system for registration of domestic and foreign drug establishments.

OMB Approved Burdens for Drug Registration under Control Number 0910-0045

Table 1.—Estimated Annual Reporting Burden					
Activity	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
New registrations, including new labeler codes requests	39	14.72	574	4.5	2,583
Annual updates of registration information	3,256	2.99	9,735	4.5	43,808
Total					46,391

13. Estimates of Other Total Annual Cost Burden to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

There are no additional Federal government costs as a result of the "Guidance for Industry on Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration."

15. Explanation for Program Changes or Adjustments

There are no changes in burden from the previous burden estimates for this information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish tabulated results of these information collection requirements.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

All forms associated with OMB Control Number 0910-0045 bear the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.