



June 9, 2014

BY REGULATIONS.GOV

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Re: Standards for the Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format; Public Workshop; Request for Comments 79 Fed. Reg. 18562 (Apr. 2, 2014) [Docket No. FDA-2014-N-0337]

Dear Dr. Jung:

The Healthcare Distribution Management Association (HDMA) thanks you and the Food and Drug Administration (FDA) for the opportunity to participate in the Workshop regarding *Standards for the Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format* held on May 8 and 9. HDMA believes the Workshop was a highly productive effort. We were pleased to have the opportunity to meet with agency officials, supply chain representatives, and other interested parties and stakeholders in order to collectively assess some of the issues the FDA and supply chain face as we all move towards implementation of Title II of Public Law No. 113-54, the Drug Supply Chain Security Act (DSCSA).

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.

During the Workshop, HDMA agreed with most of the key considerations that appeared to garner general consensus among participating stakeholders. These include, but are not limited to:

- In order to enable supply chain members to meet the January 1, 2015 deadline for passing Transaction Information (TI), Transaction History (TH), and Transaction Statement (TS), FDA must allow flexibility to transmit the required information using existing systems, 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, and, at least initially, paper.
- In order to facilitate the transmission of the required TS, FDA should permit a simplified version of the TS.
- FDA must issue its draft guidance as quickly as possible, preferably well before the statutorily imposed November 27 deadline, in order to enable supply chain members to meet the January 1, 2015 deadline for complying with information transmission requirements.

HDMA and its members who participated in the Workshop also heard discussions and/or perspectives on the nature and content of the information exchange that we had not considered previously, that were different from how our own businesses and operations are conducted, or that might affect supply chain trading partners in ways that we were not previously cognizant of.

The attachment to this letter contains a brief description of particular discussions, comments, or questions raised during the Workshop; each is followed by HDMA's perspective on how it should be addressed. Some of the issues were raised during the "report-outs" after each table discussion session; others were discussed at individual tables but not necessarily mentioned in the report-outs.

The topics discussed in greater length in the attachment include:

- Verification of lot number upon receipt;
- Standardization of the "what" but not the "how";
- Identification of buyer's/seller's addresses;
- Transaction date;
- Number of containers in the TH;

- TI for direct purchase repackager;
- Elements of TH and TS the manufacturer must pass;
- The definition of “co-licensed partner”;
- Verification of authorized trading partner;
- The definition of “electronic”; and
- Use of e-mail, web portals, paper invoices, and/or paper packing slips to transmit TI, TH, and TS.

HDMA is pleased to provide comments on the above points and believes that compliance efforts will benefit from further assessment based on the broader representation of wholesale distributors that our membership is able to provide.

* * *

HDMA thanks you for this opportunity to provide further input on the initial standards for the interoperable exchange of information. We appreciate FDA’s efforts and hope that these comments are helpful to FDA’s efforts as it prepares the guidance as required under the DSCSA. We 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

Healthcare Distribution Management Association (HDMA)
Comments on the FDA Workshop
Standards for the Interoperable Exchange of Information for Tracing of
Human, Finished, Prescription Drugs, in Paper or Electronic Format
79 Fed. Reg. 18562 (Apr. 2, 2014) [Docket No. FDA-2014-N-0337]

HDMA is pleased to provide our perspective on points raised during FDA's Workshop on the *Standards for the Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format*¹ ("Workshop") held on May 8 and 9, 2014.²

Below is a brief description of a comment or question presented during the Workshop, followed by HDMA's perspectives on, and recommendations for, how FDA could best address the issue to facilitate supply chain compliance with the Drug Supply Chain Security Act (DSCSA) by January 1, 2015. Some of these matters are based on the "report-outs" after each table discussion; others are based on individual discussions held at each table but not necessarily mentioned in the report-outs. The issues may generally be organized into four areas:

- A. Priority concerns
- B. Definitions of Transaction Information (TI), Transaction History (TH), and Transaction Statement (TS) and related terms
- C. Data transmission issues
- D. Electronic formats, paper formats, and other issues

A. PRIORITY CONCERNS

1. **Verification of lot number upon receipt:** At one table, the argument was made that distributors should verify the lot number on the product against the lot number provided in the supplier's TI.

HDMA Response: The Drug Supply Chain Security Act (DSCSA) specifies what wholesale distributors must do when receiving drug product from suppliers. Verification of lot is not a requirement of the statute and would severely disrupt the distribution of life-saving pharmaceuticals.

In the DSCSA, Congress specified precisely what a trading partner must do in order to accept a prescription drug product from another trading partner. The DSCSA merely prohibits

¹ *Standards for the Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format; Public Workshop; Request for Comments*, 79 Fed. Reg. 18562 (April 2, 2014).

² HDMA previously provided comments to FDA on the *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. These comments are already on file at <http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0200-0011> and are referenced and incorporated here.

acceptance of ownership of a product unless the previous owner provides the TI, TH, and TS as required. *See* § 582(c)(1)(A)(i), 21 U.S.C. § 360eee-1(c)(1)(A)(i)³. Amidst its many requirements, the statute says nothing of, and does not require, wholesale distributors (or any other supply chain member) to also verify the lot number of the product actually received with the lot number in the TI provided. If Congress expected wholesale distributors to physically compare the lot number on each of the thousands of products it receives from manufacturers every day, it would have so stated in the DSCSA. It did not.

Congress *did* explicitly state when wholesale distributors must engage in lot verification processes. Under the DSCSA, a wholesale distributor must have systems in place to enable it to: determine if it is in possession of suspect product; respond to verification requests made by FDA; notify FDA that suspect product is not illegitimate; and, determine, in coordination with the manufacturer that a product is illegitimate. *See* § 582(c)(4), 21 U.S.C. § 360eee-1(c)(4). Wholesale distributors do have and will have in place the DSCSA-required systems to aid in the detection of suspect and illegitimate product. Nothing in the DSCSA, however, requires that these systems include physical inspection of the lot number of every single one of the tens of thousands of products entering a wholesale distributor's facility every day.

Concerns about verification of lot number seem to arise from a misunderstanding of routine supply chain transactions between established trading partners. Deliveries of prescription drugs to wholesalers are preceded by notification, often in the form of an Advance Ship Notice (ASN) electronically communicated from the supplier to the distributor. Prescription drugs arrive at a wholesale distributor's facility from manufacturer suppliers in commercially predictable ways. Wholesale distributors have exception-based systems that specify appropriate investigatory action when product does not arrive in accordance with the prior notice provided and common business practice. Nothing in the DSCSA itself, or in established business processes, suggests that these systems must include examination of the lot number of every product entering a wholesale distributor's warehouse.

Further, requiring lot verification of every drug a distributor receives would have a catastrophic effect upon the timely delivery of life-saving medicines to dispensers and patients. Verifying the lot number on a single bottle of a drug assumes the lot number is present and readable. Currently, lot numbers may be embossed or inked on a carton or bottle, so each of the thousands of bottles, cartons, and packages entering a wholesale distributor warehouse every day would need to be visually inspected. Even if, and when, lot numbers are embedded in a machine readable two-dimensional (2-D) barcode or an equivalent machine readable code containing (or referencing) the lot number, still, each product would have to be individually and manually scanned – and this assumes that the bar codes and readers are standardized and readable across the entire healthcare supply chain. Such a manual, labor-intensive verification is so slow as to be virtually impossible. The processing of product entering a wholesale distributor's warehouse would go from a rapid, efficient flow, to a slow trickle. Certainly, distributors would not be able

³ For convenience and ease, where relevant provisions of the DSCSA are cited, HDMA provides both the relevant section of the Federal Food, Drug and Cosmetic Act (FDC Act), and where that provision is codified in the U.S. Code.

to perform this manual function without a cost-prohibitive impact on the entire healthcare system.

We question also whether FDA could, in its anticipated November guidance, or any other guidance, require distributors to perform a highly burdensome, unprecedented task that the implementing statute does not require. Wholesale distributor verification of lot numbers on incoming product is beyond the scope of the DSCSA and if Congress had expected wholesale distributors to perform such an extraordinary action, so at odds with current practice and requirements under state laws, it would have so specified when it identified the many other requirements to which wholesale distributors must adhere in § 582(c), 21 U.S.C. § 360eee-1(c) (wholesale distributor requirements). Having identified specifically when a wholesale distributor must verify lot numbers, it is not reasonable to conclude that Congress expected wholesale distributors to confirm lot numbers in other circumstances not specified in the statute.

2. **Standardize the “What” but not the “How”:** Some Workshop report-outs recommended that when FDA develops guidance on standards for TI, TH, and TS, that it would be preferable if the agency standardized “what” must be passed, but left the “how” up to industry.

HDMA Response: Because there is significant variability in the sophistication and technological capabilities of supply chain members, HDMA does not believe that all supply chain members are currently capable of implementing a single “how-to” solution by January 1, 2015, even if clearly presented in draft guidance.

Our previous comments to the agency emphasized that the draft guidance for electronic 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 requirements. Thus, insofar as initial standards are concerned, we believe that clarity regarding “what” must be done is more important than “how,” as supply chain partners will, at least initially, likely be exchanging data in various ways, across a range of technologies.

We note that the DSCSA seems to support this more flexible view. For example, § 582(a)(2)(A) recognizes that the November guidance is intended to be for “initial standards.” Further, in “...establishing such standards, [FDA] shall consider the feasibility of establishing standardized documentation to be used by members of the pharmaceutical supply chain” to convey TI, TH, and TS and “...to facilitate the exchange of lot level data.” Realistically, HDMA believes that given the widely varying capabilities and sophistication within the supply chain, no single, prescriptive approach is possible. If FDA does issue a guidance specifying a single approach, the supply chain will need time and flexibility from the agency so that supply chain members may implement it, particularly if the guidance’s proposed approaches differ significantly from what companies have begun to implement.

B. DEFINITIONS OF TI, TH, TS AND RELATED TERMS

3. **Buyer's/Seller's addresses:** TI requires identification of the addresses of the person from whom ownership is being transferred and of the person to whom ownership is being transferred. § 581(26)(I)-(J), 21 U.S.C. § 360eee(26)(I)-(J). Some Workshop participants noted that there was confusion regarding what address should be provided if, for example, the buyer or seller's corporate ownership address is different from the address where the product is physically shipped to or from.

Additionally, according to the FDA Workshop summary released on June 3, stakeholders also discussed identifying entities in TI and TH by including a standard facility identification number, such as DUNS, or Drug Enforcement Administration (DEA) registrant number. Use of standardized facility numbers would, it was argued, enable trading partners to more precisely identify one another. *See* FDA DSCSA Workshop Summary, pages 4-5 (June 3, 2014), <http://www.fda.gov/downloads/Drugs/NewsEvents/UCM399693.pdf>.

HDMA Response: We recommend that FDA specify that trading partners should identify the U.S. address of the principal place of business of the entities from and to whom product ownership is being transferred. HDMA does not recommend mandating identification of trading partners by a “standard” number.

Currently, trading partners typically communicate physical “ship from” and “ship to” locations. However, in the experience of wholesale distributors, their supply chain partners may use various addresses, depending upon commercial needs. Thus, it is appropriate and useful for FDA to clarify what buyer and seller address should be provided to comply with the DSCSA.

We recommend that FDA specify that trading partners identify the U.S. address of the principal place of business of the entities from and to whom **ownership** is being transferred. This address should be stable and static. The address will likely be the entity's U.S. corporate address.

As to mandating identification of trading partners by a “standardized” number, first, and most fundamentally, the DSCSA does not require inclusion of a facility number identifier. Trading partners are already working diligently to develop the means to meet the DSCSA data transmission requirements. Adding new data elements risks slowing compliance efforts.

We note that trading partners already, routinely and voluntarily, exchange numerous facility numbers in their product and financial transactions. Numbers that trading partners use include, but are not limited to:

- National Provider Identifier (NPI), formerly known as the National Council for Prescription Drug Programs (NCPDP) number;
- Health Industry Number (HIN);
- DUNS number;

- DUNS +4 character suffix;
- Practitioner's Medical License number;
- GS1 Global Location Number; and
- DEA registration number.

Because of this multiplicity of numbers, HDMA strongly urges FDA to avoid specifying that numerical facility identifiers should be used in TI and TH. There are many identification numbers, used for many commercial purposes that are established and supported by different standards organizations. There is no single, standardized location number used consistently and uniformly across all supply chain entities.

Certain numbers may also not be appropriate in TI and TH as they reflect a facility's physical manufacturing, distribution, or dispensing location, and not the address of the corporate owner of the product. The DEA registration number mentioned in the FDA summary is an example of a number tied to a physical location where particular controlled substances are held. However, the DSCSA requires identifying the name and address of drug product owners – who is transferring ownership and to whom ownership is being transferred. It is entirely possible that the business address of the corporate owner of a drug never takes physical possession of any pharmaceuticals at all and so may not have many facility numbers assigned to that location.

FDA specifically raised the possibility of use of the DEA registration number in the Workshop summary. However, DEA actively discourages the use of its number for any purposes other than to identify registration with DEA. Further, not all entities within the supply chain purchase, hold, distribute or dispense DEA regulated controlled substances and, therefore, do not necessarily register with DEA. Such entities would be unable to comply with an FDA mandate to provide a DEA registration number as a means of identifying the seller or buyer. Given the above, HDMA has serious misgivings about FDA specifying use of the DEA registration number in TI and TH.

- 4. Transaction date:** TI requires identification of the transaction date. § 581(26)(G), 21 U.S.C. § 360eee(26)(G). Many Workshop participants requested maximum flexibility in identifying this date, consistent with good business practices and commercial needs. Some stated they might use the date of invoicing. However, certain product transactions might have time gaps, such as product sold on consignment, which would be delivered but might not be invoiced until it is actually sold.

HDMA Response: HDMA agrees that flexibility is needed in identification of transaction date in the TI due to varying business practices and commercial needs.

“Transaction” in the DSCSA is defined as “the transfer of product between persons in which a change of ownership occurs.” § 581(24)(A); 21 U.S.C. § 360eee(24)(A). In our prior comments to FDA, HDMA explained that 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 the shipper's dock, when the goods are delivered to the buyer's

dock, or when the buyer opens the truck, inspects the delivery, and accepts it. If the parties are using the ASN to transfer TI, TH, and TS, the actual point of transfer of title might not be known at the time of issuance of the ASN, which is generated prior to delivery of the goods to the buyer. HDMA, therefore, initially recommended that FDA recognize that the date of invoicing is deemed to satisfy the “date of the transaction” requirement.

Wholesale distributors recognize, however, that this invoice date may not be sufficient to satisfy all of the commercial needs of their trading partners. HDMA therefore agrees with the positions set forth at the Workshop. We recommend that FDA permit trading partners to use any commercially reasonable and supportable transaction date, including, but not limited to, the date of invoicing.

- 5. Number of containers in the TH:** Some participants at the Workshop believe the DSCSA requires the wholesale distributor to include in the TH it provides to its customer/buyer the total number of containers that it originally received from the manufacturer (as reflected in the TI that it received from its supplier).

HDMA Response: HDMA recommends that FDA clarify that a subsequent seller need not identify to its buyer the total number of containers of product that it originally received.

HDMA addressed this issue in its previous comment to FDA. We do not read the DSCSA as requiring the wholesale distributor to identify to its customer the total number of containers it received from its supplier. It is incongruous, confusing, and unnecessary for the wholesale distributor to provide to its customer information about containers of drug product the distributor’s customer did not order and did not receive. The wholesale distributor is only required to provide to its customer data concerning the product that is being sold in that discrete transaction. The seller is not required to and should not be providing information about products that are not part of that transaction.

Given, however, that confusion regarding this issue persists, we ask FDA to clarify in the draft guidance 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 the seller need not provide to its customer (as part of the TH that it provides) the number of initial containers it received from its supplier.

C. DATA TRANSMISSION ISSUES

- 6. TI for Direct Purchase Repackager:** Workshop participants raised the issue of what TI a repackager (that purchased directly from the manufacturer) should pass to its customer, assuming that it assigns the repackaged drug a new lot number and new NDC number that are different from those assigned by the original manufacturer. HDMA notes also that there is ambiguity regarding where TH begins when a wholesale distributor has purchased directly

from either a repackager (that purchased directly from the manufacturer) or the manufacturer's exclusive distributor.

HDMA Response: With respect to the information that should be passed between trading partners, we believe the exclusive distributor of the manufacturer or a repackager that purchased directly from the manufacturer is, for all practical and functional purposes, the manufacturer. Therefore, we believe the TH the wholesale distributor receives or passes to a subsequent purchaser should start with the exclusive distributor or the direct purchase repackager.

Treatment of purchases by wholesale distributors from the manufacturer's exclusive distributor or a repackager who purchased directly from the manufacturer merits special attention. On the one hand, the definitions of "exclusive distributor," "manufacturer," "repackager," and "transaction history" (§ 581(6),(10),(16),(25), 21 U.S.C. § 360eee(6),(10),(16),(25)), as well as the provisions in § 582 regarding the TI the repackager must pass (§ 582 (e)(1)(A)(ii), 21 U.S.C. § 360eee-1(e)(1)(A)(ii)), suggest that the exclusive distributor or repackager that purchased product directly from the manufacturer must provide complete TI and TH back to the original manufacturer. Yet, this position is at odds with § 582(c)(1)(A)(ii), 21 U.S.C. 360eee-1(c)(1)(A)(ii), which creates the direct purchase option and treats exclusive distributors and repackagers that purchased direct from the manufacturer the same as manufacturers for the purpose of passing TI and TH.

We believe the intent of the DSCSA was to recognize that purchases from an exclusive distributor or a repackager that purchased directly from the manufacturer share the same qualities of security, accountability, and credibility as purchases direct from the manufacturer. Related to the transfer of TI and TH, for all practical and functional purposes, the exclusive distributor or repackager who purchased directly from the manufacturer is equivalent to the manufacturer.

Therefore, in the case of the repackager who purchased directly from a manufacturer, we believe the better reading of the DSCSA is that the repackager would be required to pass to its customer the NDC number and lot number it assigned to the repackaged product, and not the lot number or NDC number of the original manufacturer (to the extent that they differ from the manufacturer-assigned numbers). We believe this approach is consistent with FDA's historical regulation of repackagers and its traditional enforcement posture that the entity identified on the product label is the legally responsible party in the first instance for the drug. The repackager should be plainly identified as the party responsible for the drug product. Additionally, the repackager must have sufficient records and systems in place so that, in the event of a problem, the product can be traced back to the original manufacturer.

Further, we believe that the TH for all subsequent transactions should begin with the exclusive distributor or direct purchase repackager. As reflected in the DSCSA's "direct purchase provision" (§ 582(c)(1)(A)(ii), § 360eee-1(e)(1)(A)(ii)) and the principles and intent underlying that part of the statute, the exclusive distributor or direct purchase repackager is "standing in the shoes" of the manufacturer. For these very secure transactions, we believe the

TH the wholesale distributor passes to subsequent purchasers should be the same as if it had purchased from the manufacturer.

- 7. Elements of TH and TS the manufacturer must pass:** Beginning January 1, 2015, manufacturers must pass TI, TH, and TS to a subsequent owner. § 582(b)(1)(A)(i), 21 U.S.C. § 360eee-1(b)(1)(A)(i). Participants at the Workshop noted that it does not make sense to read the DSCSA as requiring manufacturers to provide TH (which is defined as TI “going back to the manufacturer of the product” (§ 581(25), 21 U.S.C. § 360eee(25)) or to require manufacturers to attest to certain elements of TS (specifically, § 581(27)(B), (C), and (G), 21 U.S.C. § 360eee(27)(B), (C), and (G), regarding attestations about receipt of the product and passage of TH).

HDMA Response: HDMA agrees that clarity on this issue would be useful and defers to the related discussion provided by the Pharmaceutical Distribution Security Alliance (PDSA), of which HDMA is a member.

- 8. “Co-licensed partner”:** Workshop participants noted the need for clarity regarding the definition of “co-licensed partner,” which is a term used within the statutory definition of “manufacturer.” *See* § 581(10)(B), 21 U.S.C. § 360eee(10)(B).

HDMA Response: The PDSA has prepared a supply chain stakeholder consensus position on the need for clarity of, and a recommendation for, the definition of “co-licensed partner” (which also includes Private Label Distributors). HDMA supports the PDSA position and urges FDA to accept PDSA’s recommendation and to provide clarity through guidance, regulation, or other reasonable means.

D. ELECTRONIC FORMATS, PAPER FORMATS, AND OTHER ISSUES

- 9. Verification of authorized trading partner:** Some Workshop attendees requested that FDA allow them to verify a wholesale distributor’s authorization by reviewing the FDA database listing of distributors’ state licenses. It was argued that, if FDA has identified a distributor’s state license on its website, querying the website should be deemed sufficient to determine whether a wholesale distributor trading partner is “authorized.”

HDMA Response: HDMA has no view on whether a member of the pharmaceutical supply chain may use the contemplated database for verification, but notes that wholesale distributors will only be required to submit information to the FDA database annually.

Beginning January 1, 2015, the DSCSA requires wholesale distributors to report their state licenses to FDA “on an annual basis pursuant to a schedule determined by [FDA].” § 503(e)(2)(A)(i), 21 U.S.C. § 353(e)(2)(A)(i). FDA then is required to create a database on its website that contains information identifying each authorized wholesale distributor by name,

contact information, and each state where it is licensed. § 503(e)(1)(B), 21 U.S.C. § 353(e)(1)(B)). HDMA intends to submit further information to FDA on this point shortly.

For now, we note that although the DSCSA selects January 1, 2015 as the beginning of the annual reporting obligation, state licenses expire and renew upon different dates that are not necessarily aligned with January 1. Further, even though a license is renewed, the wholesale distributor may not receive the actual, written, renewal notification from the state licensing authority for several weeks after it submits its renewal application. Therefore, we recommend to FDA that a wholesale distributor report annually its state licenses that are in effect on January 1 and that a wholesale distributor have until the last business day in January to make the report.

The publicly available database of wholesale distributor state licensure information that FDA must make available will need to recognize that the DSCSA specifies that the wholesale distributor state licensure information the database contains is only submitted annually.

10. Define “electronic”: Workshop participants requested that FDA clarify that interoperable exchange of information in “electronic format” does not include email and .pdf files.

HDMA Response: HDMA addressed this issue in its previous comments to the agency. We recommended that FDA clarify that electronic mail with file attachments in Excel, comma-delimited, or other formats, is not a business-to-business “electronic” system, nor are they controlled by a standard-setting body. Thus, electronic mail with file attachments cannot ultimately be expanded to implement the DSCSA fully. While such methods 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.

11. Use of e-mail, web portals, paper invoices, and/or paper packing slips to transmit TI, TH, and TS: Workshop participants discussed the challenges of paper-based vehicles for the transmission of TI, TH, and TS. On the one hand, existing paper-based transaction documents (e.g., invoices) may contain sensitive financial information; alternatively some members of the supply chain may only be able to use paper-based systems at first. Also noted was a suggestion that trading partners, even when a single document is required, might provide TI and TH by way of an electronic or paper system, but include a reference to a web portal for the TS.

HDMA Response: HDMA addressed this issue in our previous comment to FDA. Wholesale distributors recognize that some of their 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. Accordingly, while we would recommend that FDA’s draft guidance permit the exchange of transaction-related information via paper records, we also would recommend that the agency encourage movement away from paper records as soon as possible. Additionally, when a trading partner must provide TI, TH and TS in a single document, it would not be appropriate to transmit the TI and TH in one document (electronic or paper) and refer to another document for accessing the TS.