4164-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2026-N-0684]**

# Agency Information Collection Activities; Proposed Collection; Comment Request; Approved Organizations for Wholesale Drug Distributors and Third-Party Logistics Providers

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on approved organizations involved in the licensure and inspection process for wholesale drug distributors ("wholesale distributors") and third-party logistics providers ("3PLs"), as directed by the Drug Supply Chain Security Act (DSCSA).

**DATES:** Either electronic or written comments on the collection of information must be submitted by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received

by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions*: All submissions received must include the Docket No. for "Approved Organizations for Wholesale Drug Distributors and Third-Party Logistics Providers." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

*Docket*: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-1244, PRAStaff@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Approved Organization for Wholesale Drug Distributors and Third-Party Logistics

PROVIDERS --21 CFR PART 205

OMB Control Number-NEW

*Approved Organizations for Wholesale Distributors*

This information collection supports Food and Drug Administration (FDA) regulations. Section 583(c) of the Federal Food, Drug, and Cosmetics Act FD&C Act states that to satisfy the statutory inspection requirement for wholesale distributors, "the Federal or State licensing authority may conduct the inspection or may accept an inspection by the State in which the facility is located, or by a third-party accreditation or inspection service (AOs) approved by the Secretary or the State licensing such wholesale distributor." Subpart D of the proposed rules defines the scope of work these AOs would be tasked with performing, as well as the standards an AO must meet to become approved by FDA. Additionally, this subpart will explain the circumstances in which an inspection conducted by an AO may be used, what activities the AOs have the authority to conduct and are expected to conduct, and the qualifications that each third-party organization must possess to become approved by FDA.

*Approved Organizations for Third-Party Logistics Providers (3PLs)*

Section 584(d)(2)(A) of the FD&C Act, states that such regulations shall "establish a process by which a third-party accreditation program approved by the Secretary shall, upon request by a third-party logistics provider (3PL), issue a license to each third-party logistics provider that meets the requirements set forth in this section." Accordingly, FDA interprets the language of 584(d)(2)(A) of the FD&C Act to mean that a third-party organization approved by FDA —an approved organization (AO) —will conduct a review of the 3PL's qualifications for licensure and issue a report to FDA regarding whether the 3PL "demonstrates that all applicable requirements for licensure . . . are met," which FDA can rely on when issuing a license per section 584(e) of the FD&C Act.

A licensure review consists of performing a review of all documents submitted to the licensing authority in support of an application for 3PL licensure and conducting an inspection of the facility as directed by the licensing authority. If a review of documentation supports licensure of the 3PL facility, the facility will then be inspected by an AO, as directed by FDA. Upon completion of the inspection, the AO would then provide FDA with a report based on the inspection within 7 days. Using the report submitted by the AO, FDA makes the final determination as to whether a wholesale distributor or a 3PL facility should be issued a license.

It is important that FDA can verify an AO's continued compliance with the approval requirements. Therefore, to keep its approval, FDA is proposing to require that an AO maintain certain records for a period of at least 5 years and these records must be readily available to FDA upon request. On February 4, 2022, FDA published the proposed rule "National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers" (87 FR 6708) to codify regulations in 21 CFR part 205. Proposed §§ 205.17, 205.18, and 205.19 contain the process that FDA will use to approve organizations and the qualifications to become an AO for 3PLs and proposed §§205.31, 205.32, and 205.33 contain the process that FDA will use to approve organizations and qualifications to become an AO for wholesale drug distributors (wholesale distributors).

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

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

| Proposed 21 CFR Part 205 Section; IC Activity | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | 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, | 3 | 1 | 3 | 2 | 6 |

| | | | | | |
|---|---|---|---|---|---|
| revocations, suspensions, renewals, reinstatements for AO status | | | | | |
| SUBPART D (Approved Organizations for WDDs) §§ 205.32 and 205.33; documentation of qualifications and disclosures to FDA | 6 | 31 | 186 | 5 | 930 |
| Total | 15 | | 279 | | 1,386 |

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

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

| Proposed 21 CFR Part 205 Section; IC Activity | No. of Recordkeepers | No. of Records per Recordkeeper | Average Burden per Recordkeeping | Average Burden per Response | Total Hours |
|---|---|---|---|---|---|
| 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 D (Approved Organizations for WDDs) 205.31; records demonstrating qualification status | 6 | 1 | 6 | 1 | 6 |
| Total | 18 | | 102 | | 204 |

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

FDA therefore request OMB approval of Approved Organizations for Wholesale Drug Distributors and Third-Party Logistics Providers pursuant to Sections 584(d)(2)(A) and Section

583(c) of the FD&C Act and codified regulations in 21 CFR Parts 205.17-19, and 205.31-33 as discussed in this notice.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs*.

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