UNITED STATES FOOD & DRUG ADMINISTRATION

National Standards for the Licensure of
Wholesale Drug Distributors and Third-Party Logistics Providers

OMB Control No. 0910-0251; Reinstatement With Change

RIN 0910-AH11

SUPPORTING STATEMENT

Part A: Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports agency rulemaking entitled "*National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers*." The Food and Drug Administration (FDA) is issuing this proposed rule to establish national standards for the licensing of wholesale distributors (WDDs) and third-party logistics providers (3PLs). In passing the Drug Supply Chain Security Act (DSCSA) (Title II of Pub. L. 113-54), Congress recognized the need for national standards for the storage, handling, and transport of certain prescription drugs and directed FDA to establish such standards by regulation. These national standards are necessary to help diminish opportunities for dangerous and criminal conduct affecting the supply of these prescription drugs in the United States, and this information collection request (ICR) is necessary for the States or FDA to assess the ability of 3PLs or wholesale distributors to properly maintain drug quality and security while these drug products are under their possession or control. We are therefore revising agency regulations found in 21 CFR part 205.

The regulations are intended to ensure that the supply chain remains secure and that those prescription drugs subject to the DSCSA that are moving through the supply chain are properly stored, handled, and transported. These measures are intended to help protect American consumers from drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. Specifically, proposed revisions to part 205, subpart A would establish national licensing standards for State and federal licenses issued to 3PLs pursuant to section 584 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-3). Proposed part 205, subpart C would set forth the national licensing standards for State and federal licenses issued to wholesale distributors pursuant to sections 503(e) and 583 of the FD&C Act (21 U.S.C. 353 and 21 U.S.C. 360eee-2)) and replace the existing regulations in proposed part 205 that outlined guidelines for State licensing of wholesale distributors that were developed under the Prescription Drug Marketing Act (Pub. L. 100-293), sections that were replaced by added sections of the DSCSA.

In addition, the FD&C Act, as amended by DSCSA, provides for FDA to approve third parties to evaluate the qualifications of 3PLs for licensure or inspect wholesale distributors facilities on behalf of the FDA. These organizations are referred to as AOs. The application to become an

AO and the information to be submitted is the same for evaluation of the qualifications of 3PLs for licensure, inspection of wholesale distributors facilities, or both. Subparts B and D of the proposed regulation outline the qualification for AOs to perform licensure reviews/inspections for 3PL facilities and inspections of wholesale distributors respectively.

Accordingly, we are requesting to reinstate, with change, information collection provisions associated with requirements in 21 CFR part 205.

2. Purpose and Use of the Information Collection

The proposed regulations outline requirements that 3PLs and wholesale distributors must meet to obtain a license. Such licenses will be used to ship drug products into a state. The licensing authority is the State, from which the 3PLs distribute drug or the State from which wholesale distributors distribute drug. However, if a State does not establish the licensure programs for 3PLs or wholesale distributors consistent with these regulations, FDA will issue the licenses to 3PLs or wholesale distributors in that State.

3. Use of Improved Information Technology and Burden Reduction

As required under by section 582 of the DSCSA, FDA is continuing to institute the standards for the interoperable exchange of transaction information with regard to the tracing of drug products throughout the supply chain. This electronic system will increase efficiency by providing uniformity in the content and format of reports, thereby making the information easier to process. We therefore estimate that 100% of the respondents will use electronic means to fulfill the information collection requirements, however we intend to account for costs associated with implementation under OMB control no. 0910-0806.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Entities

The information collection does not impose undue burden on small entities.

6. Consequences of Collecting the Information Less Frequently

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

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

There are no special circumstances relating to this information collection.

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

We published a rule in the Federal Register of February 4, 2022 (87 FR 6708), including a PRA analysis, inviting public comment on the proposed collection of information. Related references, including the agency's Preliminary Regulatory Impact Analysis (PRIA) may be found in the public docket, FDA-2020-N-1663

9. Explanation of Any Payment or Gift to Respondents

No remuneration is associated with the information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. We have determined that the ICR does not collect personally identifiable information (PII) or information of a personal nature, and therefore the ICR is not subject to the Privacy Act of 1974 and the requirements of the Privacy Act, such as displaying a Privacy Act Statement on a collection form, do not apply.

Only information that is releasable under agency's regulations in 21 CFR part 20 would be released to the public. This information is also safeguarded by Section 301(j) of the FD&C Act and would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)).

11. Justification for Sensitive Questions

There are no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden

Proposed 21 CFR Part 205 Section; IC Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response (in hours)	Total Hours
SUBPART A (3PLs) §§ 205.5 and 205.6; application and process requirements	459	1	459	2	918
§ 205.7; changes to licensure	6	1	6	1	6
§ 205.8; expiry and renewal of licensure	149	1	149	1	149
§ 205.9; denials, suspensions, reinstatements, revocations	35	1	35	1	35
§ 205.11; personnel list	459	1	459	0.5	230
§ 205.15; annual reports	459	1	459	0.25	115

Proposed 21 CFR Part 205 Section; IC Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response (in hours)	Total Hours
SUBPART B (Approved Organizations for 3PLs) § 205.17; licensure review and inspection reports of 3PL facilities	6	15	90	5	450
§ 205.19; applications, denials, revocations, suspensions, renewals, reinstatements for AO status	3	1	3	2	6
SUBPART C (WDD Standards) §§ 205.22 and 205.23; application and process requirements for licensure	1,951	1	1,951	2	3,902
§ 205.24; changes to WDD information	39	1	39	1	39
§ 205.26; confirmation of theft or loss of Rx drug	25	1	25	0.5	13
§§ 205.29 and 205.30; denials, suspensions, reinstatements, revisions, and terminations – requests for hearing	38	1	38	1	38
§ 205.29(a) – WDD annual reports	1,951	1	1,951	1	1,951
SUBPART D (Approved Organizations for WDDs) §§ 205.32 and 205.33; documentation of qualifications and disclosures to FDA	6	31	186	5	930
Total			5,850		8,782

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

Proposed 21 CFR part 205 section; IC Activity	No of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response (in hours)	Total Hours
SUBPART A (3PLs) 205.4; general requirements (retrievable records)	459	1	459	.5	230
205.12; written procedures	459	1	459	21	9,639
205.13; record and document maintenance	459	1	459	1	459
205.14; list of trading partners	459	1	459	2	918
SUBPART B (Approved Organizations for 3PLs) 205.17; licensure review and inspection records	6	15	90	2	180
205.19; written procedures, policies, training records	6	1	6	3	18
SUBPART C (WDD Standards)					
205.21; surety bond	1,951	1	1,951	1	1,951
205.25; personnel records	1,951	1	1,951	1	1,951
205.26; facility records	1,951	1	1,951	1	1,951

Proposed 21 CFR part 205 section; IC Activity	No of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response (in hours)	Total Hours
205.28; inspection records	1,951	1	1,951	1	1,951
SUBPART D (Approved Organizations for WDDs) 205.31; records demonstrating qualification status	6	1	6	1	6
TOTAL			9,742		19,254

Reporting Burden

Among the reporting requirements found in proposed part 205 are content and format provisions pertaining to issuance, changes, expiry, renewal, and annual reports for 3PLs, as well as WDDs, as reflected above in table 1. The proposed regulations also prescribe procedural steps and reporting schedules for submitting information regarding licensure, changes to licensure, reinstatement, and annual reporting, including requisite reporting timeframes. Consistent with our PRIA, we estimate that 459 3PL facilities and 1,951 WDDs will become subject to the reporting requirements described in proposed part 205, where we ascribe specific burden associated with the provisions found in table 3. Because we currently lack specific submission data regarding the proposed reporting requirements, we rely on our experience with similar information collection as the primary basis for our estimates. However, we invite specific comment from potential respondents regarding burden estimates we ascribe to the reporting elements found in the proposed regulations, along with a discussion of the basis for their computation.

Recordkeeping Burden

As set forth in the proposed regulations, 3PLs and WDDs must maintain records documenting procedures, management practice, policies, training, and personnel, among others. Under proposed § 205.4, all records are subject to FDA inspection and must be made available upon request in the format prescribed by the proposed regulations. Additional specific recordkeeping practice elements are also enumerated in the proposed regulations. Consistent with our PRIA, we estimate that 459 3PLs and 1,951 WDDs will become subject to these requirements if the proposed rule is finalized. These provisions are reflected above in table 4, along with an estimated number of annual records and recordkeeping hours we attribute to the corresponding activity. As with the proposed reporting requirements, we currently lack specific data regarding recordkeeping associated with the proposed regulations. We invite specific comment from potential respondents regarding burden estimates we ascribe to the recordkeeping activities, along with a discussion of the basis for their computation.

12b. Annualized Cost Burden Estimate

As discussed in the PRIA, affected entities would incur costs to renew licenses, create and revise written procedures, and maintain surety bonds.. Affected entities will incur costs to maintain bonds. Estimation of those costs is approximately equivalent to the product of the

surety bond's principal and interest rate. We estimate that the total annual cost to maintain surety bonds is $0.08 million ($1,750 per year × 47 firms) for firms with greater than $10 million in annual revenue and $0.11 million ($438 per year × 244 firms) for firms with less than $10 million in annual revenue. Thus, estimated total cost of maintaining surety bonds equals $0.19 million per year.

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

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

14. Annualized Cost to the Federal Government

Consistent with annualized cost projections found in our PRIA, we estimate annual costs in the amount of $1.48 million annually, using upper-bound but discounted figures.

15. Explanation for Program Changes or Adjustments

We are revising regulations in 21 CFR part 205 and are revising the corresponding, inactive information collection 0910-0251 to implement these provisions.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no publications or other schedules.

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 statement.