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 or we) 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: Submit written comments (including recommendations) 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 submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review--Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0045. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, 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--Revision

This information collection supports implementation of drug establishment registration and listing requirements governed by FDA. These requirements 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 (PHS) Act (42 U.S.C. 262) and provide for electronic submission of information. Agency regulations implementing these provisions are found in part 207 (21 CFR part 207) and set forth the scope, applicability, and content of information to be included in submissions. Except as provided in § 207.65 (21 CFR 207.65), all information submitted under part 207 must be transmitted to FDA in an electronic format by using our electronic drug registration and listing system, in a form that we can process, review, and archive. For more information pertaining to drug establishment registration and listing, we invite you to visit our website at: https://www.fda.gov/drugs/drug-approvals-and-databases/drug-establishments-current-registration-site.

We have revised the information collection to include the collection of certain information required by the Coronavirus Aid, Relief, and Economic Security (CARES) Act (Pub. L. 116-136). Section 3112(e) of the CARES Act amended section 510(j) of the FD&C Act to require that registrants under section 510 of the FD&C Act must annually report the amount of each drug listed that was manufactured, prepared, propagated, compounded, or processed by such person for commercial distribution. Section 510(j) of the FD&C Act, as amended by section 3112(e) of the CARES Act, also authorizes FDA to require that registrants report this information electronically and to require that registrants report this information at the time a public health emergency is declared.

To assist respondents to the information collection with the current electronic reporting requirements, we issued the guidance document entitled “Providing Regulatory Submissions in

Electronic Format--Drug Establishment Registration and Drug Listing" (June 2009), available from our website at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-drug-establishment-registration-and-drug-listing. Guidance on the submission of the reporting required under section 510(j) of the FD&C Act, as amended by section 3112(e) of the CARES Act, is included on CDER's 2021 guidance agenda available from our website at: https://www.fda.gov/media/134778/download. Agency guidance documents are issued consistent with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

Registration under part 207: Unless otherwise exempt under section 510(g) of the FD&C Act or 21 CFR 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. We will accept registration or listing information submitted by a private label distributor only if the distributor is acting as an authorized agent for and submitting information that pertains to an establishment that manufactures, repacks, relabels, or salvages drugs.

Listing requirements under part 207: Under § 207.41 (21 CFR 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 in § 207.41(c).

In the *Federal Register* of May 10, 2021 (86 FR 24871), we published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment about reporting provisions newly established by section 3112(e) of the CARES Act. Specifically, the comment questioned the utility of information submitted by respondents who have limited knowledge of the marketing of products and also recommended that FDA limit reporting by certain respondents to final retail packages intended to be marketed. We appreciate this comment and note that we will consider the utility of this information as we continue to implement the information collection. No comments were received requesting that FDA revise its estimate of burden associated with the information collection.

On our own initiative, we have downwardly revised the burden estimate found in our 60-day notice regarding reporting elements associated with reporting requirements under section 510(j) of the FD&C Act. Section 510(j) provides for certain exemptions from these reporting requirements. Specifically, section 510(j)(3)(B) of the FD&C Act authorizes the Secretary of Health and Human Services, by order, to exempt from some or all of these reporting requirements certain biological products or categories of biological products regulated under section 351 of the PHS Act if the Secretary determines that such reporting is not necessary to protect the public health. Elsewhere in this issue of the *Federal Register*, FDA is issuing a proposed order that, if finalized, would exempt the following two categories of biological products from such reporting requirements: (1) blood and blood components for transfusion, and (2) cell and gene therapy products, where one lot treats a single patient.

We estimate the burden of the information collection as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Activity; 21 CFR Section/Statutory Citation	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours

Initial establishment registration; §§ 207.17, 207.21, and 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 National Drug Code); §§ 207.33, 207.41, 207.45, 207.49, 207.53, 207.54, and 207.55	1,713	7.28	12,470	1.5	18,705
June and December review and update (or certification) of listing; §§ 207.35 and 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 request; § 207.81(c)	100	1	100	1	100
Manufacturing amount information; CARES Act section 3112	11,020	22.5	247,950	0.25 (15 minutes)	61,988
Total			379,481		168,254

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

Table 2.--Estimated Annual Recordkeeping Burden[1]

Guidance Recommendation	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Preparing Standard Operating Procedures for Creating and Uploading the Structured Product Labeling File	1,000	1	1,000	40	40,000

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

According to internal data, we estimate 1,480 respondents will submit 2,960 new establishment registrations annually. We estimate that 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 drug producers who are not exempt from registration and approximately 30 manufacturers of plasma derivatives.

We assume 1 hour is necessary for registrants to submit initial registration information electronically for each new establishment. We assume 30 minutes is necessary for each annual review and update of registration information (including any expedited updates) or each review and certification that no changes have occurred. Our estimate reflects the average amount of

time and effort necessary to register a domestic or foreign establishment, and the average amount of time and effort necessary to review and update registration information, or review registration information and certify no changes have occurred.

Based on the number of drugs listed annually since June 2009, we estimate 1,713 registrants will report approximately 12,469 new listings annually (including the information submitted to obtain a labeler code and to reserve a National Drug Code (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 positron emission tomography 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 experience with electronically listing submissions since June 2009, we assume it takes 1 hour and 30 minutes to submit information electronically for each drug listed 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 an electronic format (for drugs subject to an approved marketing application, the electronic submission of the content of labeling under 21 CFR 314.50(*l*)(1)(i) is approved under OMB control number 0910-0001).

We assume it takes 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).

We estimate 1,000 firms will expend 40 hours to prepare, review, and approve a standard operating procedure (SOP), for a total of 40,000 hours annually. Although we expect most respondents will have already prepared and implemented an SOP for the electronic submission of drug establishment registration and drug listing information, we retain an estimate for new firms that will do so, as recommended in the guidance.

Finally, we estimate 12,800 respondents are now subject to the reporting provisions introduced by the CARES Act under section 3112(e), and assume it will take 15 minutes to prepare and submit the requisite information, as shown in our 60-day notice. However, we have reduced this figure by 1,780 to 11,020 to reflect proposed reporting exemptions pertaining to: (1) blood and blood components for transfusion and (2) cell and gene therapy products, where one lot treats a single patient. Consistent with section 510(j)(3)(B) of the FD&C Act, we have proposed to exempt these biological product categories from the reporting requirements in section 510(j)(3)(A) of the FD&C Act. If our proposed order is not finalized, we will adjust our estimate accordingly upon reevaluation of the information collection.

Overall, the information collection reflects an increase which we attribute to the new reporting required by section 510(j) of the FD&C Act, as amended by the CARES Act. We have otherwise retained the currently approved burden estimates for the provisions in part 207.

Dated: October 21, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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