II. References

The following references are on display with the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at *https://www.regulations.gov* as these references are copyright protected.

1. Peiser, M., T. Traulau, J. Heidler, et al., ''Allergic Contact Dermatitis: Epidemiology, Molecular Mechanisms, In Vitro Methods and Regulatory Aspects. Current Knowledge Assembled at an International Workshop at BfR, Germany.'' *Cellular and Molecular Life Sciences,* 69:763–781, 2012.

2. Westat, Inc. ''An Investigation of Consumers' Perceptions of Adverse Reactions to Cosmetic Products.'' Final report submitted to U.S. Department of Health, Education, and Welfare, Food and Drug Administration. June 1975.

Dated: November 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24441 Filed 11–7–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0742]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution

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 written comments on the collection of information by December 10, 2018.

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: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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—21 CFR Part 207; OMB Control Number 0910–0045—Extension

This information collection supports FDA's drug establishment registration and listing regulations and associated guidance intended to assist respondents in this regard. Requirements for drug establishment registration and drug listing are set forth in section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360), and section 351 of the Public Health Service Act (42 U.S.C. 262). Section 224 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85) amended section 510(p) of the FD&C Act to require electronic drug establishment registration and drug listing. Regulations implementing these provisions are established under part 207 (21 CFR part 207). Except as provided in § 207.65, all information submitted must be transmitted to FDA in electronic format by using our electronic drug registration and listing system, in a form that we can process, review, and archive. Establishment registration information helps FDA identify who is manufacturing, repacking, relabeling, and salvaging drugs and where those operations are performed. Drug listing information gives FDA a current inventory of drugs manufactured, repacked, relabeled, or salvaged for commercial distribution. Both types of information facilitate implementation and enforcement of the FD&C Act and are used for many important public health purposes.

I. Registration Under Part 207

Unless otherwise exempt under section 510(g) of the FD&C Act or § 207.13, all manufacturers, repackers, relabelers, and salvagers must register each domestic establishment that manufactures, repacks, relabels, or salvages a drug, or an animal feed bearing or containing a new animal drug, and each foreign establishment that manufactures, repacks, relabels, or salvages a drug, or an animal feed bearing or containing a new animal drug, that is imported or offered for import into the United States. When operations are conducted at more than one establishment and common ownership and control among all the establishments exists, the parent, subsidiary, or affiliate company may submit registration information for all establishments.

Private label distributors who do not also manufacture, repack, relabel, or salvage drugs are not required to register under part 207. FDA will accept registration or listing information submitted by a private label distributor only if it is acting as an authorized agent for and submitting information that pertains to an establishment that manufactures, repacks, relabels, or salvages drugs.

Under § 207.21, domestic manufacturers, domestic repackers, domestic relabelers, and domestic drug product salvagers must complete initial registration of each establishment no later than 5 calendar days after beginning to manufacture, repack, relabel, or salvage a drug. In addition, foreign manufacturers, foreign repackers, foreign relabelers, and foreign drug product salvagers must register each establishment before the drug is imported or offered for import into the United States.

The information that must be provided to FDA for registration is described in § 207.25 and includes the following: (1) Name of the owner or operator of each establishment; if a partnership, the name of each partner; if a corporation, the name of each corporate officer and director, and the place of incorporation; (2) each establishment's name, physical address, and telephone number(s); (3) all name(s) of the establishment, including names under which the establishment conducts business or names by which the establishment is known; (4) registration number of each establishment, if previously assigned by FDA; (5) a Unique Facility Identifier in accordance with the system specified under section 510 of the FD&C Act; (6) all types of operations performed at each establishment; (7) name, mailing address, telephone number, and email address of the official contact for the establishment, as provided in § 207.69(a); and (8) additionally, with respect to foreign establishments subject to registration, the name, mailing address, telephone number, and email address must be provided for: (a) The U.S. agent, as provided in § 207.69(b); (b) each importer in the United States of drugs manufactured, repacked,

relabeled, or salvaged at the establishment that is known to the establishment; and (c) each person who imports or offers for import such drug to the United States.

Registrants must update their registration information as prescribed under § 207.29.

II. National Drug Code (NDC)

The NDC for a drug is a numeric code. Each finished drug product or unfinished drug subject to the listing requirements of part 207 must have a unique NDC to identify its labeler, product, and package size and type. The format of an NDC is described under § 207.33.

Under § 207.35, registrants must notify us of a change in any of the drug characteristics (except certain identifying information) for an NDC in § 207.33, and assign a new product code and package code for that drug.

III. Listing Under Part 207

Under § 207.41, registrants must list each drug that it manufactures, repacks, relabels, or salvages for commercial distribution. Each domestic registrant must list each such drug regardless of whether the drug enters interstate commerce. When operations are conducted at more than one establishment, and common ownership and control exists among all the establishments, the parent, subsidiary, or affiliate company may submit listing information for any drug manufactured, repacked, relabeled, or salvaged at any such establishment. A drug manufactured, repacked, or relabeled for private label distribution must be listed in accordance with the requirements.

Registrants must provide listing information for each drug in accordance with the listing requirements described in §§ 207.49, 207.53, and 207.54 that correspond to the activity or activities they engage in for that drug. For both animal and human drugs, each registrant must list each drug it manufactures, repacks, or relabels for commercial distribution under the trade name or label of a private label distributor using an NDC that includes such private label distributor's labeler code.

Additionally, in the case of human drugs, each registrant must list each human drug it manufactures, repacks, or relabels using an NDC that includes the registrant's own labeler code, regardless of whether the drug is commercially distributed under the registrant's own label or trade name or under the label or trade name of a private label distributor.

Under § 207.45, for each drug being manufactured, repacked, relabeled, or salvaged for commercial distribution at an establishment at the time of initial registration, drug listing information must be submitted no later than 3 calendar days after the initial registration of the establishment.

Each registrant must provide the listing information described under § 207.49 for each drug it manufactures for commercial distribution. Each registrant must also provide the listing information for each drug it repacks or relabels under § 207.53. A registrant who also relabels or repacks a drug that it salvages must list the drug it relabels or repacks in accordance with § 207.53. Registrants who perform only salvaging with respect to a drug must provide the listing information for that drug as required under § 207.54. Additional information may be requested for a listed drug as described in § 207.55.

Under § 207.57, registrants must update drug listing information submitted previously (either when the change is made or, at a minimum, each June and December). Registrants must also notify FDA if any listed drug has been discontinued from marketing or if any discontinued drug has been reintroduced and provide listing information for any drug not yet listed (at the time of annual establishment registration if not sooner).

In the **Federal Register** of July 18, 2018 (83 FR 33934), 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 information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section(s)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Initial establishment registration; §§ 207.17, 207.21, 207.25.	1,480	2	2,960	1	2,960
Annual review and update of registration information (including expedited updates); § 207.29.	10,000	1	10,000	0.5 (30 minutes)	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	0.75 (45 minutes)	79,500
Waiver requests; § 207.65	1	1	1	0.5 (30 minutes)	1
Public disclosure exemption requests; § 207.81(c)	100	1	100	1	100
Total					106,266

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Standard Operating Procedure (SOP) for creating and uploading the Structured Product Labeling file	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Preparation of SOP	1,000	1	1,000	40	40,000

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

Based on FDA data, we estimate that 1,480 respondents will submit 2,960 new establishment registrations annually. Based on the number of registered establishments in our database, we estimate 10,000 registrants will provide 10,000 annual reviews and updates of registration information (including expedited updates) or reviews and certifications that no changes have occurred. The estimates include the registration of establishments for both domestic and foreign manufacturers, repackers, relabelers, and drug product salvagers, and registration information submitted by anyone acting as an authorized agent for an establishment that manufactures, repacks, relabels, or salvages drugs. The estimates include an additional 80 positron emission tomography (PET) drug producers who are not exempt from registration and approximately 30 manufacturers of plasma derivatives.

We estimate that it will take 1 hour for registrants to submit initial registration information electronically for each new establishment. We also estimate that it will take approximately 30 minutes for each annual review and update of registration information (including any expedited updates) or each review and certification that no changes have occurred. The burden hour estimates above are based on our familiarity with the amount of time it takes registrants to input registration information electronically since June 2009. The estimates are an average of the time it would take to register a domestic or foreign establishment and an average of the time it would take to review registration information and update several registration items in the database or review registration information and only certify that no changes have occurred.

Based on the number of drugs listed annually since June 2009, we estimate that approximately 1,713 registrants will report 12,469 new listings annually (including the information submitted to obtain a labeler code and to reserve an NDC for future use).

Based on the number of drugs in our listing database and the current number of changes to listing information submitted, we estimate 5,300 registrants will each report 20 reviews and updates (including the information submitted to revise an NDC) for a total of 106,000 annually.

The estimates for the number of drug listings include both domestic and foreign listings, listings submitted by registrants for products sold under their own names as well as products intended for private label distribution, and information submitted related to an NDC and to obtain a labeler code. The estimate for the number of drugs subject to the listing requirements includes PET drugs and approximately 30 plasma derivatives. The estimates for the number of June and December reviews and updates of listing information include the number of changes to drug characteristics pertaining to the drug product code to obtain a new NDC and the reports of the withdrawal of an approved drug from sale under § 314.81(b)(3)(iii) (21 CFR 314.81(b)(3)(iii)).

Based on our familiarity with the time required to input listing information electronically since June 2009, we estimate that it will take registrants 1 hour and 30 minutes to submit information electronically for each drug they list for the first time (for both foreign and domestic registrant listings). These estimates are an average of the time it will take manufacturers, repackers, relabelers, and drug product salvagers, with drug product salvagers taking considerably less time than manufacturers. The estimates include the time for submitting the content of labeling and other labeling in electronic format. (For drugs subject to an approved marketing application, the electronic submission of the content of labeling under § 314.50(*l*)(1)(i) is approved under OMB control number 0910–0001.) We also estimate that it will take 45 minutes for each June and December review and update. These estimates represent the average amount of time to review and update listing information or to review and certify that no changes have occurred. The estimates include the time for submitting any labeling for each drug, changes to the drug's characteristics submitted for a new NDC, and reports of the withdrawal of an approved drug from sale under § 314.81(b)(3)(iii).

In 2009, to help respondents transition to the current electronic reporting requirements, FDA issued the guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing.'' The document provides guidance to industry on 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. The burden attributed to the guidance includes the preparation of an SOP for creating and uploading the SPL file. Although most firms will already have prepared an SOP for the electronic submission of drug establishment registration and drug listing information, each year additional firms will need to create an SOP. As reflected in table 2, FDA estimates that approximately 1,000 firms will expend 40 hours to prepare, review, and approve an SOP, for a total of 40,000 hours annually.

Cumulatively, the information collection reflects a decrease of 3,295 in both annual responses and burden hours. This adjustment results from eliminating burden previously attributable to guidance recommendations for creating drug establishment registration and drug listing files for electronic submission. Because electronic registration and listing is now mandatory, we believe respondents have since developed and implemented SOPs consistent with meeting the technical format specifications set forth in the regulations and we no longer attribute burden to this activity.

Dated: November 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24440 Filed 11–7–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0253]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarketing Adverse Drug and Biological Product Experience Reporting and Recordkeeping

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 written comments on the collection of information by December 10, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of