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Connie T. Jung, R.Ph., PhD.
Associate Director for Policy and Communication
Office of Compliance
Food and Drug Administration
Room 2242, White Oak Office Building 51
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Draft Guidance for Industry on Drug Supply Chain Security Act Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers; Availability; 79 Fed. Reg. 73083 (December 9, 2014) [Docket No. FDA–2014–D–2083]

Dear Dr. Jung:

The Healthcare Distribution Management Association (HDMA) appreciates this opportunity to comment upon the Food and Drug Administration's (FDA) Draft Guidance, *DSCSA Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers* (Draft Guidance or Draft), announced in the *Federal Register*, 79 Fed. Reg. 73083 (Dec. 9, 2014).

In conjunction with the release of the Draft Guidance, FDA also revealed a new webpage for wholesale distributors and third-party logistics providers (3PLs) at www.fda.gov/wdd3plreporting and opened CDER's Direct Electronic Submissions Portal (the portal). HDMA's distributor members have already begun using the portal to submit their state licensure information to FDA as required by the Drug Supply Chain Security Act (DSCSA).[1]

Below we provide detailed comments on the *Federal Register* notice, the Draft Guidance and the portal, which we hope will be constructive in aiding the agency in developing a Final Guidance and improving the portal interface. HDMA's key findings and recommendations are summarized as follows:

1. For security reasons, HDMA recommends that FDA's public database of license information contain only the ***minimum*** necessary to meet the DSCSA's requirements.
2. HDMA urges the agency to provide additional support on how to use the portal, including a webinar and better contact information. Based upon the time

[1] §503(e)(2)(A) of the Federal Food, Drug and Cosmetic Act (FDC Act), 21 U.S.C. §353(e)(2)(A).

commitments members are reporting to submit licensure information, we also urge FDA to revise its "burden hour" estimates.

3. Though the DSCSA and Draft Guidance do not require wholesale distributors to report licenses more than once a year, wholesale distributors would like the option of updating their license information in the portal throughout the year.
4. HDMA recommends revising some of the information required for submission and/or eliminating certain data elements all together.
5. HDMA believes many of the difficulties experienced with the portal would be resolved if FDA were to provide a means for wholesale distributors to submit state licensure information electronically in a standardized template.

1. Confidentiality and Public Availability of Wholesale Distributor State Licensure Information

HDMA recommends that FDA's public database of wholesale distributors' state licenses only contain the *minimum* information necessary to satisfy the DSCSA. To better maintain facility security, we urge including in the public database *only* the distributor's name, phone number (*OR* email address), and the states in which it is licensed to engage in wholesale distribution.

The Draft Guidance did not address the confidential treatment of the licensure-related data wholesale distributors and 3PLs must now submit to FDA. Because easy public access to wholesale distributor facility information has critical implications for supply chain security, we are taking this opportunity to provide our views on this important issue.

The DSCSA provides that wholesale distributor state licensure information shall be collected in a database. The DSCSA states:

> Such database shall—
>
> > (i) identify each authorized wholesale distributor by name, contact information and each state where such wholesale distributor is appropriately licensed to engage in wholesale distribution;
> > (ii) be available to the public on the Internet website of the Food and Drug Administration; and
> > (iii) be regularly updated on a schedule determined by the Secretary.[2]

The DSCSA specifically recognizes that some of the information that wholesale distributors submit to FDA may be confidential:

[2] §503(e)(2)(B), 21 U.S.C. §353(e)(2)(B).

> Nothing in this paragraph shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information …[3]

Wholesale distributors are particularly concerned that this public database ***not*** include the physical addresses of their facility locations listed with FDA. Nor should the public database contain information that could make it easier to obtain those physical locations, such as DUNS®[4] numbers.

Distribution centers are large, secure and very anonymous to avoid attracting the attention of would-be thieves. By their very nature, wholesale distribution warehouses hold large stores of drugs that are in very high demand, such as drugs in shortage. They also store controlled substances that are in demand on the "street" and are very readily, and illegally, sold on the black market. All of these factors make these facilities highly attractive targets for criminals, addicts, and others intent on theft or diversion.

Because of these security concerns, we ask that FDA not include wholesale distributor physical addresses in the public database. A likely effect of making this information easily available in one place would be to give even a relatively unsophisticated criminal another tool for tracking down large caches of drug products in high demand – thereby undermining our members' security efforts. While individual facility addresses may be available in local telephone directories, all wholesale distributor addresses are not, currently, easily accessible at a single website. Including physical address information in the FDA database that would be easily searchable on the agency's website could increase the risk that distribution centers might be targeted.

The DSCSA requires the database to make publicly available *only* an authorized wholesale distributor's name, contact information and each state where it is licensed. Given the security concerns, we urge FDA to construe §503(e)(2)(B) strictly and "to the letter." The fact that wholesale distributors provide street addresses and other information to FDA[5] ***does not*** mean that this same information must, automatically, be made available on the public database when the statute expressly does not require it. Indeed, the inclusion of broader language in §503(e)(2)(A)(i)(II) (registration information provided to FDA including "the name, address, and contact information of each facility") and the narrower language in §503(e)(2)(B) (information available in public database includes only name, contact information and states where licensed) strongly suggests a deliberate omission by Congress and that the address of each facility is ***not*** required to be included in the public database.

[3] §503(e)(2)(D), 21 U.S.C. §353(e)(2)(D).

[4] Data Universal Numbering System or D-U-N-S® Number is Dunn and Bradstreet's (D&B's) copyrighted, proprietary means of identifying business entities.

[5] §503(e)(2)(A)(i)(II), 21 U.S.C. §353(e)(2)(A))(i)(II)).

For these same reasons, we urge FDA to not include a facility's DUNS® number in the publicly available database. The DSCSA does not require that wholesale distributors provide a DUNS® or other facility number to FDA; nor does the statute require inclusion of the DUNS® or other facility number in the public database. As a DUNS® number can be used to identify a facility's address, its disclosure introduces another potential security threat for wholesale distributors who wish to keep their facilities as anonymous as possible. Moreover, the DUNS® number is typically used for business and financial purposes, and its availability should be safeguarded for business confidentiality reasons. There is no good reason to include DUNS® numbers on the public database, and many excellent reasons why it should not be included.

The DSCSA does require that the public database include "contact information."[6] However, neither the statute nor the Draft Guidance identify what this publicly available "contact information" will be. HDMA suggests that the public database include a phone number ***OR*** an email address. A new field will need to be added to the portal to allow for entry of this information. Ideally, the field would be very clearly identified to the person entering the data, such as: *Phone Number That Will Appear In Public Database*; and *Email Address That Will Appear In Public Database*. Additionally, we urge FDA to allow the person entering the data to designate whether they prefer to have the phone number ***OR*** the email address included in the public data base so that they may select the "contact information" that they believe will pose a lesser security risk. Further, the submitter should be able to designate for the public database one email or phone number for multiple facilities.

2. Providing Additional Support and Training

Based upon wholesale distributor and 3PL experiences thus far in entering state licensure information through the portal, HDMA suggests the agency consider the following measures that we believe will improve the functionality of the site and the quality of the data submitted to it:

a. Conduct a Webinar tutorial on using the portal.
b. Provide a telephone number so that those reporting can directly discuss and resolve portal and submission problems with knowledgeable agency staff.
c. Revise and expand the tutorial/guidance available on the FDA website to correct errors, reflect changes and provide more complete guidance.
d. Revise the "burden hour" estimates reported in the *Federal Register* notice announcing the Draft Guidance.

At the outset, we urge FDA to increase its outreach on how to use the portal and submit licensure information. We believe a Webinar would be especially useful. In that way,

[6] §503(e)(2)(B).

the agency could provide an overview of the portal, with tips on how to access and navigate it. Further, the opportunity to ask questions and have them answered and demonstrated in a Webinar would allow FDA to provide a onetime answer to the same question that many individuals may have.

HDMA would gladly host such an event with FDA.

Also, it would be invaluable if the agency could provide an FDA phone number so that submitters having difficulties with the portal could speak with a knowledgeable agency employee directly. Though emails are helpful, the ability to discuss a problem in real time while navigating the portal is imperative, particularly when so many issues are not with what to report – which is clear enough – but how to report it and use the portal. "Troubleshooting" with an agency expert over the phone may also eliminate the need for multiple, time-consuming emails between the submitter and FDA.[7]

We also urge FDA to expand the tutorial[8] to include more description of how to use the portal and provide much more detail. The tutorial would also benefit from the inclusion of specific examples such as what information is contained in the "drop down" boxes, how to select them and other features. A video tutorial would be especially helpful so that the viewer could follow how FDA keys data into the portal. The tutorial should also be kept updated when the portal changes.

Last, HDMA believes that the "Report Burden" noted in the *Federal Register*[9] is underestimated. Under Table 1, the *Federal Register* indicates that the average burden per response would be 0.5 hour (30 minutes) per wholesale distributor.[10] HDMA's wholesale distributor members, however, found that data entry took far longer.

Most indicated that considerable time was spent in gathering their internal state licensure data, reading and comprehending the tutorial, opening the portal, and other start-up efforts, even *before* beginning the actual data entry. Further, the combined effort to prepare, then submit the data, typically required the individual performing the submission up to two hours per facility (or, per "wholesale distributor" if our assumption about the agency's intent

[7] Submitters have reported that questions they have submitted to the portal's email address have sometimes had to be submitted multiple times, in multiple ways, before the question that was posed is answered in a helpful way. Sometimes the responder has merely repeated the Draft Guidance. The ability to pose questions orally, to a live person, over the phone, would likely resolve these matters far more quickly.

[8] The tutorial is available at: https://direct.fda.gov/apex/f?p=100:LOGIN_DESKTOP:16469273533952.

[9] 79 Fed. Reg. at 73085.

[10] Although the term "wholesale distributor' is not defined, we assume that for purposes of identifying the reporting burden in the *Federal Register*, this term is meant to indicate the reporting burden per individually licensed facility.

in describing the reporting burden is correct) to complete the data entry. Thus, the burden estimate should be increased substantially for the initial reports. Although HDMA agrees with the *Federal Register*'s notation that the annual reporting burden in the future should be shorter than for the initial entry as facility information already entered in the portal would merely be updated, the annual reporting burden is also likely underestimated. Thus, we recommend a similar increase.

3. Reporting Intervals And Updates

HDMA agrees with the reporting intervals specified in the Draft Guidance but recommends that FDA also permit submitters to update and correct information throughout the year.

The DSCSA requires wholesale distributors to report their state licenses to FDA "on an annual basis pursuant to a schedule determined by [FDA]" beginning on January 1, 2015.[11] The Draft Guidance lays out a very realistic schedule for this annual reporting obligation, with wholesale distributors making their first licensure submission from January 1, 2015 to March 31, 2015 and from January 1 to March 31 annually thereafter.[12] Significant disciplinary actions must be reported within 30 days of final action.[13] HDMA agrees with and supports FDA's proposed reporting schedules and timeframes.

However, we note that FDA appears to assume in the Draft Guidance that both wholesale distributors and 3PLs must report final, significant disciplinary actions; the DSCSA, however, applies this reporting requirement only to wholesale distributors, not 3PLs, and the Final Guidance should be amended to accurately reflect the DSCSA's requirements. The fact that reporting of significant disciplinary actions was specifically required for wholesale distributors (§503(e)(2)(A)(ii)) and not for 3PLs (§504(b) strongly suggests a deliberate omission and that Congress did not intend for 3PLs to make such reports. Thus, we also urge FDA to modify the portal to eliminate the interface for 3PLs to submit significant disciplinary actions.

HDMA notes that it has been unclear if the portal permits changes once a wholesale distributor submits all its licenses. The Draft Guidance seems to assume that a wholesale distributor may do so: "If a company chooses to update expired licenses during a time frame outside of the annual reporting time period … the company should still report during the defined annual reporting period."[14] Some wholesale distributors have reported that the portal

[11] §503(e)(2)(A)(i), 21 U.S.C. §353(e)(2)(A)(i).

[12] Draft Guidance at lines 236, 244.

[13] Draft Guidance at line 252.

[14] Draft Guidance at lines 230-232.

"locks them out" and that they cannot go back in to edit their submitted information. Given that data entry errors might be discovered after a submission is complete, and that state licenses can expire throughout the year, wholesale distributors would like the option of entering the portal at any time, both to update state licensure information, if they chose to do so, and to correct any discovered errors.

4. Portal-Related Data Element and Entry Issues

HDMA recommends that:

a. FDA refrain from requiring the DUNS® number as part of the submission into the portal.

b. Submission of contact and other information should be clarified.

In the Draft Guidance FDA requests that submitters include the DUNS® number, which the agency states is its "preferred" identifier.[15] The DSCSA does not require wholesale distributors to obtain or submit a DUNS® number or other unique facility identifier to FDA. Despite FDA's politely worded request and the absence of any statutory authority, the portal does not allow entry of other facility identifiers, nor does it allow for submission of licensure information without a DUNS® number. Thus, obtaining and including a DUNS® number in its licensure reporting has become a requirement for wholesale distributors accomplished through a Draft Guidance and a quirk of website design.

We believe it highly unlikely that the agency will be able to issue a Final Guidance before the reporting time frame ends on March 31. Although the agency's intent surely was to help the regulated community meet a statutory deadline, we believe this imposition of these new obligations in this manner is inconsistent with FDA's Good Guidance Practices requirements.

If a company does not hold a DUNS® number, or maintains several licensed facilities and is required to provide a separate DUNS® number for each, it must obtain the numbers before it can submit its licensure information. Wholesale distributors must now also maintain additional data in their internal recordkeeping systems in order to accurately associate each state license a facility holds with the DUNS® number. This creates an unexpected paperwork burden for wholesale distributors and is particularly cumbersome given that any individual facility can hold licenses in many, or even all, the states.

Moreover, the DUNS® number may not necessarily align with the other information being submitted to the agency – information that, unlike the DUNS® number, ***is required*** by statute in §503(e)(2)(A)(i). Some wholesale distributors report being unable to enter data for

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[15] Draft Guidance at line 183.

multiple facilities under a single corporate DUNS® number. Others were able to enter data under a single corporate DUNS® number, but were unable to include the individual facility street addresses if they did so.[16] Still others experienced difficulty with entering information for both a wholesale distribution facility and a 3PL facility when co-located at the same address, in the same building and therefore sharing a single DUNS® number.

Given these difficulties, and that submission of a DUNS® number or other unique facility identifier is not required under the DSCSA, we ask that FDA eliminate the "voluntary" submission of the DUNS® number. At the very least, we urge FDA to disengage the portal's restrictions on providing the licensure data unless accompanied by a DUNS® number. If FDA retains a requirement for submission of DUNS® numbers, as discussed above, we believe its easy availability could compromise warehouse security, and strongly urge the agency not make those numbers available in the public database.

Other data entry issues have also arisen and require clarification. First, the DSCSA requires submission of contact information which the Draft Guidance interprets as requiring a person's name, an email address and a telephone number.[17] Insofar as contact information that should be provided to the agency is concerned (as opposed to contact information published on FDA's public database discussed above) we support the Draft Guidance as written. We do, however, request clarification that a single individual may be the contact for multiple facilities.

We also note that the Draft Guidance at lines 105-107, 128-130 and line 165 states that the submitter must provide the name of the contact person who will "interact with FDA." We recommend that the Draft Guidance clarify that the contact person who is identified for interactions with FDA be FDA's contact *only for purposes of the licensure submission*. Wholesale distributors and FDA may communicate on matters unrelated to submitting licensure information to the portal, such as suspect and illegitimate product queries and inspections, and these and other interactions should continue to be directed to the appropriately responsible persons.

Additionally, the DSCSA and Draft Guidance require submission of "Significant disciplinary actions by any State or ***Federal*** agency."[18] However, the disciplinary action submission is linked to a license within the portal. Since there is no ability in the portal to submit a Federal license, nor any legal requirement to do so, there is also no way to report Federal disciplinary actions. The portal will need to be amended to "decouple" the reporting of disciplinary actions from a specific license entered into the database.

[16] HDMA understands that the problem of using a single DUNS® number for multiple facilities may have been corrected on the portal.

[17] §503(e)(2)(A)(i)(II); and Draft Guidance at lines 128-130.

[18] Draft Guidance at line 137 (emphasis supplied).

5. Submitting State Licensure Information to FDA

HDMA recommends that FDA provide a means for wholesale distributors to submit state licensure information electronically in a standardized template. We attach a sample EXCEL spreadsheet as an example of the desired format.

While we realize that the agency has devised the portal to facilitate submission of state licensure information, wholesale distributors have found its use to be very cumbersome and incompatible with the way in which wholesale distributors are licensed. Further, as FDA specifically invited comment on "…ways to minimize the burden of the collection of information on respondents…"[19] HDMA believes that a simple change in how wholesale distributors submit state licenses to the agency would go a very long way to meeting that objective.

In a June 18, 2014 letter to FDA, HDMA recommended that the agency permit wholesale distributors to submit state licensure information via an EXCEL spreadsheet template.[20] We believed adoption of this recommendation would facilitate a simple, accurate submission to the agency that aligned with how wholesale distributors are licensed and maintain their licensure information. Unlike other regulated entities using similar FDA data entry portals, wholesale distributors are licensed by each state in which they reside, and usually by the states into which they ship product. Thus, a single wholesale distributor facility (and many distributors have multiple facilities) could have licenses in 50 states, as well as Puerto Rico and U.S. territories, and also possibly hold multiple state licenses as a 3PL. Further, each state has its own license numbers of varying length, characters, and with different renewal time frames.

We proposed licensure submission by an electronic file in a standardized format because this was how wholesale distributors already maintained the information and believed it would ease the supply chain's reporting burden and minimize the potential for error. We further believed such a format would support FDA's ability to conduct licensure searches and otherwise use the data for their own internal purposes. We continue to support this simple approach. The agency seems to be open to the possibility of an electronic submission in a file format, stating that a wholesale distributor could "submit an XML file in the SPL format via an account through the FDA Electronic Submissions Gateway."[21] We support the option of providing the licensure submission in a standard file format, but believe the SPL format may

[19] 79 Fed. Reg. at 73084.

[20] Letter to Connie T. Jung, R.Ph., PhD., Associate Director for Policy and Communication, FDA, Re: Annual Licensure of Wholesale Distributors, §204 of Public Law No. 113-54, the Drug Supply Chain Security Act (DSCSA), 21 U.S.C. §353(e)(2), June 18, 2014.

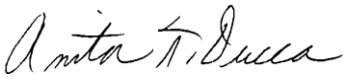
[21] Draft Guidance at line 282.

not be appropriate for facility and licensure information. We welcome the opportunity to discuss this issue further with FDA and include a sample form template for your consideration.

* * *

HDMA thanks you for this opportunity to provide suggestions on wholesale distributor licensure reporting. If you have any questions, please contact me at 703-885-0240 or at aducca@hdmanet.org.

Sincerely,



Anita T. Ducca
Senior Vice President, Regulatory Affairs

Attachment: EXCEL spreadsheet for reporting of licensure information

Report to FDA by any person who owns or operates an establishment engaged in wholesale prescription drug distribution 21 U.S.C. 353(e)(2)(A)(i)

Example - Not for Official Use					
Name of facility	**Address**	**Contact information**	**Other trade names**	**State**	**State Lic. Number**
Facility name	Facility street address, city, state, zip code	Contact information	Trade Name 1	State 1	License #1
			Trade Name 2	State 2	License #2
			Trade Name 3	State 3	License #3
				State 4	License #4
				State 5	License #5
EXAMPLE:					
123 Distributor	123 Main St., Sacramento, CA 00000	License Department	XYZ Distributor	AK	1
			ATD Distributor	CA	12345678
			Model Healthcare	OR	xy12345
				WA	wa134895
				NV	xyz123987

Attachment
Letter to Connie T. Jung, RPh, PhD
From the Healthcare Distribution Management Associaton
Annual Licensure of Wholesale Distributors; § 204 of Public Law No. 113-54, DSCSA
June 18, 2014