Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers: Questions and Answers

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DRAFT GUIDANCE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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Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers: Questions and Answers Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance addresses questions and clarifies FDA's expectations for annual reporting to FDA by prescription drug wholesale distributors (wholesale distributors) and third-party logistics providers (3PLs) as required under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by the Drug Supply Chain Security Act of 2013 (DSCSA).[2]

FDA previously published a draft guidance for industry entitled *DSCSA Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers* (Annual Reporting draft guidance).[3] This question-and-answer guidance supplements the information in the Annual Reporting draft guidance by addressing questions and comments that FDA received about annual reporting since publication of the Annual Reporting draft guidance.[4]

In general, FDA's guidance documents 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

[1] This guidance has been prepared by the Office of Compliance in the Center for Drug Evaluation and Research in cooperation with the Center for Biologics Evaluation and Research and the Office of Regulatory Affairs at the Food and Drug Administration.

[2] Title II of Public Law 113-54. In particular, see sections 503(e)(2) and 584 of the FD&C Act (21 U.S.C. 353(e)(2) and 360eee-3).

[3] In December 2014, FDA issued the draft guidance entitled *DSCSA Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers*. When final, that guidance will represent FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA Drugs guidance Web page at: *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*.

[4] More information about reporting is on the Wholesale Distributor and Third-Party logistics Providers Reporting Web page (http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm423749.htm).

the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. CLARIFICATION OF WHO MUST REPORT

1. Is a manufacturer, currently licensed by a State as a wholesale distributor, required to report this license?

A manufacturer that is engaged in wholesale distribution, as defined in section 503(e)(4) of the FD&C Act (21 U.S.C. 353(e)(4)), as amended by the DSCSA, is required to report information related to its wholesale distributor license (see section 503(e)(2)(A) of the FD&C Act). However, the distribution of a manufacturer's own drug is exempt from the definition of wholesale distribution (section 503(e)(4)(H)). As a result, if a manufacturer is only distributing its own drug, it would not be engaged in wholesale distribution, and would not be required to report under Federal law, even if the manufacturer has a wholesale distributor license issued by a State.

2. Do wholesale distributors or 3PL facilities that distribute only over-the-counter drugs need to report?

No. The annual reporting requirements under the DSCSA apply to wholesale distributors[5] that distribute and 3PL facilities[6] that provide services related to human prescription drugs.[7]

3. Should wholesale distributors that only distribute bulk prescription drug substances report?

Yes. The definition of *wholesale distribution* in section 503(e)(4) of the FD&C Act means the distribution of a human prescription drug subject to section 503(b) of the FD&C Act, which FDA considers to include bulk drug substances.[8]

4. Do 3PL facilities that only provide services related to bulk prescription drug substances need to report?

No, unless the bulk prescription drug substance is in finished dosage form. The annual reporting requirements apply to 3PL facilities that provide or coordinate warehousing, or other logistics services of a *product* in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a *product*. *Product* is defined in section 581(13) of the FD&C Act to mean human prescription drugs in finished dosage form. If a 3PL facility handles only bulk drug substances that are free form active pharmaceutical ingredients (API) and have yet to undergo

[5] See section 503(e)(4) of the FD&C Act.
[6] See section 581(22) of the FD&C Act (21 U.S.C. 360eee(22)).
[7] See section 581(12) and 581(13) of the FD&C Act (21 U.S.C. 360eee(12) and 360eee(13)).
[8] Under current FDA regulations, the term *bulk drug substances* means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances (21 CFR 203.3(e)).

manufacturing, processing, or packaging to become the finished dosage form of the drug, the 3PL facility does not need to report. However, if a 3PL facility handles bulk drug substances that have already been manufactured into a human prescription drug in finished dosage form but may need further processing for distribution (e.g., bottling, packaging, or labeling), the 3PL facility must report.

5. Do wholesale distributors and 3PL facilities that only distribute and provide services related to animal drugs need to report?

Wholesale distributors and 3PL facilities only distributing animal drugs (i.e., drugs subject to section 512 of the FD&C Act (21 U.S.C. 360b)) do not need to report. [9]

DSCSA requires wholesale distributors and 3PL facilities that distribute human prescription drugs to comply with the annual reporting requirements regardless of whether the human prescription drug is ultimately used to treat animals.

6. Do 3PL facilities that provide services related to only prescription drug samples need to report?

Yes, 3PL facilities that provide services related to only prescription drug samples are required to report. Prescription drug samples are not exempt from the definition of *product* in section 581(22) of the FD&C Act. *Product* is defined in section 581(13) of the FD&C Act to mean human prescription drugs in finished dosage form.

7. I am a 3PL in a State without a licensing requirement for 3PLs. Before the effective date of the Federal regulations, do I need to report to FDA?

Yes, as of November 27, 2014, 3PL facilities are required to report to FDA annually.[10] Information about the facility should be reported even if there is no State licensing requirement for 3PLs (see response 11, below).

8. If a pharmacy is currently also licensed in a State as a wholesale distributor, is this pharmacy required to report this license?

If the pharmacy engages in *wholesale distribution* as defined in section 503(e)(4) of the FD&C Act, as amended by the DSCSA, it is required to report information related to its wholesale distributor license, regardless of other license(s) it may have based on individual State requirements.

[9] See section 581(12) ("The term 'prescription drug' means a drug for human use subject to section 503(b)(1)").
[10] See section 584(b) of the FD&C Act (21 U.S.C. 360eee-3(b)).

9. I am a new drug application (NDA) or biologics license application (BLA) holder that contracts out the manufacturing of my prescription drug products, and therefore, I am not registered as an establishment under section 510 of the FD&C Act (21 U.S.C. 360). Do I have to report as a wholesale distributor?

Section 581(10) of the FD&C Act defines *manufacturer* to include application holders such as NDA[11] and BLA[12] holders. The wholesale distributor reporting requirement does not apply to a manufacturer unless the company is engaged in *wholesale distribution* as defined in section 503(e)(4) of the FD&C Act. A manufacturer's distribution of its own drug is exempt from the definition of *wholesale distribution* (section 503(e)(4)(H)).

III. CLARIFICATION OF WHAT SHOULD BE REPORTED

10. Which licenses should a wholesale distributor report, home State license or all States where each facility holds a license?

Wholesale distributors should report all licenses that authorize wholesale distribution. This includes licenses the wholesale distributor holds from any State that the wholesale distributor ships human prescription drug from and any licenses the wholesale distributor holds from States that the wholesale distributor ships into.

11. I am a 3PL in a State without a licensing requirement for 3PLs. What information should I report?

If a 3PL facility has no license information to report, a 3PL facility should report the name and address of the facility, as well as the facility contact information.

12. Should 3PL facilities report all State licenses, including those licenses that classify the 3PL as a wholesale distributor?

The DSCSA does not permit states to license 3PLs as wholesale drug distributors.[13]

Third-party logistics provider facilities must report any State licenses that classify them as 3PLs. Until the FDA regulations on standards for 3PL licensing go into effect, if an entity meets the *3PL* definition in section 581(22) of the FD&C Act but is not licensed by a State as a 3PL, the 3PL facility should report but not submit any license information for that facility (see response 11, above).

13. For a wholesale distributor, what disciplinary actions must be reported?

Wholesale distributors must report any significant disciplinary actions, including suspension or revocation of a wholesale distributor license, taken by a State or the Federal Government during

[11] See section 505 of the FD&C Act (21 U.S.C. 355).
[12] See section 351 of the Public Health and Service Act (42 U.S.C. 262).
[13] See section 585(b)(2) of the FD&C Act (21 U.S.C. 360eee-4(b)(2)), effective November 27, 2013.

the reporting period against the wholesale distributor. FDA considers significant disciplinary actions taken by a State or Federal government to include disciplinary actions that limit the ability of that entity to distribute human prescription drugs, such as actions taken against the wholesale distributor's United States Drug Enforcement Agency (DEA) registration.[14]

14. I am a wholesale distributor. Should we provide our DEA registration or State controlled-substance license(s) information when reporting?

No. For routine annual reporting, wholesale distributors should not report DEA registration numbers or State controlled-substance licenses to FDA. The only exception is when there is a disciplinary action issued by the DEA or the State controlled-substance licensing authority that would limit the ability of an entity to distribute human prescription drug products. In that case, information about the DEA registration or State controlled-substance license should be reported because the disciplinary action is reported under that specific license or registration (see response 13, above).

15. For 3PLs, what disciplinary actions should be submitted?

FDA is requesting that 3PL facilities report significant disciplinary actions taken by a State or Federal Government that limit the ability of the 3PL to distribute human prescription drug products, such as suspension or revocation of a license. Disciplinary actions taken against a manufacturer, repackager, wholesale distributor, or dispenser for which the 3PL conducts warehousing or other logistics services should not be reported by the 3PL facility unless the disciplinary actions involved the 3PL.

16. I am a 3PL. Should we provide our DEA registration or State controlled-substance license(s) information when reporting?

No. For routine annual reporting, 3PL facilities should not report DEA registration numbers or State controlled-substance licenses to FDA. The only exception is when there is a significant disciplinary action issued by the DEA or the State controlled-substance licensing authority that would limit the ability of an entity to distribute human prescription drug products. In that case, information about the DEA registration or State controlled-substance license should be reported because the disciplinary action is reported under that specific license or registration.

17. Should the Unique Facility Identifier (UFI) be reported for the reporter?

Yes, the UFI is used to either obtain an account to report using the Center for Drug Evaluation and Research (CDER) Direct Electronic Submissions Portal (CDER Direct or CDER Direct system), or to report using an alternative mechanism such as through the FDA Electronic Submissions Gateway. More information about these reporting systems is included under Section V., below.

[14] See section 503(e)(2)(A)(ii) of the FD&C Act.

18. Does the UFI need to be reported for each facility?

The UFI is not required for each facility at this time. However, if a UFI is reported, the electronic system will perform a validation of the UFI against the company name and facility address that corresponds with that UFI. If the company name and address do not correspond with the information associated with the UFI, the system will not accept the submission. A UFI should be obtained for each separate address. The UFI can be verified by checking https://www.dandb.com/dunsnumberlookup/.

19. Does every facility name need to be different?

The facility name should be the business name of the facility that corresponds with the UFI. Do not include the city, doing business as (DBA) name, or other extraneous information in the field for "name of the facility" unless it is included in the official business name of the facility.

20. Who should be reported as the contact person for a facility?

The facility contact person should be the facility manager or designated representative of the facility manager who has authority to address inquiries about the facility and its operations with FDA, the licensing authority, and other trading partners.

21. I am the contact person for a facility. What contact information should I provide?

FDA considers contact information to include the email address, telephone number, and name of individual (if applicable). NOTE: This information is included in the public database.

IV. CLARIFICATION OF WHEN TO REPORT

22. Does reporting need to be performed just once a year or do wholesale distributors and 3PL facilities need to report throughout the year if they have a change in license expiration date or a disciplinary action?

The DSCSA requires that wholesale distributors and 3PL facilities report annually.[15] FDA is requesting that wholesale distributors and 3PL facilities report between January 1st and March 31st of each year. If an entity chooses to update expired licenses during a time frame outside of this annual reporting time period, the entity should still report during the next defined annual reporting period. FDA requests that disciplinary actions be reported within 30 days of the final ruling by the State or Federal licensing authority. FDA also requests that entities that go out of business or voluntarily withdraw a license report this to FDA within 30 days.

[15] See sections 503(e)(2)(A) and 584(b) of the FD&C Act.

23. If there are no changes to the information reported the previous year, do I need to report again?

Yes, the DSCSA requires that wholesale distributors and 3PL facilities report annually.[16]

24. If I missed the requested reporting deadline of March 31st, do I need to wait until the next reporting period (January 1st – March 31st)?

No, wholesale distributors and 3PL facilities should not wait until the next reporting period (January 1st – March 31st) to report under those circumstances. The DSCSA requires that wholesale distributors and 3PL facilities report to FDA annually.[17] If you have missed the requested deadline, wholesale distributors and 3PL facilities must still report annually and should do so as soon as possible. Reporting after the requested deadline, or submitting updates, can be done using the CDER Direct system at any time.

25. I have been informed by the State licensing authority of a potential disciplinary action, but the hearing with the State Board has not occurred. Do I have to report within 30 days of the notification or within 30 days after the final ruling by the State?

For wholesale distributors and 3PLs, disciplinary actions should be reported within 30 days of the final ruling, along with any supporting documentation of the disciplinary action taken.

V. CLARIFICATION OF HOW TO REPORT

26. If I reported information using CDER Direct, can I go back and enter additional information to that submitted report?

It is not possible to enter additional information to a previously accepted submission. However, additional information may be submitted by creating a new version by following these steps:

- Log into CDER Direct.
- Choose the last Submission Accepted and open it.
- Click on "Create New Version" (the version number should increase by 1).
- Enter or update information as necessary.
- Submit the report in Structured Product Labeling (SPL) format by clicking on "Submit the SPL."

This same process may be used to re-report annually, update license expiration dates, or report disciplinary actions.

[16] *Id.*

[17] See sections 503(e)(2) and 584(b) of the FD&C Act.

27. Do I need to use CDER Direct to enter the license information?

No, FDA developed reporting through CDER Direct for the convenience of wholesale distributors and 3PLs and highly recommends its use. Companies using CDER Direct for entry and submission will not be required to convert the information to extensible markup language (XML) in SPL format; this formatting will happen automatically when using the CDER Direct system. The information will be entered once and saved in the system for future review and updating.

If a wholesale distributor or a 3PL facility chooses not to use CDER Direct for reporting, alternative methods for reporting include either:

- Submitting a properly formatted XML file in the SPL format via an account through the FDA Electronic Submissions Gateway (ESG), or
- Uploading a zipped XML file in the SPL format into CDER Direct.

The specifications for the XML in the SPL format for wholesale distributors and 3PLs can be found in the SPL Implementation Guide with Validation Procedures (available on the FDA Web site at http://www.fda.gov/downloads/ForIndustry/DataStandards/StructuredProductLabeling/UCM321876.pdf).

Wholesale distributors and 3PL facilities that use alternative methods other than CDER Direct should check the SPL format before submitting because updates to the system are implemented from time to time and the SPL format may change.

28. How do I report annually in CDER Direct if I have no new information?

To satisfy the reporting requirement, if CDER Direct is used:

- Log into CDER Direct.
- Choose the last Submission Accepted and open it.
- Click on “Create New Version” (the version number should increase by 1).
- Submit the SPL.

29. How do I update a previously reported disciplinary action that has been resolved satisfactorily?

- Log into CDER Direct.
- Choose the last Submission Accepted and open it.
- Click on “Create New Version” (the version number should increase by 1).
- Add a new disciplinary action and choose “resolved” from the drop-down menu.
- Upload the document that corresponds to the action. Do not delete or edit the previously reported action.
- Submit the SPL.

30. Can a third party report on behalf of a wholesale distributor or 3PL?

Yes, a wholesale distributor or 3PL may designate a third party to enter the facility information into CDER Direct or create the XML file in the SPL format if direct data entry in CDER Direct is not used. The third party should identify itself as the contact for the "reporter contact name"; however, the UFI and reporter name should be the company for which the reporter is reporting. If this is not done, then all companies that the third party is reporting on behalf of would be in the same SPL record. In addition, the contact information for each facility should reflect the appropriate facility representative who will interact with FDA (see response 19, above).

31. If I reported in error (I am not a 3PL facility or a wholesale distributor), how do I eliminate my entire entry?

To withdraw a report, do the following steps:

- Log into CDER Direct.
- Choose the last Submission Accepted and open it.
- Click on "Create New Version" (the version number should increase by 1).
- Under "Document Type" at the top under "Header Details," select "Withdrawal of wholesale drug distributor and third-party logistics facility report" from the drop-down menu.
- Submit the SPL.

32. If I go out of business, what should I report?

To report going out of business, a wholesale distributor or 3PL facility should perform the following steps within 30 days of going out of business:

- Log into CDER Direct.
- Choose the last Submission Accepted and open it.
- Click on "Create New Version" (the version number should increase by 1).
- Under "Document Type" at the top under "Header Details," select "Out of Business Notification" from the drop-down menu.
- Submit the SPL.

33. If I sell a facility, how do I delete that facility from my report?

To delete one facility in a report that contains more than one facility, follow these steps:

- Log into CDER Direct.
- Choose the last Submission Accepted and open it.
- Click on "Create New Version" (the version number should increase by 1).
- Click on the edit pencil next to the facility to be deleted.
- A separate page will open and click "delete facility" from the top bar. This will delete the facility and all information, including licenses associated with that facility.
- Submit the SPL.

34. If my company has a change of ownership, what should I do with the current report? Do I need to report the new company?

Following the company change of ownership, a wholesale distributor or 3PL should follow State licensing laws to obtain new licenses if required. Wholesale distributor and 3PL facilities that are newly licensed should initially report within 30 days of obtaining a State or Federal license. After the change is complete and new licenses (if applicable) are obtained, CDER Direct has a mechanism for withdrawing the current report (see process in response 30, above). After withdrawing the current report, you should then report the information for the new company, including all applicable wholesale distributor or 3PL licenses issued by States to the new company. Trading partners will be able to access the information about the new company in the FDA public database.

VI. PUBLIC AVAILABILITY OF INFORMATION

35. Why are some facility addresses not available in the public database?

The DSCSA does not require facility address to be available in the publicly available database.[18] FDA received comments indicating that making addresses or UFIs publicly available for certain facilities could be a safety risk. FDA has added a field in CDER Direct where a reporter can indicate if a facility address should remain confidential. If the field is selected, FDA will not publish the street address on the public Web site. However, pursuant to a Freedom of Information Act request or FDA's regulations, FDA may ultimately make determinations as to whether the street address can be disclosed to the public under the Trade Secrets Act, the Freedom of Information Act, and other applicable law.

36. How long does it take to see updates in the public database?

The public database is updated the next business day, usually by 12:00 pm (EST).

37. Why are some companies listed both in FDA's eDrug Registration and Listing System (eDRLS) and in the wholesale distributor and 3PL public database?

The DSCSA requires annual reporting to FDA of licensure and other information by wholesale distributors and 3PL facilities.[19] Section 510 of the FD&C Act requires any person who owns or operates any establishment that manufactures, prepares, propagates, compounds, or processes drugs in the United States, or that are offered for import into the United States, to register with FDA. If a firm meets the requirements under DSCSA and under section 510, it would be required to report to both systems. Also, in some cases, firms may have mistakenly registered under one system or the other.

[18] See section 503(e)(2)(B) of the FD&C Act.

[19] See sections 503(e)(2)(A) and 584(b) of the FD&C Act.

38. Why are disciplinary actions not listed in the public database?

Although the DSCSA requires that certain types of disciplinary actions be reported to FDA, the statute does not require that the public database contain disciplinary actions. Currently, FDA's public database does not list disciplinary actions submitted to FDA. However, pursuant to a Freedom of Information Act request or FDA's regulations, FDA may ultimately make determinations as to whether a disciplinary action can be disclosed to the public under the Trade Secrets Act, the Freedom of Information Act, and other applicable law.

39. Why isn't "doing business as" a field in the public database?

Although you may not be able to see the "doing business as" name in the public database, FDA has linked the "doing business as" name to the facility name field in the CDER Direct system. If you search for a "doing business as" name, the facility name will appear in the generated table.