
Dear Doctor Bernstein, Doctor Jung, and Mr. Bellingham:

The Healthcare Distribution Alliance (HDA) appreciates this opportunity to provide public comments to the Food and Drug Administration (FDA) regarding the Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers: Questions and Answers; Draft Guidance for Industry, 82 Fed. Reg. 3004 (Jan. 10, 2017), Dkt. No. FDA-2016-D-4646 (Draft Guidance).
HDA represents the nation’s primary, full-service healthcare distributors. Our members are large national companies and regional, family-owned and small businesses. HDA member companies deliver nine million healthcare products to more than 200,000 pharmacies, hospitals, nursing homes, physician offices, and clinics across the United States. This essential function is provided with little public recognition or visibility, and at great savings to the healthcare system. HDA members serve as the central link in a sophisticated national supply chain. HDA members take this mission very seriously, and we support manufacturers, healthcare providers and the government in ongoing efforts to ensure the U.S. medicine supply remains secure, efficient and highly regulated.

HDA agrees with and supports most of the Questions & Answers (Q&As) in the Draft Guidance. HDA believes the Q&As offer helpful information for distributors and third-party logistics providers (3PLs) undertaking compliance with the annual licensure reporting requirements.

Below, we comment on a few, individual Q&As where we believe further clarification and/or modification would be beneficial. Where we suggested revised or modified language, HDA’s proposed wording is in blue, bold italics. Suggested deletions are in strikeout and in red.

1. **Lines 101-107, Q&A 8**

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.

**Response:**

HDA supports the underlying concepts of Q&A 8. However, wholesale distributors continue to find that dispensers, state licensing authorities and others persist in the belief that dispensers can engage in DSCSA-covered transactions with wholesale distributors and other dispensers and yet not be licensed as wholesale distributors and not comply with the wholesale distributor requirements in § 582(c). For instance, HDA continues to observe state licensing boards permitting pharmacies to make up to five percent of sales to persons and entities other than patients without having to be licensed as a wholesale distributor. Dispensers continue to believe that they can promote and sell excess inventory to other dispensers without implicating the DSCSA’s licensure and data requirements.
For these reasons, we suggest expanding the response to Question 8 as follows:

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. *This means that a dispenser must be licensed as a wholesale distributor and comply with the DSCSA’s other requirements (such as receive, provide and maintain transaction data) if it engages in a transaction, other than a saleable return with a wholesale distributor. A dispenser must also comply with the other DSCSA requirements applicable to wholesale distributors if it exchanges ownership of a product with another dispenser, and the transaction or product is not exempt from the DSCSA’s definitions of “transaction,” “product” or “wholesale distribution.”* (Draft Guidance footnotes omitted)

2. Lines 110-119, Q&A 9

9. I am a new drug application (NDA) or biologics license application (BLA) holder that registered as an establishment under section 510 of the FD&C 112 Act (21 U.S.C. 360). Do I have to report as a wholesale distributor? (footnotes omitted)

Section 581(10) of the FD&C Act defines manufacturer to include application holders such as NDA and BLA 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)).

**Response:**

HDA supports Q&A 9. However, wholesale distributors are aware of instances where state licensing bodies are requiring manufacturers to be licensed as wholesale distributors even though they are distributing their own products and the DSCSA expressly exempts these transactions from the definition of wholesale distribution. We suggest the following clarifying language:

Section 581(10) of the FD&C Act defines manufacturer to include application holders such as NDA and BLA 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)) and a manufacturer should not
submit licensure information as a wholesale distributor if it is only
distributing its own drugs.

3. Lines 196-203, Q&A 18

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/.

Response:

HDA does not object to Q&A 18. However, we note that as the supply chain moves
toward 2023 electronic interoperability, we believe that trading partners will need to use
Global Location Numbers (GLNs) to identify their facilities. We ask that FDA support
migration to GLNs, including encouraging trading partners to use GLNs and that FDA
try to reduce the usage of different, competing numbers that are also in use. To that
end, we suggest that FDA provide a field in “CDER Direct” (the licensure submission
website) for optional provision of a facility’s GLN.

4. Lines 217-221, Q&A 21

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.

Response:

HDA proposes that FDA change “name of individual” to “point of contact.” The
DSCSA does not require identification of an individual by name. The statute states
wholesale distributors must submit “the name, address, and contact information of each
facility” and that the public database should include “each authorized wholesale
distributor by name, contact information, and each State” where the distributor is
licensed. § 503(e)(2)(A)(i)(II), (2)(B). The DSCSA thus requires contact information
but does not specify that an individual’s name be publicly available.
There are sound reasons for not coupling the name of a person within a wholesale distribution facility with that individual’s contact information and making that information public. HDA believes publicizing such information could put members’ individual employees at risk. These individuals work in warehouses that store large volumes of high-value drugs, including controlled substances, and wholesale distributor warehouses undertake significant and costly efforts to maintain very secure environments. We believe making an individual’s name and contact information publicly available significantly undermines the security of that individual and the warehouse.

We request that FDA remove the individual contact name from the public database and that the publicly available contact information be a phone number and email address that the wholesale distributor provides. We suggest the following clarifying language:

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

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

5. Lines 253-259, Q&A 25

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.

Response:

HDA believe the disciplinary action reporting time frame incorporated into the answer, i.e., 30 days of the final ruling, to be “reasonable” as the DSCSA contemplates in § 503(e)(2)(A)(ii). We support its inclusion.

However, HDA objects to and urges deletion of the requirement to provide “supporting documentation.” This is a new information submission requirement, is first imposed upon wholesale distributors in a Draft Guidance document, and has no support in the DSCSA. Section 503(e)(2)(A)(ii) requires that wholesale distributors “report to the Secretary within a reasonable period of time and in a reasonable matter, as determined
by the Secretary, any significant disciplinary actions…” Section § 503(e)(2)(A)(ii) neither requires nor contemplates submission of any such “supporting documentation.” The DSCSA requires only that a disciplinary action must be reported within a reasonable time and we believe the proposed 30 days of final ruling is reasonable.

The DSCSA also requires that that report be made in a reasonable manner and we believe that using the CDER Direct licensure portal to make the report, as described in Q&A 26, is reasonable. However, FDA exceeds in statutory authority under the DSCSA by attempting to impose in a guidance document a new requirement for submission of additional information.

HDA recommends the following editorial changes to Answer 25.

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.

6. Lines 312-321, Q&A 29

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.

Response:

HDA objects to Q&A 29 as exceeding the requirements of the DSCSA. As discussed above, § 503(e)(2)(A)(ii) requires that wholesale distributors “report to the Secretary within a reasonable period of time and in a reasonable matter, as determined by the Secretary, any significant disciplinary actions taken by a State or the Federal Government during the reporting period against the wholesale distributor.”

While HDA agrees that FDA’s interpretation of § 503(e)(2) as requiring that a wholesale distributor report a disciplinary action within 30 days of final ruling is reasonable, the DSCSA does not mandate reporting that the notification of the final ruling be updated. Moreover, as only final rulings are to be reported, there is nothing that would be “resolved” to merit updating “a previously reported disciplinary action
that has been resolved satisfactorily” as Q&A 29 contemplates. We recommend that Q&A 29 be deleted in its entirety.

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HDA thanks FDA for the opportunity to provide input to the Agency as it develops revisions to the Final Guidance. Should you have any questions about these comments, please feel free to contact me at 703-885-0240 or aducca@hda.org.

Sincerely,

Anita T. Ducca
Senior Vice President, Regulatory Affairs