Requirements for Foreign and Domestic Establishment Registration and Listing
for Human Drugs, Including Drugs That Are Regulated Under
a Biologics License Application, and Animal Drugs
RIN 0910-AA49
OMB Control No. 0910-NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports agency rulemaking that amends regulations governing drug establishment registration and drug listing. The rulemaking describes when and how to register and list, what information must be submitted for registration and listing, clarifies the National Drug Code (NDC) system for drugs, and requires that each drug product subject to the listing requirements of this final rule have a unique NDC. The rulemaking codifies the current statutory requirement that registration and listing information be submitted to FDA electronically instead of using paper forms unless a waiver is obtained. Historically, drug establishment registration and drug listing information was submitted using Form FDA 2656 (Registration of Drug Establishment/Labeler Code Assignment), Form FDA 2657 (Drug Product Listing), and Form FDA 2658 (Registered Establishments' Report of Private Label Distributors). Before the enactment of the Food and Drug Administration Amendments Act (FDAAA), section 510(p) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) expressly provided for electronic submission of drug establishment registration information upon a finding that electronic receipt was feasible, and section 510(j) of the FD&C Act specified that drug listing information was to be prepared in the form and manner prescribed by FDA. Section 224 of FDAAA, which amended section 510(p) of the FD&C Act, now requires electronic drug listing in addition to electronic drug establishment registration. In certain cases, as discussed below, if it is unreasonable to expect a person to submit registration and listing information electronically, FDA may grant a waiver from the electronic submission requirement.

In June 2009, FDA made available the electronic registration and listing guidance (74 FR 26248) to provide recommendations on fulfilling the statutory requirement to submit electronically drug establishment registration and drug listing information. The guidance describes the types of information to include for purposes of drug establishment registration and drug listing and how to prepare and submit the information in an electronic format (Structured Product Labeling (SPL) files) that FDA can process, review, and archive. In June 2009, FDA began accepting submissions required under the part 207 regulations into our electronic drug registration and listing system. The format for these electronic submissions employs Extensible Markup Language (XML) and uses the SPL standard to organize the data within the file. This electronic registration and listing enables FDA to employ a number of automated validations to ensure the quality of the data received.

In addition to the information that previously was collected on the FDA Forms, the electronic registration and listing guidance addresses, with respect to part 207, the electronic submission of other statutorily required information as follows:

- The name of each importer that is known to the establishment (the U.S. company or individual in the United States that is an owner, consignee, or recipient of the foreign establishment's drug that is imported into the United States) (section 510(i)(1)(A) of the FD&C Act);

- The name of each person who imports or offers the foreign establishment's drug for import (the name of each agent, broker, or other entity, other than a carrier, that the foreign drug establishment uses to facilitate the import of its drug into the United States) (section 510(i)(1)(A) of the FD&C Act); and

- For a registered foreign drug establishment, the name, address, and telephone number of its U.S. agent (§ 207.40(c)).

The electronic registration and listing guidance also recommends the voluntary submission of the following additional information, when applicable:

- The email address for the U.S. agent, and the telephone number(s) and email address for the importer and person who imports or offers for import their drug;

- A site-specific Data Universal Numbering System (DUNS) number for each entity (in November 2014, we issued the "guidance for industry entitled "Specification of the Unique Facility Identifier System for Drug Establishment Registration" (79 FR 65977, November 6, 2014) and obtained OMB approval to broaden the entity identification number covered in OMB Control Number 0910-0045 (discussed below));

- The NDC product code for the source drug that is repacked or relabeled;

- Distinctive characteristics of certain listed drugs (i.e., the flavor, the color, and image of the actual solid dosage form); and

- Registrants may indicate that they view as confidential an inactive ingredient or the registrant's business relationship with an establishment.

2. Purpose and Use of the Information Collection

The information collection is used in support of FDA's mission to protect the public health through post-marketing surveillance for serious adverse drug reactions, inspection of drug manufacturing and processing facilities, and monitoring of drug products imported into the United States. The information collection is also intended to improve management of drug establishment registration and drug listing requirements and make these processes more efficient and effective for industry and for FDA. Finally, the information collection implements the electronic prescribing provisions of the Medicare Prescription Drug, Improvement, and

Modernization Act of 2013 (MMA) and the availability of current drug labeling information through DailyMed, a computerized repository of drug information maintained by the National Library of Medicine.

3. Use of Improved Information Technology and Burden Reduction

The information collection establishes mandatory electronic reporting, however waivers may be issued in individual cases. Registration of establishments takes place annually during the period beginning on October 1 and ending on December 31. We estimate that most all respondents will submit the information electronically. Finally, FDA has issued guidance for industry entitled, *Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing* (currently approved under OMB Control No. 0910-0045), and sponsors online Webinars to help respondents with drug establishment registration and listing requirements.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

As explained in the Final Regulatory Flexibility Analysis (FRIA), the rulemaking does not impose a significant burden on a substantial number of small entities, and FDA certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

6. Consequences of Collecting the Information Less Frequently

Information collection schedule is consistent with statutory requirements.

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

There are no special circumstances related to the information collection.

8. Comments in Response to the Proposed Rule and Efforts to Consult Outside the Agency

In the Federal Register of August 29, 2006 (71 FR 51276) FDA published a proposed rule entitled, "Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs," including a PRA analysis and invited public comment. While several comments were received, none addressed the four information collection solicited in the proposal. Substantive comments are addressed in the agency's final rule that published August 31, 2016 (81 FR 60170) at Section III and may be found under Docket No. FDA–2005–N–0464 (formerly Docket No. 2005N–0403).

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

Confidentiality of drug listing information is safeguarded by 21 CFR 207.37.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature.

12. Estimates of Annualized Hour Burden and Costs

12a. Annualized Hour Burden Estimates

In the tables below, we estimate burden we believe is being introduced by the rulemaking. Because the rulemaking revises regulations currently supported by approved ICRs, we have organized the tables accordingly. As FDA revises the affected collections, we will discontinue this information collection in support of the rulemaking.

Description of Respondents: Manufacturers, repackers, relabelers, drug product salvagers, and private label distributors as described in the final rule.

I. Burden to be incorporated into OMB Control No. 0910-0045

TABLE 1. Estimated Annual Reporting Burden Under Part 207

Reporting Requirement; 21 CFR Citation	Number of Respondents	No. of Responses Per Respondent	Total Annual Responses	Hours Per Response	Total Hours
Initial establishment registration; §§207.17, 207.21, 207.25	1,400	2	2,800	1	2,800
Annual review and update of registration information (including expedited updates); § 207.29	10,000	1	10,000	.50	5,000
Initial listing (including NDC); 207.33, 207.41, 207.45, 207.49, 207.53, 207.54, 207.55	1,713	7.28	12,470	1.5	18,705
June and December review and update (or certification) of listing; 207.35, 207.57	5,300	20	106,000	.75	79,500
Waiver requests; 207.65	1	1	1	.50	1

Public disclosure exemption requests; 207.81(c)	100	1	100	1	100
TOTAL	18,514		131,371		106,106

TABLE 2. Estimated Annual Recordkeeping Burden Under Part 207

SOP for creating and uploading the SPL file	Number of Recordkeepers	Number of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
One-time preparation of SOP	1,000	1	1,000	40	40,000
SOP maintenance	3,295	1	3,295	1	3,295
Total					43,295

II. Burden to be incorporated into OMB Control No. 0910-0052

TABLE 3. Estimated Annual Reporting Burden Under Part 607

21 CFR Sections	Number of Respondents	Number of Responses Per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Initial Establishment Registration and Product Listing (607.22(a) and 607.25(a) and (b)(3))	68	1	68	1	68
Annual Review and Update of Establishment Registration and Blood Product Listing (607.22(a) and 607.25(a) and (b)(3))	2,615	1	2,615	0.5	1,308
Waiver requests (607.22(b))	25	1	25	1	25
TOTAL	2,708		2,708		1,401

III. Burden to be incorporated into OMB Control No. 0910-0543

TABLE 4. ESTIMATED ANNUAL REPORTING BURDEN UNDER PART 1271

21 CFR Sections	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Initial Establishment Registration and Listing (1271.25)	225	1	225	0.75	168.75
Annual Review and Update of Establishment Registration and Listing (1271.25)	2,700	1	2,700	0.5	1,350
Waiver requests (1271.23)	100	1	100	1	100
Amend Establishment Registration (1271.26)	1,200	1	1,200	0.25	300
Total	4,225		4,225		1,918.75

12b. Annualized Cost Burden Estimates

The FRIA uses an hourly wage of $66.50 from the Bureau of Labor Statistics corresponding to management occupations in pharmaceutical and medicine manufacturing. This base wage is multiplied by a factor of two to adjust for benefits and overhead. The result is an adjusted wage of $133. By multiplying $133 times the total hours in the tables above, FDA estimates an annual cost burden of $20,311,726.75.

13. Estimates of Other Total Annual Cost Burden to Respondents and Recordkeepers

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

14. Annualized Cost to the Federal Government

Registration and listing responsibilities are currently funded out of allocated resources. The burden from the information collection revise and thus will be incorporated into three existing

ICRs wherein the cost of collection is discussed. Therefore we estimate no cost to the Federal government for this collection of information.

15. Explanation for Program Changes or Adjustments

This is a new information collection reflecting burden introduced by rulemaking. Because the rulemaking revises regulations currently supported by three currently approved ICRs: 0910-0045 Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution; 0910-0052, Blood Establishment Registration and Product Listing; and 0910-0543, Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). FDA will revise these collections accordingly and upon doing so will discontinue this collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Information collected under this rulemaking will not be tabulated or published.

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

Display of OMB Expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.