DSCSA Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers

Guidance for Industry

DRAFT GUIDANCE

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For questions regarding this draft document contact CDER Office of Compliance at 301-796-3130 or wdd3plrequirements@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

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Procedural

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Drug Supply Chain Security Act Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance describes FDA's expectations for prescription drug wholesale distributors (wholesale distributors) and third-party logistics providers (3PLs) for the annual reporting to FDA as required under the Drug Supply Chain Security Act of 2013 (DSCSA). Under section 584(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-3(b)), beginning November 27, 2014, 3PLs must report certain information to FDA, including State licensure information for each facility and the name and address for each facility. Under section 503(e)(2)(A) (21 U.S.C. 353(e)(2)(A) (as amended by the DSCSA), beginning January 1, 2015, wholesale distributors also must report certain information to FDA, including State licensure information for each facility, contact information for each facility, and any significant disciplinary actions taken by a State or the Federal Government. This guidance outlines the information that should be submitted to FDA, the timing of the submissions, a preferred format for the submissions, and a preferred method for reporting to FDA.

This guidance does not address all requirements described in the DSCSA for wholesale distributors and 3PLs pursuant to sections 503(e)(2) and 584. The information provided in this guidance is limited to reporting of information by wholesale distributors and 3PLs. Some information outlined in the guidance is required to be reported under section 503(e)(2)(A) and section 584(b) of the FD&C Act, as amended by the DSCSA.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidances means that something is suggested or recommended, but not required.

[1] This guidance has been prepared by the Office of Compliance in the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER).

II. BACKGROUND

On November 27, 2013, the DSCSA (Title II of Public Law 113-54) was signed into law. The DSCSA outlines new requirements to develop and enhance drug distribution security over the next 10 years, including establishing national standards for the licensing of prescription drug wholesale distributors and 3PLs.

Section 204 of the DSCSA amends section 503(e) of the FD&C Act and outlines requirements for reporting by wholesale distributors. Section 503(e)(2)(A) of the FD&C Act (as amended) requires wholesale distributors to report certain information annually, beginning on January 1, 2015. Information to be reported includes State licensure information and contact information for each facility. Wholesale distributors must also report to FDA any significant disciplinary actions taken by the State or Federal Government, such as revocation or suspension of a license. Section 204 of the DSCSA also amends section 503(e)(2)(B) of the FD&C Act and requires FDA to make certain information about wholesale distributors' licensure available to the public on FDA's Web site. Updates to the public information are to be made on a schedule to be determined by FDA.

Section 205 of the DSCSA adds section 584 to the FD&C Act. Section 584 sets forth requirements for licensure and reporting by 3PLs. Under section 584(b) of the FD&C Act (as amended), 3PLs must report annually to FDA, beginning on November 27, 2014 (1 year after the date of enactment of the DSCSA). Third-party logistic providers must report State licensure information, the name and address for each facility, and all trade names under which each facility conducts business.

III. WHO MUST REPORT

A. Prescription Drug Wholesale Distributors

Section 503(e)(2)(A) requires that any person who owns or operates an establishment that engages in wholesale distribution, as defined in section 503(e)(4) of the FD&C Act, as amended by the DSCSA, must report. Companies should refer to the applicable definitions in section 503(e)(4) of the FD&C Act to determine if they conduct wholesale distribution and would be required to report annually to FDA.

B. Third-Party Logistics Providers

Section 584 requires that any facility of a 3PL, as defined in section 581(22) of the FD&C Act, as amended by DSCSA, must report. A 3PL is an entity that provides or coordinates warehousing, or other logistics services of a product[2] in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

[2] Product as defined under section 581(13) of the FD&C Act (21 U.S.C. 360eee), as amended by the DSCSA.

C. Dual Roles

Any person or entity that acts as both a wholesale distributor and a 3PL is subject to the reporting requirements of both section 503(e)(2) and section 584. The person or entity should report according to the relevant requirement for each respective facility. If a company conducts both prescription drug wholesale distribution and 3PL services from the same facility, that facility should be reported separately under each category as a wholesale distributor and a 3PL.

IV. WHAT SHOULD BE REPORTED

A. Discussion

The DSCSA requires FDA to make a database of authorized wholesale distributors available to the public on FDA's Web site. In addition, FDA believes it would be helpful for enforcement of the DSCSA to make information about 3PLs available on FDA's Web site, because having the license status of 3PLs in one publicly available database would be helpful for FDA, trading partners, and other stakeholders, in determining whether 3PLs are authorized or not. Therefore, all of the information reported to the FDA may be made available to the public on the FDA Web site, to the extent allowable by law.

The DSCSA requires contact information to be submitted by wholesale distributors. FDA considers contact information to include the email address and telephone number of the person who will interact with the FDA. In addition to the specific information required by DSCSA to be submitted to the Agency, FDA has identified additional information that will enhance efficiencies and improve accuracy in the management of the licensing and facility information submitted to the Agency. Therefore, FDA is requesting that certain additional information be submitted to FDA on a voluntary basis. This additional information will be useful to FDA in its enforcement of the Act and to stakeholders as they make decisions about their drug product distribution. Furthermore, FDA is requesting the same information from wholesale distributors and 3PLs. The ultimate goal is for the public database to serve as a single repository of licensing and facility information for wholesale drug distributors and 3PLs conducting business in the United States.

B. Initial Report

The initial report from a wholesale distributor is the first report submitted to FDA to meet the reporting requirements under section 503(e)(2)(A) of the FD&C Act, as amended by the DSCSA.

1. For each facility, a wholesale distributor must provide:

a) Identifying information for the facility

- Name of company (FDA recommends providing the company name in the same form as it appears on the license)
- Address of the facility

- Contact information (FDA recommends providing the name of a contact person to interact with FDA, an email address and a telephone number)
- All trade names that the company does business as (i.e., any other names listed as "dba")

b) Licensure information for each State
- State
- State license number (identification number)
- Significant disciplinary actions by any State or Federal agency (FDA recommends describing any significant disciplinary action that occurred in the 12 months preceding the initial report by identifying the type of disciplinary action, the date of final disciplinary action, and the state where the disciplinary action occurred)

2. For each facility, a wholesale distributor should provide:

a) Unique facility identifier
b) Expiration date for the license
c) Documents associated with the disciplinary action, such as a consent decree, final State Board ruling, etc.

The initial report from a 3PL is the first report submitted to FDA to meet the reporting requirements under section 584(b) of the FD&C Act, as amended by the DSCSA.

1. For each facility, a 3PL must provide:

a) Name of company (FDA recommends providing the company name in the same form as it appears on the license)
b) Address of the facility
c) All trade names that the company does business as (i.e., any other names listed as "dba")
d) Licensure information for each State
- State
- State license number (identification number)

2. For each facility, a 3PL should provide:

a) Name of contact person to interact with FDA
b) Email address
c) Telephone number
d) Unique facility identifier
e) Expiration date for the license
f) Significant disciplinary actions by any State or Federal agency that occurred in the 12 months preceding the initial report the past 1 year
- State where disciplinary action occurred

- Date of final action
- Type of disciplinary action
- Description of violation
- Documents associated with the disciplinary action, such as a consent decree, final State Board ruling, etc.

In addition to the name and address of the facility, FDA is requesting that wholesale distributors and 3PLs submit a unique facility identifier for each facility. The site-specific unique facility identifier for a facility is a useful resource for FDA in identifying and confirming certain business information for that entity. The current unique facility identifier preferred by FDA is the D-U-N-S® number. Businesses may obtain D-U-N-S® numbers for no cost directly from Dun & Bradstreet (D&B) (http://www.dnb.com).[3]

State license information must be provided for each State from which the drug products are distributed with State licensure programs and for each State that requires a license to ship product into that State. Third-party logistics providers are considered to be licensed under section 582(a)(7) of the FD&C Act (as amended) (21 U.S.C. 360eee-1) until the effective date of the 3PL licensing regulations and may not have information to report to FDA about specific State licensure unless a State has a 3PL licensing program. However, 3PLs are still required to report to the FDA under the DSCSA.

FDA is also requesting submission of the date(s) that State license(s) expires. This information is essential for determining the licensure status for each wholesale distributor and 3PL facility during the reporting period. Pursuant to section 503(e)(1) of the FD&C Act, as amended by the DSCSA, wholesale distributors will be licensed by the State from which the drug is distributed or by FDA if the State from which the drug is distributed has not established a licensure program. Wholesale distributors will also be licensed by the State into which the drug is distributed if required by that State. Similarly, pursuant to 584(a) of the FD&C Act, as amended by the DSCSA, 3PLs will be licensed by the State from which the drug is distributed or by FDA if the State has not established a licensure program. And 3PLs will be licensed by the State into which the drug is distributed if that State requires the licensure of a person that distributes drugs into the State and the 3PL is not licensed by FDA.

Significant disciplinary actions taken against wholesale distributors must be reported to FDA, as required under section 503(e)(2)(ii) of the FD&C Act, as amended by the DSCSA. In addition, FDA is requesting that 3PLs report significant disciplinary actions to FDA. It is important for FDA and others to know whether a wholesale distributor or 3PL has had a license revoked or suspended or whether a wholesale distributor or 3PL has had any other significant disciplinary actions taken against them that limits the ability of a facility to conduct drug-related business. Reports of significant disciplinary actions should include any action by State or Federal government that limits or prevents a wholesale distributor or 3PL from distributing or facilitating

[3] As explained in FDA's *Guidance for Industry: Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration* (available at http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm367199.pdf), alternative identifiers can also be used by contacting FDA.

the distribution of prescription drugs, including for-cause revocation, termination, or suspension of a license.

C. Subsequent Reports

To meet the continuing reporting requirements under sections 503(e)(2)(A) and 584(b) of the FD&C Act , as amended by DSCSA, any reports from a wholesale distributor or 3PL submitted to FDA after the "Initial Report" for a particular facility is considered a subsequent report for that facility. The required and voluntary components of subsequent reports are the same as those for initial reports.

V. WHEN TO REPORT

The following section describes the time frames for reporting for wholesale distributors and 3PLs to FDA to meet the reporting requirements under DSCSA and provide additional information to FDA voluntarily. If a company chooses to update expired licenses during a time frame outside of the annual reporting time period as defined below, the company should still report during the defined annual reporting period.

A. Initial Report

1. *Wholesale distributors: January 1, 2015–March 31, 2015*
2. *3PLs: November 27, 2014–March 31, 2015*
3. *Wholesale distributor and 3PL facilities that are newly licensed after the dates noted above should initially report within 30 days of obtaining a State or Federal license.*

B. Subsequent Annual Reports

1. *Wholesale distributors: January 1–March 31 annually*
2. *3PLs: January 1–March 31 annually*

C. Significant Disciplinary Action Reports

Reports of significant disciplinary actions should be submitted to FDA when a final action or ruling has been made by a State or Federal licensing authority.

1. *Wholesale distributors: within 30 days of final action*
2. *3PLs: within 30 days of final action*

D. Other Voluntary Reports

A company should notify FDA if a facility goes out of business or decides to voluntarily withdraw a State or Federal license.

1. *Out of business: within 30 days of business closing*
2. *Voluntary withdrawal of a State license: within 30 days*

VI. HOW TO REPORT

A. Format

FDA prefers the use of extensible markup language (XML) files in a standard Structured Product Labeling (SPL)[4] format.

B. Submission

FDA is providing a method to enter and submit the required and voluntary reporting and significant disciplinary actions for wholesale distributors and 3PLs. A link to the Web portal can be accessed from FDA's Web site. Wholesale distributors and 3PLs should access FDA's Web page at http://www.fda.gov/wdd3plreporting and follow the instructions to complete the required and voluntary reporting. Companies using the FDA Web portal for entry and submission will not have to convert the information to XML in the SPL format; appropriate formatting will happen automatically via the web portal. This portal will allow a company to act as a reporter for all of the facilities that they own without having to create a separate account for each facility. If the reporter wants to enter information for multiple facilities, contact information about the reporter, including the reporter's UFI, will be needed. An alternative method for reporting is to submit an XML file in the SPL format via an account through the FDA Electronic Submissions Gateway (ESG). If you want to use an alternative method for your submissions, contact FDA via email at WDD3PLRequirements@fda.hhs.gov for more information.

VII. PUBLIC AVAILABILITY OF INFORMATION

FDA will make the information collected publically available on its Web site. FDA plans to make the wholesale distributor and 3PL significant disciplinary action information publicly available to the extent allowable by law. This information will be updated on a regular basis. The public information will be available for download from FDA's Web site at http://www.fda.gov/wdd3plreporting.

[4] SPL is a Health Level Seven, Inc., standard for the exchange of product information using XML.