UNITED STATES FOOD & DRUG ADMINISTRATION

Registration of Producers of Drugs and
Listing of Drugs in Commercial Distribution

OMB Control No. 0910-0045

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports implementation of drug establishment registration and listing requirements governed by 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). Agency regulations implementing these provisions are found in part 207 (21 CFR part 207) and include reporting and recordkeeping requirements. Respondents to the collection of information are those who manufacture, repack, relabel, or salvage 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. As set forth in the 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. 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 Federal Food, Drug, and Cosmetic Act and are used for many important public health purposes.

Consistent with provisions in 21 CFR § 207.61, except as provided in § 207.65, all registration and listing information must be submitted electronically in a format that we can process, review, and archive. Also consistent with 21 CFR § 207.61 (see 207.61(a)), we may periodically issue guidance on how to provide registration and listing information electronically to assist respondents in this regard. All agency guidance documents are issued in accordance with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time, and we maintain a searchable guidance database on our agency website. Accordingly, 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).

The information collection also includes the submission of data elements as established by the Coronavirus Aid, Relief, and Economic Security (CARES) Act. Specifically, section 3112 of

the CARES Act requires that registrants annually report the amount of each drug listed that was manufactured, prepared, propagated, compounded, or processed for commercial distribution. Section 3112(e) authorizes FDA to require this information be submitted electronically. In addition, section 3112(e) grants FDA authority to require that registrants report this information at the time a public health emergency is declared. Section 3112(e) of the CARES Act also provides for certain exemptions. 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 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. This provision is intended to help FDA identify potential drug product shortages.

Relatedly, the information collection includes activity attendant to the reporting of information associated with potential 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 FDA in its efforts to prevent or mitigate shortages of animal drugs.

We are also clarifying with this submission that the unique facility identifier (UFI) and the accompanying data elements referenced in section 510(b),(c), and (i) of the FD&C Act are 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.

We therefore request OMB approval of information collection associated with section 510 of the FD&C Act pertaining to the registration of producers of drugs; regulations in 21 CFR part 207; applicable agency guidance and associated forms, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

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.

3. Use of Improved Information Technology and Burden Reduction

Consistent with provisions in § 207.61, except as provided in § 207.65, all registration and listing information must be transmitted to FDA electronically in an electronic, in a 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, we also maintain a registration database that includes a publication of currently registered establishments on our website at https://www.fda.gov/drugs/drug-approvals-and-databases/drug-establishments-current-registration-site.

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-resourcese, 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, our Center for Drug Evaluation and Research (CDER) continues to develop a "CDER NextGen" platform that utilizes interactive data submission technology for a number of its programs, including submissions under 21 CFR part 207 applicable to foreign and domestic establishment registration and listing for human drugs, including drugs that are regulated under a biologics license application, animal drugs, and the national drug code (NDC). We believe most, if not all, respondents to the collection of information use this platform to submit required drug registration and listing information and invite comment on our assumption.

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

The information collection poses no undue burden on small entities.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320

No special circumstances are associated with the information collection.

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

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. Although no comments were received, we provided further clarifications in our 30-day notice on December 20, 2024, and discuss these more fully at Q-12 and Q-15 of our SSA.

9. Explanation of Any Payment or Gift to Respondents

No incentives, payments, or gifts are associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974

Upon consulting with our Privacy Office to ensure appropriate identification and handling of any personably identifiable information (PII) collected, we have determined that the information collection is not a Privacy Act System of Records, and the requirements of the Privacy Act, such as to present a notice statement on any forms used to collect PII, do not apply.

The Freedom of Information Act (FOIA)

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1 to 9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The information collection does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

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

Collection Activity; Authority to Collect Information	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Initial establishment registration; 21 CFR §§ 207.17, 207.21, and 207.25	593	2	1,186	1	1,186

Collection Activity; Authority to Collect Information	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Annual review and update of registration information (including expedited updates); 21 CFR § 207.29	10,480	3	31,440	0.5 (30 minutes)	15,720
Initial listing (including National Drug Code (NDC)); 21 CFR §§ 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; 21 CFR §§ 207.35 and 207.57	5,153	20	103,060	0.75 (45 minutes)	77,295
Waiver requests; 21 CFR § 207.65	1	1	1	0.5 (30 minutes)	1
Public disclosure exemption request; 21 CFR § 207.81(c)	30	1	30	1	30
Manufacturing amount information; FD&C Act sec. 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			0		0

[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 CDER Direct or CDER NextGen submission platforms. 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 21 CFR 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 21 CFR § 207.81 from 100 to 30 to reflect a decrease of activity.

Intending to mitigate the potential for drug shortages, 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 one 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*." We assume that most respondents have already developed a Plan as recommended by the 2011 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 two 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*," (May 2023).

12b. Annualized Cost Burden Estimate

We assume the median average wage rate $60.00 per hour for a science technician series using Bureau of Labor Statistics 2024 data. When multiplied by the total number of burden hours, we calculate an annual cost to industry of $19,396,260.

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

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

14. Annualized Cost to the Federal Government

Assuming an allocation of 13 FTEs for maintaining the registration and listing database for human and veterinary drugs and biologics, and factoring a fully-loaded coast of $250,000 per FTE, we estimate annualized government costs of $3,250,000.

15. Explanation for Program Changes or Adjustments

Although no comments were received in response to our 60-day notice, in the *Federal Register* of December 20, 2024 (89 FR 104188), we noted some clarifications and modifications with regard to the information collection and therefore recharacterized the action as a revision rather than an extension. Specifically, we removed burden we had attributed to developing and implementing SOPs for electronic data systems as we now regard this activity as usual and customary. At the same time, we increased our estimate of the time needed for some of the activities to account for corresponding record maintenance. Because the requirement to submit registration and listing information to FDA electronically has been in effect for more than ten 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.

We also clarified 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 are included among the scope of activity covered by the information collection. We explain that the procedural guidance document entitled, "*Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration*," (November 2014), communicates 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, and that FDA has been using the DUNS number as a registration number for drug establishments since its implementation of electronic drug registration and listing. Finally, we remind respondents the guidance document is available for download from our website at https://www.fda.gov/media/89926/download.

Cumulative adjustments and modifications result in a decrease of 67,004 responses and an increase of 87,413 burden hours, annually.

16. Plans for Tabulation and Publication and Project Time Schedule

No tabulation or publication is planned for the information collection.

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

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.