620 and the average burden hours per response increased from 0.17 to 0.33.

• Key Personnel Minimum Qualifications Checklist and Attestation (Form A–14)

○ Revise the introductory text to the form to remove repetition and improve readability.

○ Revise Section D: Candidate Minimum Qualifications to:

■ Reorganize how the minimum qualifications for each position are displayed to make it easier for the respondent to understand the requirements.

■ Change the ''Candidate does not meet minimum qualification'' checkbox into a question that asks ''Does the candidate meet the minimum qualification?'' with yes/no options so that the respondent may more clearly communicate whether the candidate meets minimum qualifications.

■ Update the qualifications for each position and add two new positions (Background Check Specialist and Lead Medical Coordinator) to reflect revisions that are under consideration for ORR's residential services cooperative agreement.

○ Revise the burden estimate to account for an increase in the number of care provider facilities, a decrease in the number of forms submitted, and more accurately reflect how long it takes to complete the form. The annual number of respondents increased from 235 to 300, the annual number of responses per respondent decreased from nine to six, and the average burden hours per response increased from 0.17 to 0.42.

• ORR Waiver Request (Form A–15)

○ Add a burden statement at the top of the form.

○ Break the form into several sections to make it more digestible for respondents.

○ Rephrase several field labels for clarity and succinctness.

○ Add a field for the respondent to specify whether they are a care provider facility or a home study or post-release service provider.

○ Change the ''Type of Facility/Provider'' field label to ''Level of Care'' and update the related checkbox options to better reflect care provider facility levels of care.

○ Add a place where respondents can upload a supervision or training plan when applicable for their request.

○ Revise the burden estimate to account for an increase in the number of care provider facilities. The annual number of respondents increased from 235 to 300.

Revisions to Burden Estimates Only for Existing Forms

• Authorization for Release of Records (Form A–5)

○ Revise the burden estimate to account for an increase in the number records requests submitted and more accurately reflect how long it takes to complete the form. The annual number of respondents increased from 4,000 to 9,620 and the average burden hours per response increased from 0.25 to 0.5.

Respondents: ORR grantee and contractor staff; advocacy groups, faith-based organizations, researchers, and government officials; attorneys, legal service providers, child advocates, and government agencies; and other stakeholders.

Annual Burden Estimates:

Form	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual total burden hours
Care Provider Facility Tour Request (Form A–1A)	620	1	0.33	205
Notice to Unaccompanied Children for Flores Visits (Forms A–4 and A–4s)	20	1	0.25	5
Authorization for Release of Records (Form A–5)	9,620	1	0.50	4,810
Key Personnel Minimum Qualifications Checklist and Attestation (Form A–14)	300	6	0.42	756
ORR Waiver Request (Form A–15)	300	2	0.33	198
Estimated Annual Burden Hours Total:				5,974

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 6 U.S.C. 279; 8 U.S.C. 1232; 45 CFR 410; Flores v. Reno Settlement Agreement, No. CV85–4544–RJK (C.D. Cal. 1996)

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–30384 Filed 12–19–24; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3902]

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 and Related Collections of Information

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: Submit written comments (including recommendations) on the collection of information by January 21, 2025.

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 and Related Collections of Information

OMB Control Number 0910–0045—Revision

This information collection supports implementation of requirements related to drug establishment registration and listing governed by section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360), including registrant reporting under section 510(j)(3) of the FD&C Act with respect to listed drugs. The information collection also supports implementation of section 510(j)(3)(B) of the FD&C Act, which authorizes the Secretary of Health and Human Services (the Secretary), by order, to exempt from some or all of the section 510(j)(3) reporting requirements certain biological products or categories of biological products regulated under section 351 of the Public Health Service (PHS) Act if the Secretary determines that such reporting is not necessary to protect the public health. Agency regulations implementing drug establishment and registration provisions are found in part 207 (21 CFR part 207) and include reporting and recordkeeping requirements.

The information collection utilizes guidance documents intended to facilitate reporting and recordkeeping provided for by section 510 of the FD&C Act. All 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. To search available FDA guidance documents, visit the FDA guidance web page at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Because FDA relies on establishment registration and drug listing information for several of its programs, complete, accurate, and up-to-date information is essential to FDA's role in ensuring public health.

Respondents to the collection of information are domestic establishments that manufacture, repack, relabel, or salvage a drug, or an animal feed bearing or containing a new animal drug, and foreign establishments that manufacture, repack, relabel, or salvage a drug, or an animal feed bearing or containing a new animal drug, that is imported or offered for import into the United States. As set forth in the applicable regulations, 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. Establishment registration information helps FDA identify who is manufacturing, repacking, relabeling, and salvaging drugs and where those operations are performed.

Consistent with provisions in § 207.61 (21 CFR 207.61), except as provided in § 207.65 (21 CFR 207.65), all registration and listing information must be transmitted to FDA using FDA's electronic drug registration and listing system in an electronic format that we can process, review, and archive. For more information regarding FDA's Electronic Drug Registration and Listing System (eDRLS), including ''Latest News'' updates, we encourage respondents to visit our website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/electronic-drug-registration-and-listing-system-edrls.* Updated daily, a registration database we also maintain that includes a publication of currently registered establishments is on our website at *https://www.fda.gov/drugs/drug-approvals-and-databases/drug-establishments-current-registration-site.*

Since our last evaluation of the information collection, we have made the following modifications as a result of the Coronavirus Aid, Relief, and Economic Security (CARES) Act (Pub. L. 116–136):

- The scope of activity for the information collection now reflects exemptions from reporting under section 510(j)(3) of the FD&C Act applicable to: (1) blood and blood components for transfusion and (2) cell and gene therapy products, where one lot treats a single patient, as announced in the **Federal Register** of April 13, 2023 (88 FR 22454) (April 2023 final order).
- We have added recommendations from the guidance document entitled ''Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products'' (March 2011) (available at *https://www.fda.gov/media/120092/download*), to the scope of activity included in the collection of information. The guidance document is intended to encourage manufacturers of drug and therapeutic biological products, and any raw materials and components used in those products, to develop a written Emergency Plan (Plan) for maintaining an adequate supply of medically necessary drug products during an emergency that results in high employee absenteeism. The guidance document discusses the elements that should be covered by such a Plan and recommends notifications to FDA's Center for Drug Evaluation and Research (CDER) when activating or deactivating a Plan.
- Section 510(j)(3) of the FD&C Act requires that registrants annually report the amount of each listed drug that they manufacture, prepare, propagate, compound, or process (hereinafter manufacture) for commercial distribution. Section 510(j)(3) of the FD&C Act also authorizes the Secretary to require that the information be reported in an electronic format as determined by the Secretary, and that it be reported at the time a public health emergency is declared. To provide instruction in this regard, we issued the guidance document entitled ''Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act'' (February 2024) (available at *https://www.fda.gov/media/175933/download*). In addition to supporting FDA's response to drug shortages, the guidance document is also intended to facilitate FDA's access to information useful in making decisions regarding the appropriate level of drug facility surveillance.
- As we continue to receive similar information regarding animal drug shortages, we developed and issued the guidance document ''Reporting and Mitigating Animal Drug Shortages'' (Center for Veterinary Medicine GFI #271) (May 2023) (available at *https://www.fda.gov/media/137722/download*). The guidance document is intended to assist respondents in notifying FDA about changes in the production of animal drugs that will, in turn, help the Agency in its efforts to prevent or mitigate shortages of animal drugs.

In the **Federal Register** of September 5, 2024 (89 FR 72403), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. On our own initiative however, we are noting some clarifications and modifications with regard to the information collection and

are therefore recharacterizing this action as a revision rather than an extension.

First, we have removed the information collection element exclusively attributable to the development of standard operating procedures for providing regulatory submissions in an electronic format. The requirement to submit registration and listing information to FDA electronically has been in effect for more than 10 years and is now standard business practice. We assume that most, if not all, respondents to the information collection now implement and utilize electronic data systems compatible with FDA and invite comment on our assumption. FDA uses a structured product labeling (SPL) standard to support submissions through our electronic submission gateway (ESG). On our website at *https://www.fda.gov/industry/fda-data-standards-advisory-board/structured-product-labeling-resources,* we provide informational resources regarding the SPL format standard, including Agency guidance, intended to assist respondents with technological considerations in submitting regulatory information to FDA.

Additionally, CDER continues to develop and refine submission tools that utilize interactive data submission technology for a number of its programs. We believe most, if not all, respondents to the collection of information use these platforms to submit required drug registration and listing information and invite comment on our assumption.

We are also clarifying that submission of the unique facility identifier (UFI) and the accompanying data elements referenced in section 510(b), (c), and (i) of the FD&C Act is included among the scope of activity covered by the information collection. The procedural guidance document entitled ''Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration,'' (November 2014), explains that FDA's currently 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. FDA has been using the DUNS number as a registration number for drug establishments since its implementation of electronic drug registration and listing. The guidance document is available for download from our website at *https://www.fda.gov/media/89926/download.*

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Collection activity; authority to collect information	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Initial establishment registration; §§ 207.17, 207.21, and 207.25.	593	2	1,186	1	1,186
Annual review and update of registration information (including expedited updates); § 207.29.	10,480	3	31,440	0.5 (30 minutes)	15,720
Initial listing (including National Drug Code (NDC)); §§ 207.33, 207.41, 207.45, 207.49, 207.53, 207.54, and 207.55.	3,040	7.28	22,130	1.5	33,197
June and December review and update (or certification) of listing; §§ 207.35 and 207.57.	5,153	20	103,060	0.75 (45 minutes)	77,295
Waiver requests; § 207.65	1	1	1	0.5 (30 minutes)	1
Public disclosure exemption request; § 207.81(c)	30	1	30	1	30
Manufacturing amount information; FD&C Act section 510(j)(3).	8,700	22.5	195,750	1	195,750
Maintenance of, and notifications associated with, plans to ensure availability of medically necessary drug products during emergency; FDA topic-specific guidance, section III.F.	2	1	2	16	32
Reporting and Mitigating Animal Drug Shortages; FDA topic-specific Guidance, section III.	30	2	60	1	60
Total			353,659		323,271

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

Although we denote that table 1 reflects reporting activity, we include the retention and maintenance of corresponding records in our calculation and assessment of burden. While there are 10,480 establishments currently registered with FDA, registration and listing data is subject to frequent fluctuation as a result of the volume of activity.

Based on our experience with the information collection, we estimate 593 respondents will submit 1,186 new establishment registrations annually using the CDER Direct submission platform. We assume an average of 1 hour is necessary for this activity. Similarly, we estimate that 10,480 registrants will provide 31,440 annual reviews and updates of registration information (including expedited updates) or reviews and certifications that no changes have occurred. Our estimate includes 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 estimate also includes an additional 80 positron emission tomography drug producers who are not exempt from registration and approximately 30 manufacturers of plasma derivatives. 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.

Although we have not received a request for waiver as provided for in § 207.65, we retain a placeholder of 1 for such activity and assume 30 minutes is necessary to prepare and make the submission. Relatedly, we reduced our estimate of requests for exemption from public disclosure the information submitted in accordance with § 207.81 from 100 to 30 to reflect a decrease of activity.

The reporting of manufacturing amount information under section 510(j)(3) of the FD&C Act is a new element to the information collection. We assume it takes 1 hour to prepare and submit the necessary reporting information and estimate an average of 22.5 reports will be submitted annually from 8,700 registrants. We exclude 1,780 respondents from the 10,480 registrants, (accounting for both biological product and drug product registrants) to reflect the reporting exemptions implemented under section 510(j)(3)(B). Also, based on informal communications, we have increased the estimate of burden we attribute to preparing and submitting the requisite information from 15 minutes to 1 hour.

Similarly, intending to ensure the availability of medically necessary drug products during emergencies that might result in high absenteeism at production facilities, we account for burden associated with the development of a manufacturing contingency plan as recommended in Agency guidance ''Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products,'' (March 2011), referenced above. We assume that most respondents have already developed a Plan as recommended by the guidance document as a usual and customary business practice, and limit therefore, our current burden estimate to updates, maintenance, and the reporting to FDA of the activation and deactivation of the Plan. We assume two notifications (for purposes of this analysis, we consider an activation and a deactivation notification to equal one notification) will be submitted to CDER annually, and estimate each notification requires an average of 16 hours to prepare and submit.

Finally, animal drug shortage information is also a new element to the information collection. Although not statutorily required, we estimate that 30 respondents will provide 2 notifications annually and that it will take 1 hour to prepare and submit each notification as recommended in the guidance document entitled ''Reporting and Mitigating Animal Drug Shortages,'' referenced above.

Cumulatively, these adjustments and modifications result in a decrease of 67,004 responses and an increase of 87,413 burden hours, annually. We have removed burden we attributed to developing and implementing electronic data systems as we now regard this activity as usual and customary, however we have increased our estimate of the time needed for some of the activities to account for corresponding record maintenance.

Dated: December 16, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–30355 Filed 12–19–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 8W–25A, Rockville, Maryland 20857; (301) 443–6593, or visit our website at: *http://www.hrsa.gov/vaccinecompensation/index.html.*

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.,* provides that those seeking compensation are to file a petition with the United States Court of Federal Claims and to serve a copy of the petition to the Secretary of HHS, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that ''[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**.'' Set forth below is a list of petitions received by HRSA on October 1, 2024, through October 31, 2024. This list provides the name of the petitioner, city, and State of vaccination (if unknown then the city and State of the person or attorney filing the claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master ''shall afford all interested persons an opportunity to submit relevant, written information'' relating to the following:

1. The existence of evidence ''that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,'' and

2. Any allegation in a petition that the petitioner either:

a. ''[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by'' one of the vaccines referred to in the Table, or

b. ''[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine'' referred to in the Table.