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BY REGULATIONS.GOV

Connie T. Jung, RPh, 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

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Notice; establishment of docket; request for comments: Standards for the Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format, 79 Fed. Reg. 9745 (Feb. 20, 2014), Docket No. FDA-2014-N-0200

Dear Dr. Jung:

The Healthcare Distribution Management Association (HDMA) thanks you and the Food and Drug Administration (FDA) for the collective efforts to begin implementation of Title II of Public Law No. 113-54, the Drug Supply Chain Security Act (DSCSA). One of FDA's earliest obligations under the DSCSA is to promulgate draft guidance by November 27, 2014 (hereinafter "draft guidance") that establishes standards for the interoperable exchange of transaction information (TI), transaction history (TH) and transaction statements (TS).¹ FDA issued a call for comment in advance of issuing the draft guidance and asked numerous questions so that stakeholders might share information and current practices with the Agency.²

HDMA is the national association representing primary wholesale distributors, the vital link between the nation's pharmaceutical manufacturers and healthcare providers. Each business day, HDMA member companies ensure that 15 million prescription medicines and healthcare products are delivered safely and efficiently to nearly 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. HDMA and its members work daily to provide value and achieve cost savings, an estimated \$42 billion each year to our nation's healthcare system. For more information, visit www.HealthcareDistribution.org.

¹ See 21 U.S.C. § 360eee-1(a)(2).

² 79 Fed. Reg. 9745 (Feb. 20, 2014)

A. EXECUTIVE SUMMARY

In the comments below, HDMA responds to various questions FDA poses and asks that the draft guidance recognize common supply chain practices for exchanging transaction information and clarify certain important issues. Our response includes the following:

- The draft guidance for interoperable data exchange should provide *initial* standards, for *initial* implementation, in a way that provides supply chain stakeholders the flexibility to leverage existing industry practices to comply with the January 1, 2015 deadline. (See Section C. 1.)
- Supply chain stakeholders cannot wait for FDA to issue its draft guidance in November 2014; they must begin making system changes now to meet the January 1, 2015 deadline. As such, it is important that FDA issue guidance as soon as possible. Once issued, the supply chain will need time and flexibility to implement any changes the draft guidance necessitates. (See Section C. 2.)
- Supply chain stakeholders currently use various systems and processes to exchange business transaction information, including electronic and paper formats. FDA's draft guidance should recognize and permit these existing systems and processes, including, but not limited to, frameworks for data exchange, such as the Advance Ship Notice (ASN) and Electronic Product Code Information Services (EPCIS), as well as methods that are not interoperable but widely used, such as Internet portals. FDA should encourage supply chain stakeholders to move away from paper and other systems using non-supported standards that are, therefore, not viable options for achieving the long-term goals of the DSCSA. (See Section D, response to Question 1.)
- Currently, primary wholesale distributors provide information about prior transactions when required to do so to comply with applicable federal or state law and do so via methods that are usually paper-based. (See Section D, response to Question 2.)
- Primary wholesale distributors frequently receive lot numbers from manufacturers though in a human-readable form. Consequently, primary wholesale distributors do not currently have an efficient means of transmitting lot information to dispensing customers. (See Section D, response to Question 3.)
- HDMA understands that its wholesale distributor members intend to move toward electronic formats as soon as possible for DSCSA compliance. (See Section D, response to Question 4.)

- Primary wholesale distributors urge FDA to permit a short phrase such as “DSCSA Compliant” to satisfy the TS and TS-direct purchase statement requirements. A short phrase more easily accommodates electronic transactions without creating the enormous TS data storage burdens of a longer statement. (See Section D, responses to Questions 6 and 7.)
- We recommend that FDA develop electronic systems for the receipt and dissemination of communications about suspect and illegitimate product. (See Section D, responses to Questions 10 and 12.)
- In the draft guidance, FDA should clarify certain elements of the TI, including number and size of containers and date of the transaction. (See Section D, response to Question 13.)
- We ask that FDA remain open to dialogue with supply chain stakeholders as DSCSA implementation proceeds. (See Section D, response to Question 13.)

B. ABOUT WHOLESALE DISTRIBUTION

Primary pharmaceutical wholesale distribution companies are the vital link in an efficient delivery system, helping pharmacies, hospitals and other healthcare providers keep their shelves stocked with the medications and products that patients need every day. 91 percent of prescription medications dispensed by healthcare providers in the United States are sold through the nation’s primary pharmaceutical distributors. The importance of this role cannot be overstated. A typical HDMA member has 57,000 different types of healthcare products in a distribution center from an average of 1,100 manufacturers. Wholesale distributors deliver 15 million prescription medicines and healthcare products every day to nearly 200,000 licensed pharmacies and other healthcare settings.

Wholesale distributors purchase these healthcare products, usually directly from the manufacturer, and, in turn, sell those products to hospitals, physicians’ offices, individual pharmacies and pharmacy chains, long-term care facilities and other dispensers. In doing so, primary wholesale distributors provide vital services to both their manufacturer suppliers and their dispensing customers. Wholesale distributors purchase drugs from manufacturers and warehouse them, as appropriate, in secure facilities. Through sophisticated logistics supply networks, wholesale distributors are able to reach the hundreds of thousands of individual dispensing sites, from large hospitals in urban centers, to chain drugstore warehouses, to individual pharmacies and physicians’ offices in rural, remote locations.

Although manufacturers frequently sell their drugs to wholesale distributors in large quantities, such as by the case and pallet, most dispensers do not have such large volume

needs. Dispensers typically require individual bottles and vials of prescription drugs produced by multiple manufacturers. Wholesale distributors are able to match a manufacturer's large scale supply with a healthcare provider's individual need by breaking down the pallets and cases they receive from hundreds or thousands of manufacturers and delivering smaller quantities of needed items, even single bottles and vials, to their customers. As an example, a dispenser could, in the evening, place an order with a wholesale distributor for next day delivery of various prescription antibiotics, asthma medications, and statins, in various strengths, from multiple manufacturers, as well as non-prescription products, such as saline solution. An individual wholesaler distribution center will repeat this process for thousands of customers every business day.

Wholesale distributors perform these and many other valuable services for their manufacturer suppliers and customers so that physicians, nurses, pharmacists and other healthcare providers can concentrate on administering and dispensing needed medications to patients. More information about the important role of primary wholesale distributors, including a short video, is available at http://www.healthcaredistribution.org/about_hdma/about_hdma.asp.

Since wholesale distributors buy prescription medications from manufacturers and sell to dispensing customers, they occupy a unique position in the center of the supply chain, and within DSCSA. Both their purchases from manufacturers and their sales to dispensers must comply with the new law. In the discussion that follows, we detail how this central place in a sophisticated and complex pharmaceutical supply chain both poses significant challenges for wholesale distributors and positions them to make important contributions to DSCSA implementation as important deadlines fast approach.

C. PRELIMINARY OBSERVATIONS

1. **The Draft Guidance should provide initial standards, for initial implementation.**

Although trading partners must begin sending and receiving the TI, TH and TS by January 1, 2015, the DSCSA contemplates a 10-year implementation process. Many things will change over this time. Product will not be individually serialized for another four years. Requirements to purchase and sell only serialized product do not apply to wholesale distributors and dispensers until years six and seven of DSCSA implementation. Once product is fully serialized and TI and TS are transferred electronically, the requirements regarding TH eventually sunset. In this long, complex process, new supply chain experiences will be gained, new insights will be gleaned, new technologies will emerge, new standards will arise and be adopted, and requirements will change.

As such, HDMA emphasizes that its comments here are intended to inform FDA's promulgation of *initial* standards. The draft guidance must, likewise, recognize that these are initial standards to guide and inform what trading partners will begin to undertake January 1, 2015. HDMA urges FDA to explicitly recognize that their initial draft guidance is primarily for addressing what must be done for January 1, 2015 implementation, and will have to change over time.

2. Swift action and flexibility are needed.

The supply chain needs guidance from FDA and flexibility as companies labor to implement practical and workable solutions to the exchange of TI, TH and TS by January 1, 2015. With a complex statute and existing data exchange practices to guide them, wholesale distributors are already designing, modifying and testing systems to accommodate the DSCSA's new requirements. We urge FDA to issue the draft guidance as swiftly as possible. Once the agency does so, supply chain stakeholders will likely need time to implement it, particularly if the draft guidance recommends processes that significantly differ from what companies have begun to do to comply with the January 1, 2015 deadline.

As part of this needed flexibility, we urge FDA to *not* promulgate a draft guidance that presents only a single way to achieve DSCSA compliance. There is significant variability in the sophistication and technological capabilities among supply chain members. We do not believe that all supply chain members are currently capable of implementing a *single* solution by January 1, 2015, even if clearly presented in draft guidance.

D. RESPONSES TO FDA'S QUESTIONS

Question 1: What types of information about transactions do you exchange? What practices, processes, or systems, either paper-based or electronic, do supply chain stakeholders use to exchange this information? Are the practices, processes, or systems based on a standard? Are they interoperable with other systems that supply chain stakeholders may be using?

Summary Response: To meet the January 1, 2015 deadline, supply chain stakeholders need the flexibility to modify existing, proven systems and processes that are currently used to exchange business transaction information. The draft guidance FDA promulgates should neither prohibit any system currently in use for the exchange of product data nor foreclose development of viable future technologies. FDA's draft guidance should recognize and permit existing systems and processes, including, but not limited to frameworks for data exchange, such as the Advance Ship Notice (ASN) and Electronic Product Code

Information Services (EPCIS), as well as methods that are widely used, but not interoperable, such as Internet portals.

Supply chain trading partners typically exchange both financial information (*e.g.*, invoicing, payments, credits, chargebacks), and logistics and other product-related information. Here, we discuss only logistics/product information and how that information is exchanged between trading partners.

a. Background on Electronic Data Interchange (EDI)

Primary wholesale distributors frequently use EDI to communicate supply chain information with trading partners. EDI is the computer-to-computer exchange of business transaction information in a standard format and was developed to facilitate the machine processing of data without human intervention. EDI standards are developed and maintained by the Accredited Standards Committee (ASC) X12, which is a committee of the American National Standards Institute (ANSI). As ANSI X12 develops standards for use by multiple industries, HDMA develops guidelines on how to implement these standards in the pharmaceutical supply chain.

Below, we describe the vehicles wholesale distributors currently use to exchange information, with a particular focus upon EDI mechanisms. We further make recommendations regarding elements we believe will be useful in the draft guidance FDA promulgates and issues for which the supply chain especially needs guidance from FDA in order to accomplish the goals of the DSCSA and begin exchanging the TI, TH and TS in barely eight months.

b. Options for exchanging information

i. ASN

As FDA explores how to incorporate supply chain stakeholders' existing systems into the draft guidance, we urge the Agency to permit use of the Advance Ship Notice or "ASN."³ The ASN electronically communicates the contents of a shipment moving from one trading partner to another. The shipping party prepares and electronically sends the ASN to the receiving party in advance of the shipment arriving at the buyer's facility. Currently, supply chain partners use the ASN to send and receive data to document pharmaceutical and other products in a shipment. Wholesale distributors already receive the ASN from some of their manufacturer suppliers and also use the ASN for shipments to some of their dispensing customers. The ASN has the desirable feature of conforming to ANSI X12 EDI standards.

³ In the EDI X12 system, the ASN is often also called the "856."

We believe the ASN has a place in DSCSA implementation and urge its inclusion in the draft guidance.

The DSCSA requires that the manufacturer provide the TI, TH and TS to the subsequent purchaser “in a single document.”⁴ Wholesale distributors must similarly provide the TI, TH and TS (with some exceptions) on a single document to dispensers.⁵ The DSCSA requires the following elements in the TI:

- the proprietary or established name or names of the product;
- the strength and dosage form of the product;
- the National Drug Code (NDC) number of the product;
- the container size;
- the number of containers;
- the lot number of the product;
- the date of the transaction;
- the date of the shipment, if more than 24 hours after the date of the transaction;
- the business name and address of the person from whom ownership is being transferred; and
- the business name and address of the person to whom ownership is being transferred.

21 U.S.C. § 360eee(26).⁶

Some trading partners may already be exchanging some of this information. Further, supply chain stakeholders have already begun the highly technical and time intensive process of updating their systems to accommodate a revised ASN that supports DSCSA requirements.

Most of the data elements for TI and TH are already present or could be added to the ASN. We believe this EDI transaction set could constitute the “single document,” *if* the ASN can also support a TS acceptable to FDA. (We address in response to Questions 6 and 7 the particular challenges of incorporating the TS into the ASN and other electronic formats).

While not all supply chain partners have the technical expertise and robust technology infrastructure to use the ASN, many do. For trading partners already using the ASN, it would likely be the most expeditious way to begin to implement the January 1, 2015 DSCSA

⁴ The DSCSA requires provision of the TI, TH, and TS in a single document in some circumstances. 21 U.S.C. § 360eee-1(b)(1)(A)(i) (manufacturer to subsequent purchaser).

⁵ 21 U.S.C. § 360eee-1(c)(1)(A)(ii)(I)(bb)(AA) (wholesale distributor to dispenser).

⁶ Where a wholesale distributor purchased product directly from the manufacturer, a manufacturer’s exclusive distributor, or a repackager who purchased directly from the manufacturer, the wholesale distributor is not required to provide TI and TH that include lot number, initial transaction date, and initial shipment date. *See* 21 U.S.C. § 360eee-1(c)(1)(A)(ii)(I)-(II).

requirements. We urge FDA to recognize the ASN as one method supply chain stakeholders may use to communicate TI, TH and TS in a single document.

ii. Web Portal

We also urge FDA to deem making the TI, TH and TS available for review via a web portal as satisfying the single document requirement.

A web-based portal hosted by the distributor is a current, common method for trading partners to exchange order, financial, logistics and product transaction information. It is a secure, confidential system that allows a trading partner to access the site, and query, retrieve, and review (but not change) the trading partner's own information, as well as order product. Though not standardized, the portals share many features and are familiar to pharmaceutical supply chain members who use them daily to transact much of their logistic, product and financial business with a trading partner.

We believe that making the TI, TH and TS available for review via a web portal constitutes a "single document" under the DSCSA and we request that FDA so state in the draft guidance. The customer could be notified that the TI, TH and TS are available at the seller's web portal by including language in an existing document already being exchanged, such as an invoice or packing slip. Using a portal greatly reduces the need to use paper and also facilitates the ability of wholesale distributors and their trading partners to respond to any request for information.

iii. Alternatives to the ASN and Web Portals

Primary wholesale distributors believe that, particularly given the looming January 1, 2015 deadline, the ASN represents a familiar electronic data exchange that, with some modifications, could be used, in at least the short term, to exchange TI, TH and TS between trading partners. The ASN is based upon EDI standards established by the ANSI X12, it provides for data exchange between trading partners, and gives advance notice to buyers of the prescription drugs that are being shipped to them by suppliers. We also believe that, for those lacking ASN capability, the web portal is another approach that trading partners could, with FDA guidance, adapt to attain DSCSA compliance by January 1, 2015.

Other modes for exchanging product and logistical information exist in the marketplace and are discussed below.

1. EPCIS

Electronic Product Code Information Services (EPCIS) is a GS1Global technical standard that some trading partners are beginning to use to exchange pharmaceutical

transaction information. Information on EPCIS is available on the GS1 Global website, <http://www.gs1.org/gsmp/kc/epcglobal/epcis>. GS1 Global is expected to approve a new version of the standard soon which envisions DSCSA compliance – though it will likely issue prior to FDA’s November draft guidance. HDMA envisions that, as serialized product enters the supply chain, companies will migrate to using EPCIS to comply with DSCSA information exchange requirements.

2. Drug Pedigree Messaging Standard (DPMS)

DPMS is GS1 US-developed architecture for the maintenance and exchange of electronic pedigree documents for use by pharmaceutical supply chain participants. While some in the supply chain are examining DPMS, we do not believe it is a viable option for DSCSA compliance and the exchange of TI, TH and TS. DPMS was developed to facilitate compliance with document-based pedigree laws, specifically for state of Florida requirements and GS1 US has elected to not support the standard. The standard will soon sunset. While we believe FDA’s draft guidance should, initially, permit supply chain members to use any DSCSA-compliant system available, HDMA does not support continued use of DPMS because DPMS is not supported by a standard-setting organization and is not an internationally recognized standard.

3. Paper and other methods

Wholesale distributors recognize that some of their valued trading partners do not yet have the capability of sending, receiving, or accessing product transaction data electronically. Nevertheless, electronic interchange is the goal of the DSCSA and we believe that although FDA should not prohibit paper records in the draft guidance, it should encourage movement away from paper records as soon as possible. Unlike electronic transactions, paper-based transactions are not subject to any standards. If paper records are allowed to persist, the millions upon millions of paper records will ultimately undermine other goals of the DSCSA, such as the ability to provide swift responses to requests for information regarding suspect and illegitimate product within the very short timeframes specified in the statute.⁷

Similarly, we recommend that in the draft guidance FDA also correct the misconception that electronic mail with file attachments in Excel, comma-delimited, or other formats, constitutes an interoperable electronic system. While some trading partners might prefer electronic mail and file transfers to paper, neither method is interoperable, and both methods lack standards and pose similar storage and retrieval difficulties.

Ultimately, FDA and the supply chain will, over the next 10 years, develop enterprise solutions for the management and exchange of information about millions of pharmaceutical

⁷ See e.g., 21 U.S.C. 360eee-1(c)(1)(C) (wholesale distributor must provide the TI, TH, TS within one business day not to exceed 48 hours).

transactions every day. While they may be necessary in the short term, paper and email file transfers do not have the necessary characteristics to be a long-term solution for DSCSA compliance.

Question 2: What practices, processes or systems, either paper-based or electronic, do supply chain stakeholders use to exchange information related to prior transactions? Are the practices, processes or systems based on a standard? Are they interoperable with other systems that supply chain stakeholders may be using?

Summary Response: HDMA's primary wholesale distributor members seldom provide information about prior transactions when they sell prescription drugs to their dispensing customers, unless they must do so to comply with applicable federal or state law. Today, any exchange of information about prior transactions is usually paper-based, is not interoperable, is not based upon any supported standard, and is not compliant with the DSCSA.

The federal Prescription Drug Marketing Act (PDMA) and the Florida pedigree law, FLA. STAT. § 499.01212 (2011), both impose requirements upon wholesale distributors to communicate prior transaction information to customers under limited circumstances. Primary wholesale distributors have systems in place to comply with the PDMA and the Florida pedigree laws. Typically, wholesale distributors use paper or DPMS to exchange information in the limited transactions for which it is required. As discussed above, we do not believe these systems can be modified and expanded for DSCSA compliance. These systems are exceptions-based, are not interoperable, are not scalable, do not comply with the DSCSA, and are not subject to supported standards.

Question 3: Do the practices, processes or systems that supply chain stakeholders use to exchange transaction information or transaction histories include or have the ability to include lot level data?

Summary Response: Manufacturers may provide lot information in their shipments to wholesale distributors. Wholesale distributors do not currently have an efficient means of capturing or transmitting lot information or lot level data to dispensing customers.

Manufacturers can and often do provide lot information for the prescription drugs they sell to wholesale distributors. Lot information can be included in the ASN the manufacturer transmits to the wholesale distributor, or it may be on the invoice or on the paper packing slip that accompanies the shipment.

Currently, wholesale distributors do not usually provide product lot numbers to their dispensing customers. Once the goals of the DSCSA are achieved and packages are fully serialized with lot information embedded in a 2D or similar bar code, lot number will be more readily available for individual saleable units.⁸ Until that time, there is no way for the wholesale distributor to retrieve lot information except by visually inspecting each individual package and manually recording the appropriate information. This type of manual processing of lot numbers is very slow and inefficient and if done on a large scale, dramatically and negatively impacts the flow of products through the supply chain.

Question 4: If you are currently using paper means to exchange transaction information or history, when do you plan to move to an electronic format?

Summary Response: Most of HDMA's wholesale distributor members intend to move toward electronic formats as soon as possible for DSCSA compliance.

While HDMA cannot say when all of its wholesale distributor members would be able to process *all* transactions electronically to meet the initial implementation requirements of the DSCSA, they are committed to electronic formats for product transactions. Primary wholesale distributors are aggressively trying to leverage or modify existing systems to meet the DSCSA's requirements. Even so, we do not believe that there will be a total migration to electronic formats for all information exchanges between all trading partners. Some supply chain members are not yet capable of managing transaction data electronically. Additionally, information such as packing slips and some financial documents will likely continue to be paper-based.

Question 5: Are there challenges to adopting and using a system, in paper or electronic format, for the interoperable exchange of transaction information or history? How can these challenges be addressed?

Summary Response: Wholesale distributors must, and already are, making systems changes in anticipation of the January 1, 2015 deadline. As such, the greatest challenges are the need for clear guidance from FDA and, once that guidance issues, all stakeholders will need adequate time to implement any changes the draft guidance necessitates and flexibility from the Agency.

We have addressed many of the greatest challenges to DSCSA implementation already. To be ready by January 1, 2015, pharmaceutical supply chain stakeholders cannot

⁸ According to internal HDMA survey data, over 90 percent of its members' prescription drug purchases are directly from the manufacturer, the manufacturer's exclusive distributor, or a repackager who purchased directly from the manufacturer. Under the DSCSA, a wholesale distributor need not provide the lot number to a subsequent purchaser so long as it purchased from one of these three aforementioned sources. See 21 U.S.C. § 360eee-1(c)(1)(A)(ii)(I)-(II).

wait until November for the clear draft guidance that is urgently needed. Stakeholders have already begun work in earnest based on their understanding of the DSCSA. Primary wholesale distributors are working closely with their trading partners to understand the DSCSA's requirements and help them prioritize and prepare for the January 1, 2015 deadline. Wholesale distributors will need to be flexible as they will surely be receiving TI, TH and TS from their suppliers in many different formats and will also have to provide that information in a format compatible with their customers' widely varying capabilities to receive it. Once FDA issues the November guidance, the supply chain will need time and flexibility from the Agency so that they may implement it, particularly if the guidance's proposed approaches significantly differ from what companies have begun to implement.

As difficult as these challenges are, wholesale distributors do not believe that the long term answer lies in a paper system for exchange of TI, TH and TS. Paper is not interoperable, is not subject to any standards, is slow, inefficient, and would require massive storage capacity to retain copies of individual pieces of paper for the millions of pharmaceuticals moving through the supply chain every day. In addition, paper would make it very difficult, if not impossible, to meet the timing requirements as outlined in DSCSA for any information requests from the Secretary. From the perspective of primary wholesale distributors, "turning back the clock" to a world of paper would severely and negatively impact the receipt and delivery of lifesaving medications.

Questions 6 and 7: Are there practices, processes or systems that supply chain stakeholders can use now to exchange the information in the transaction statement required by the DSCSA? Are there challenges to providing the transaction statement to supply chain stakeholders in either paper or electronic form? How can these challenges be addressed?

Summary Response: Primary wholesale distributors recommend that FDA permit the phrase "DSCSA Compliant" to satisfy the TS and TS-direct purchase statement requirements. A short phrase can be accommodated in the ASN and other EDI transactions. Other, longer statements would create enormous data storage burdens and that could significantly undermine the adoption and usefulness of electronic transactions.

In posing Questions 6 and 7, FDA seems to recognize, as primary wholesale distributors do, that providing the TS, particularly in an electronic transaction, poses challenges. Primary wholesale distributors do not believe that all the elements of the TS or TS-direct purchase statement can be communicated verbatim in the ASN or other EDI format for every single item in a pharmaceutical shipment, for millions of pharmaceuticals, moving every single day, without also generating massive quantities of redundant TS data and thus creating potentially insurmountable, logistical and data storage problems. HDMA is concerned that requiring verbatim TS and TS-direct purchase statements will engender data

transmission and storage problems so severe they could ultimately completely undermine the movement to electronic exchanges. In this combined response to Questions 6 and 7, we recommend that FDA permit a single, short phrase to satisfy all TS and TS-direct purchase statement requirements.

Beginning January 1, 2015, the transferring manufacturer must send to the wholesale distributor, and the wholesale distributor must receive, the TS.⁹ The TS must be in a “single document” with the TH and TI.¹⁰ Unlike the clear and limited data elements that comprise the TI, the TS is lengthy:

The ‘transaction statement’ is a statement, in paper or electronic form, that the entity transferring ownership in a transaction—

- (A) is authorized as required under the Drug Supply Chain Security Act;
- (B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;
- (C) received transaction information and a transaction statement from the prior owner of the product, as required under [§ 360eee-1];
- (D) did not knowingly ship a suspect or illegitimate product;
- (E) had systems and processes in place to comply with verification requirements under [§ 360eee-1];
- (F) did not knowingly provide false transaction information; and
- (G) did not knowingly alter the transaction history.

21 U.S.C. § 360eee(27).

Primary wholesale distributors who are currently using the ASN report that repeating all of these elements in the ASN will result in serious data storage problems that will significantly slow the rapid electronic exchange of information without providing any greater supply chain security. HDMA therefore urges FDA to specify in the draft guidance that a short statement satisfies the TS and TS-direct purchase statement requirements. Primary wholesale distributors recommend the following:

DSCSA Compliant

Trading partners using the ASN or other formats could add a field to include the statement “DSCSA Compliant,” thereby attesting that every item in the shipment that is covered under

⁹ 21 U.S.C. § 360eee-1(b)(1)(A)(i), (c)(1)(A)(i).

¹⁰ *Id.*

the DSCSA complies with the law, including each element of the TS required in 21 U.S.C. § 360eee(27).

We urge FDA to state in the draft guidance that a seller's attestation that a transaction is "DSCSA Compliant" is sufficient to satisfy the TS and TS-direct purchase statement requirements, regardless of format (electronic or paper). We believe such a statement addresses the need for brevity required for efficient electronic transactions while still providing an attestation sufficient to trigger liability for a false statement if the seller misrepresents or does not meet the elements required for a DSCSA-compliant transaction. If "DSCSA Compliant" cannot, in FDA's view, satisfy the Agency's desire for an affirmative statement, we urge FDA to provide specific guidance on an alternative, being mindful that lengthy statements will significantly undermine and slow the utility of electronic transactions. We welcome further communications with the agency on this complex issue.¹¹

Question 8: Are there standards or current practices that you would recommend for FDA to consider as a model for providing any or all of the transaction information, transaction history, or transaction statement to other supply chain stakeholders?

Please see our discussion above addressing appropriate and viable models in response to Questions 1, 6 and 7.

Question 9: Are there other technologies, systems, or solutions available now that would enable the interoperable exchange of transaction information, transaction history, or transaction statements?

Please see our previous responses above in response to Questions 1, 6 and 7.

Question 10: Are there current practices, processes, or systems that could be used to exchange information between supply chain stakeholders and FDA with respect to providing, receiving, and terminating a notification that an illegitimate product is found in distribution? Are these practices, processes, or systems effective? If not, please provide recommendations to improve these practices, processes, or systems.

Questions 10, 11 and 12 all seek similar information regarding current practices among supply chain stakeholders for communicating about suspect and illegitimate product

¹¹ As FDA develops its draft guidance and becomes more familiar with electronic transactions that trading partners currently use, we note, for the agency's benefit and information, that the ASN most commonly accepts alphanumeric characters. We believe the better approach is for FDA to avoid specifying use of non-alphanumeric characters where possible.

and seek recommendations for communicating this information among supply chain stakeholders and to and from FDA. We provide a single response to all three questions in response to Question 12 below.

Question 11: Are there current practices, processes, or systems that could be used to exchange information between supply chain stakeholders or with FDA to respond to requests to verify the lot number, expiration date, and other indices of identity assigned to a product by the manufacturer or repackager (i.e., requests for verification of suspect product)? Are these practices, processes, or systems effective? If not, please provide recommendations to improve these practices, processes, or systems.

Questions 10, 11 and 12 all seek similar information regarding current practices among supply chain stakeholders for communicating about suspect and illegitimate product and seek recommendations for communicating this information among supply chain stakeholders and to and from FDA. We provide a single response to all three questions in response to Question 12 below.

Question 12. Are there current practices, processes, or systems that could be used for providing information in response to requests from FDA or other appropriate Federal or State officials in the event of a recall or for the purpose of investigating a suspect or illegitimate product? Are these practices, processes, or systems effective? If not, please provide recommendations to improve these practices, processes, or systems.

Summary Response: HDMA provided comments to FDA on February 24, 2014 regarding general principles to aid in the development of guidance for the identification of and communication about suspect and illegitimate product; we attach those comments and incorporate them herein. We believe FDA should establish modes for receiving and sending reports of suspect and illegitimate product electronically.

In a February 24, 2014 letter to FDA (attached) HDMA offered to FDA the perspective of wholesale distributors as the agency develops draft guidance on suspect and illegitimate product. HDMA provided general principles that we believe could be a useful foundation for FDA's development of the draft guidance. We urged FDA to leverage existing processes already in place in the supply chain and urged the Agency to recognize the variability among supply chain partners as it crafts its guidance. HDMA's February 24, 2014 letter also discussed the elements in 21 U.S.C. § 360eee-1(h)(2) that Congress instructed FDA to include in the draft guidance on suspect and illegitimate product, including: the importance of evaluating suppliers; maintenance of robust SOPs; and explanation of the limited role that distributors have in identification of suspect and illegitimate product in the first instance. As

FDA develops guidance implementing the communications components of the DSCSA regarding suspect and illegitimate product, we believe our previous comments are instructive.

Other than the requirements regarding the handling of recalls in 21 C.F.R. Part 7, we are not aware of any other standards that could serve as a model for the development of procedures for the exchange of information about suspect and illegitimate product. Wholesale distributors have internal standard operating procedures for handling recall notifications. HDMA has recall guidelines for members and we believe other entities and trade associations also have created recall guidance for FDA-regulated industries. Agreements between trading partners may set out expectations regarding product recall situations.¹²

Insofar as communications with FDA regarding suspect and illegitimate product are concerned, we believe FDA should establish a stable, electronic means for receipt of this information. We suggest that the Agency explore establishing a dedicated email address or web portal. Where FDA seeks to notify the supply chain about illegitimate product, we recommend the establishment of a listserv at the outset. However, the volume of communications on the listserv will need to be carefully monitored to assure this method is effective, is used properly, and reaches its intended audience. When FDA needs to communicate to a specific supply chain stakeholder, for example, to terminate a notification, we recommend telephone and email.

Question 13: Are there other considerations related to standards for the interoperable exchange of information for tracing of human, finished, prescription drugs that have not been addressed by the previous questions? Please provide any additional information that you think could be helpful for the Agency to consider as it implements these provisions of the DSCSA.

- a. We request that FDA clarify the following elements of TI: “number of containers” should relate only to the number of containers being shipped from the current owner to the current buyer; “container size” should refer to amount of drug and/or drug packages in a container; and “NDC number” relates to the package/individual saleable unit.**

HDMA wholesale distributor members are reporting confusion among trading partners as to the meaning of certain elements in the TI in 21 U.S.C. § 360eee(26), specifically,

¹² We note that in question 12, FDA queries about current practices, processes, or systems that could be used for providing information about recalls as well as investigations of suspect or illegitimate product. While 21 C.F.R. Part 7 is a useful model for development of processes for communications about suspect and illegitimate product, we recommend continued focus upon DSCSA requirements only. We do not believe it is appropriate to tangle the already very complex implementation of the DSCSA with possible changes to current recall practices that, for primary wholesale distributors, are labor-intensive but also work very well in removing recalled pharmaceuticals from the supply chain.

“number of containers,” “container size” and “NDC number.” We urge FDA to clarify these elements in the draft guidance.

The TI requires identification of “number of containers.” As one example, it is logical for a manufacturer to identify, in the TI, the number of containers it is shipping to a wholesale distributor purchaser. Similarly, the wholesale distributor would identify the number of containers it is shipping to its buyer. It is illogical and unnecessary for the wholesale distributor to inform the dispenser as to the number of containers of that pharmaceutical it received from the previous owner. Including the “number of containers” may even be confusing and counterproductive by distracting the dispenser/purchaser from rapidly identifying other, and far more important, TI information for the customer’s purposes.¹³ The draft guidance should provide that, for subsequent transfers of ownership, “number of containers” in the TI relates to the number of containers being shipped from the current owner to the current buyer (to whom ownership is being transferred) and that TH does not need to include the number of initial containers the wholesale distributor received from the previous owner.

The TI also requires identification of “container size.” HDMA wholesale distributor members are reporting confusion among trading partners as to the meaning of this term, with some believing a seller must provide the container dimensions. FDA should clarify that “container size” logically refers to the container’s contents, which may be a single package, *e.g.*, 1 bottle of 1000 tablets, or a carton/container with several packages, *e.g.*, 5 bottles of 500 mL.

The TI also requires identification of the “NDC number.” Members of the supply chain are reporting instances in which an outside carton of a drug has a different NDC number than the package contained within. We ask that FDA clarify that the NDC number on the TI should be for the package, that is, the individual saleable unit, as defined in the DSCSA, 21 U.S.C. § 360eee(11).

b. The draft guidance should recognize that the date of invoicing is deemed to satisfy the “date of the transaction” requirement.

“Transaction” in the DSCSA is defined as “the transfer of product between persons in which a change of ownership occurs.”¹⁴ This component of the TI could cause confusion because supply agreements may specify different points for actual transfer of title of goods, *e.g.*, title may pass when goods leave shipper’s dock or might pass when the goods are delivered to the buyer’s dock, or when the buyer opens the truck, inspects the delivery, and accepts it. Thus, the actual point of transfer of title may not be known at the time of issuance of the ASN, which is generated prior to delivery of the goods to the buyer and can only

¹³ See 21 U.S.C. § 360eee-1(c)(1)(A)(ii)-(iii).

¹⁴ 21 U.S.C. § 360eee(24)(A).

estimate when the product is expected to arrive. The draft guidance should recognize that the date of invoicing is deemed to satisfy the “date of the transaction” requirement – the seller would know the invoice date at the time the ASN is generated and this could be entered in a data field.

c. Because the issues on which supply chain stakeholders need FDA guidance continue to rapidly evolve, we ask that FDA remain open to dialogue.

The DSCSA is very complex. New issues arise daily to which there are differing interpretations and no clear answers that nevertheless have significant operational and technical ramifications for transactions between trading partners. One area on which HDMA believes further dialogue may be necessary involves the definitions of supply chain entities and which data elements each entity must communicate to its trading partners. HDMA is still reviewing these issues, as well as all the issues discussed above, with its wholesale distributor members and we may suggest further clarification so that trading partners can develop the appropriate systems and processes for transmission of the data the DSCSA requires.

* * *

HDMA thanks you for this opportunity to provide comments on the initial standards for the interoperable exchange of information that will be set out in upcoming draft guidance. We are very appreciative of FDA’s efforts and look forward to working with the Agency to achieve the goals of the DSCSA. If you have any questions, please contact me at 703-885-0240 or at aducca@hdmanet.org.

Sincerely,



Anita T. Ducca
Vice President, Regulatory Affairs

Attachment: February 24, 2014 Letter from Anita Ducca, Healthcare Distribution Management Association to Ilisa B.G. Bernstein, Pharm.D., J.D. regarding Draft Guidance Development on Suspect and Illegitimate Product.