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RE: Comments to Standardization of Data and Documentation Practices for Product Tracing; Draft Guidance for Industry; Dkt. No. FDA-2018-D-0688

Dear Doctor Jung:

The Healthcare Distribution Alliance (HDA) appreciates this opportunity to provide comments to the Food and Drug Administration (FDA) regarding the Draft Guidance for Industry: Standardization of Data and Documentation Practices for Product Tracing, 83 Fed. Reg. 9004 (March 2, 2018) (“Draft Guidance” or “Guidance”).

HDA represents primary pharmaceutical distributors – the vital link between the nation’s pharmaceutical manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. This essential function is provided with little public recognition or visibility, and at great savings to the healthcare system. HDA members serve as the central link in a sophisticated national supply chain. HDA members take this mission very seriously, and we support manufacturers, healthcare providers, and the government in ongoing efforts to ensure the U.S. medicine supply remains secure, efficient, and highly regulated.

INTRODUCTION

HDA appreciates FDA’s efforts to support the supply chain by providing a Draft Guidance designed to aid supply chain trading partners’ efforts to comply with the Drug Supply Chain Security Act (DSCSA). To that end, the Draft Guidance does provide helpful clarifications that confirm FDA concurrence with certain data exchange practices that trading partners have been using for years. Some elements of the Draft Guidance could also help inform 2023 systems development.
In other instances, however, the Draft Guidance is simply far too late. Trading partners began designing systems to receive and transmit transaction data as soon as the DSCSA was enacted in November 2013. HDA immediately undertook, with wholesale distributors and manufacturers, the enormous effort of updating the 856 Advance Ship Notice (ASN) electronic data interchange (EDI) transaction set to support the exchange of DSCSA data. Condensing an EDI development process that often can take a year or more into a few months, HDA published a technical, explanatory Guideline for the ASN in mid-2014.\(^1\) Even with the ASN Guideline, the implementation challenges were immense; ultimately, FDA exercised enforcement discretion and extended the compliance date for manufacturers, repackagers and wholesale distributors,\(^2\) and did so twice for dispensers.

We also believe the supply chain has been very transparent in its DSCSA interpretations and implementation. Stakeholders repeatedly sought advice from FDA on data elements during the ASN development process and thereafter. HDA provided its Transaction Scenarios\(^3\) to FDA which set out what we believe are the data exchange requirements for various types of DSCSA transactions; the Transaction Scenarios have been widely disseminated and used throughout the supply chain for more than the last three years. Repeatedly, stakeholders informed the Agency that systems and processes were being built in reliance upon these many good faith interpretations of the DSCSA and, in the absence of any feedback, trading partners had to proceed. To the extent FDA’s new interpretations in the Draft Guidance can even be operationalized for today’s transactions (and we believe many cannot), those developing the systems to accommodate them would have needed these interpretations from the Draft Guidance by early 2014.

Now, many of the data and document “standardization” practices the Draft Guidance espouses are flatly contrary to what trading partners have been doing – and have told FDA they would be and are doing – for over three years. The Draft Guidance raises enormous state licensure and inspectional risks as we do not believe that the many currently used data practices, systems and processes can be swiftly changed, or even changed at all, to align with the Draft Guidance.\(^4\) Updating the ASN Guideline to reflect these new interpretations would require months of work stakeholders cannot afford. Supply chain experts and scarce resources are all now fixed on meeting 2019 serialization and verification requirements and preparing for 2023 compliance. There is no capacity, time or will to go back and change what was implemented between trading partners in 2015 and has been working ever since. Attempting such changes now, even assuming they are possible, would entail severe disruption and expense to the supply chain with no meaningful security enhancement. We believe pausing now to implement the Draft Guidance will set back DSCSA readiness by months or years and actively harms the pathway to 2023 compliance.

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\(^4\) The inspectional and licensure risks are very real. The Draft Guidance specifically states that it is intended to assist State and Federal officials. Line 76.
Given the many difficulties the Draft Guidance poses to current, established practices, we strongly urge FDA to immediately withdraw the Draft Guidance in its entirety.

Agency guidance on documentation and data standardization to aid future, 2023 systems development would, on the other hand, be welcome. We suggest, and believe, the best course of action is for FDA to withdraw the Draft Guidance, review the comments submitted to this docket and issue a new discussion draft. That draft, for comment purposes only, should be plainly identified as intended to stimulate discussion regarding of systems development to meet 2023 requirements.

If FDA declines to withdraw the Draft Guidance, we urge the Agency to immediately address the risks the Draft Guidance poses for the supply chain. In particular, we urge the Agency to immediately issue a statement clarifying that the Draft Guidance:

- does not apply to or change current compliance obligations,
- is not intended to provide guidance on current compliance status,
- does not describe the Agency’s current thinking on compliance with the DSCSA’s data exchange requirements, and
- should not be the basis for any enforcement action by FDA or state regulatory, licensure or inspectional bodies.

Thereafter, we request that the Agency amend the Guidance, making the changes we recommend in our lengthy comments below, and then republish the fully amended Guidance in draft for additional comment.

The Draft Guidance’s impacts are so severe, our recommendations are presented line by line. Deletions are indicated in strikethrough and additions in blue bold. We quote the language of the Draft Guidance, omitting all footnotes, and then offer comment and possible revisions.

**LINE BY LINE HDA COMMENTS, DELETIONS AND EDITS**

1. **Grandfathering; Lines 26-28 state:**

   This guidance also addresses how the product tracing requirements of section 582 apply to certain prescription drugs that entered the pharmaceutical distribution supply chain before January 1, 2015.

   **Comment and suggested revision:**

   For many reasons, HDA recommends deleting lines 26 to 28 entirely. First, it is highly unlikely that many pharmaceuticals that entered the supply chain over three years ago remain in saleable inventory. Second, as HDA and other supply chain stakeholders have explained to FDA, the ability to match a single product to a single transaction cannot be achieved until 2023 when there is item-level serialization and product identifiers are included in the data accompanying each
transaction of that product. Third, supply chain stakeholders cannot recreate data for transactions that already occurred. Last, we believe the Agency has better addressed the treatment of grandfathered product in the Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier, so this provision is unnecessary and needlessly confusing.

Therefore, HDA recommends as the preferred action, that FDA delete Lines 26-28 and the accompanying grandfathering discussion in Part IV.F., lines 620-662. If FDA elects to retain Part IV.F., we urge including revisions to the Draft Guidance language that we have described in point 20 below.

2. **Authorized Trading Partners; Lines 105-107 state:**

   In addition, for each trading partner definition an entity meets, to be considered an authorized trading partner, the entity must have the applicable registration(s) and/or license(s) for that type of trading partner.

**Comment:**

HDA supports Lines 105-107 in the Draft Guidance and agrees that an entity that meets the definition of more than one type of trading partner must be appropriately “authorized” as to that type.

3. **Trading Partner Definitions, Manufacturer; Lines 115-117 state:**

   When these situations exist, such entities should determine and specify in a written agreement which of them will be carrying out the activities required under section 582(b) of the FD&C Act.

**Comment and suggested revision:**

FDA appears in Lines 115-117 to implicitly support the proposition that if a product has more than one manufacturer, only one entity must comply with the traceability requirements. HDA supports this language and suggests adding an example for additional clarity as this issue has caused significant uncertainty among trading partners.

When these situations exist, such entities should determine and specify in a written agreement which of them will be carrying out the activities required under section 582(b) of the FD&C Act. For example, if a product has more than one manufacturer, e.g., a license holder and its co-licensed partner, the parties should agree upon which of them will be responsible for compliance with section 582’s requirements.

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4. **Exception for Licensed Health Care Practitioners; Lines 136-143 state:**

Licensed health care practitioners authorized to prescribe or administer medication under State law, or other licensed individuals under the supervision or direction of such practitioners who dispense or administer product in the usual course of their professional practice, are excepted from the product tracing requirements that apply to dispensers under section 582(d)(1) and (d)(5). The trading partners of dispensers (including licensed health care practitioners that are dispensers), however, must be authorized trading partners.

**Comment and suggested revision:**

This exception derives from 582(d)(5), which exempts “licensed health care practitioners authorized to prescribe or administer medication” from the product tracing and verification requirements in § 582(d)(1) and (d)(4). We note that in line 142, the reference to section 582(d)(5) should be changed to (d)(4).

5. **Product Name, Strength, Dosage Form, and NDC, Section V.A.1.-V.A.3.; Lines 182-260:**

Given the length of this section, we do not quote it here but reprint it only once below with our suggested, substantial edits.

**Comment and suggested revision:**

Section V.A.1.-V.A.3., Lines 182-260 of the Draft Guidance is flawed in several respects and we believe requires substantial changes to be workable. First, we are troubled by the implication, repeated several times in Section V.A.1.-V.A.3., that the way the manufacturer identified the product by name, strength, dosage form, and NDC should follow the product in each subsequent transaction. For instance, Lines 218-220 state that subsequent trading partners should “use the strength and dosage form that is on the [TI] received from the product’s previous owner.”

However, TI cannot yet “follow” a product from manufacturer, to wholesale distributor, to dispenser because product is not yet serialized with identifiers and product identifiers are not included in transaction data. With each transaction, a seller, such as a wholesale distributor, generates new TI without reference to the TI it received when it purchased the product. Even in 2023, with exchange of serialized product information, we do not see TI somehow physically or electronically attached to a single product and continually updated as the product changes ownership through the supply chain. Rather, in the contemplated distributed system, where each trading partner maintains its own transaction data, a scan of a product identifier will yield the transaction when the trading partner purchased the product and, if applicable, the transaction in which it sold the product.
In a similar way, this section seems to assume that TI is a piece of paper. Lines 219-220 state that “The strength and dosage form of the product should remain consistent in the documents for each transaction.” By 2023, TI must be communicated electronically – there is no single “document” or “documents” that can be added to or appended that follows a product through each transaction in the supply chain.

HDA also does not see any utility or benefit in attempting to compel uniformity in how product name, dosage, strength, and NDC number are presented in TI. These provisions are examples of where FDA guidance is not needed or helpful. Trying to align the supply chain’s established data format practices with the Draft Guidance would, in fact, entail profound costs, burdens and system changes, while providing no commensurate benefit to supply chain efficiency, interoperability or patient safety.

First, trading partners have developed systems for generating TI for the transactions they have been processing for over three years. Abbreviations and truncations are routine in every one of the thousands of transactions trading partners engage in every day. Each trading partner has developed its own conventions for completing TI data fields that are embedded and cross-referenced within its own proprietary systems. This means there are, conservatively, thousands of different combinations of ways that trading partners may format a product’s name, strength and/or dosage form. Even the NDC format can vary. Trying to align all trading partners and standardizing the abbreviations and truncations in use in the trade would involve costly reconfiguration of systems of every supply chain partner, and would consume enormous personnel and IT resources. We believe it would also be necessary to revise the ASN Guidelines. Manufacturers and wholesale distributors do not have the capacity to divert resources from vital work on 2019 verification systems and 2023 compliance that would be needed to do so.

Nor do we see any benefit to supply chain security that justifies attempting the herculean task of aligning all trading partners’ data entry practices with the Draft Guidance. These abbreviations and truncations have been used in purchase and sale documents in the pharmaceutical supply chain for decades predating the DSCSA. We do not believe abbreviated and truncated information in TI data fields is being misinterpreted, leading to medication errors or endangering patients. TI is for transmission of transactional data in purchase and sales between trading partners; it does not impact, and is not used for, prescribing, dispensing or patient care.

Further, the information currently being conveyed in TI, regardless of its abbreviations or truncations, is more than sufficient for trading partners to accomplish the goals of the DSCSA and identify what product they are sending and receiving. Current TI includes the drug’s NDC and, in conjunction with other information in TI and reference to trusted sources of master data, sellers and

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6 The NDC is particularly troublesome given the longstanding practice of dispensers needing to add an additional digit to the ten-digit NDC in order to process pharmaceuticals for reimbursement. To accommodate pharmacy reimbursement systems, the eleventh digit is routinely added to a drug’s NDC in transactional documents exchanged between trading partners. We believe changing the practice would require altering not just the way data is exchanged between trading partners, but pharmacy reimbursement systems as well – likely an insurmountable burden.
buyers are able to correctly identify product – even when the NDC is presented with the additional digit for alignment with pharmacy reimbursement systems.

The further precision the Draft Guidance appears to seek will also come in 2023. At that time, product identifiers will be included in TI and each identifier will include the product’s Global Trade Identification Number (GTIN) created in accordance with GS1 standards, and consistent with the FDA’s final guidance for development of standardized numerical identifiers for prescription drug packages. As with how trading partners currently use the NDC, trading partners will be able to cross reference the GTIN on a product to trusted sources of product master data. In this way, there is no ambiguity about a product’s identity in transactions.

In sum, we do not believe the Draft Guidance’s specificity on product name, strength, dosage form, and NDC is useful and strongly urge significant changes. Trading partners use NDC numbers and will use product GTINs and identifiers to access reliable sources of master data that will allow for the completion of data fields in TI efficiently and with sufficient clarity for other trading partners to be able to accurately identify the product. These are matters that have been traditionally been left to trading partners and should remain so.

Suggested edits to Lines 182-260 are below:

A. Standardizing the Transaction Information

The transaction information that trading partners are required to exchange generally consists of 10 distinct elements of information, which are set forth in section 581(26) of the FD&C Act. To help ensure that this information is provided in a consistent compliant manner, trading partners should follow the recommendations set forth below when exchanging the transaction information. Examples of situations in which a trading partner may receive transaction information that omits certain elements that are otherwise required for a product are described in section VI.C. and F. of this guidance. For these situations, a trading partner should use the reliable sources of product information such as the NDC, the product identifier, master data or on the product label, as necessary, to complete the transaction information that it provides to a subsequent purchaser.

1. Proprietary or Established Name of the Product

Trading partners should use a product’s proprietary name or established name in transaction information.

A manufacturer or repacker that is creating the first transaction information for the product it is introducing into commerce should use either the proprietary name or established name as written on the product label, in the transaction information that it

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provides to subsequent purchasers. Any subsequent trading partner should use the name that was provided in the transaction information it received from the product’s previous owner.

Trading partners should not truncate the proprietary or established name of a product in the transaction information unless the system that is being used to provide transaction information has character or space limitations that make truncation necessary. If truncation or abbreviation is used cannot be avoided, a trading partner should truncate or abbreviate the name in such a way that makes it possible to identify the product, including, for an established name that includes multiple active pharmaceutical ingredients (APIs), each of the APIs, from the truncated name. When truncation or abbreviation is used, cannot be avoided, FDA recommends truncating or abbreviating the product name in this manner to minimize the chance that the name will be misinterpreted by other trading partners or entities. Trading partners should avoid using abbreviations of drug names, symbols, and or dose designations that the Institute for Safe Medications Practices (ISMP) has identified as being frequently misinterpreted or involved in harmful medication errors.

2. Strength and Dosage Form of the Product

Trading partners are required to include strength and dosage form in transaction information. Trading partners should identify the strength and dosage form of the product sufficiently so that the product can be readily identified from the transaction information that is provided to subsequent purchasers, with reference, as necessary, to reliable master data. Manufacturers and repackagers that are creating the first transaction information for the product they are introducing into commerce should use the strength and dosage form of the product as it is written on the product label the transaction information that they provide to subsequent purchasers. Subsequent trading partners should use the strength and dosage form that is on the transaction information they received from the product’s previous owner. The strength and dosage form of the product should remain consistent in the documents for each transaction.

a. Strength

The strength of the product that is provided in the transaction information should include the amount of each API and the corresponding unit of measure (e.g., 500 mg). Units of measure may be abbreviated (e.g., mg for milligram, mL for milliliter). For some products, the strength may be expressed in the form of a concentration (e.g., 100 mg/mL), which is composed of the amount of an API and its corresponding unit of measurement per unit of volume. Appendix C of FDA’s Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the Orange Book) shows abbreviations used for strength at https://www.fda.gov/downloads/drugs/developmentapprovalprocess/ucm071122.pdf
b. Dosage form

The dosage form identifies the product in its physical form (e.g., tablet, capsule, solution, or powder). If abbreviations are used, they should consist of at least three letters. CDER’s Dosage Form data standard shows abbreviations used for dosage forms at http://wayback.archive-it.org/7993/20171115111312/https://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManual monographs/ucm071666.htm.

3. National Drug Code Number of the Product

The National Drug Code (NDC) is a three-segment number comprised of the labeler code, product code, and package code. FDA publishes the listed NDC numbers for finished drugs that are submitted as part of the listing information in the NDC Directory, which is updated daily. FDA supports the conversion of the NDC to a serialized GTIN in accordance with GS1 standards and the inclusion of that serialized GTIN in a product’s identifier in accordance with FDA’s Guidance for Industry Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages.

Some prescription drugs licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), such as certain minimally manipulated human cells, tissues, and cellular and tissue-based products (HCT/Ps), may use an alternatively formatted NDC that is approved for use by the appropriate Center Director of FDA.

Trading partners should use a product’s NDC so that the product can be readily identified from the transaction information that is provided to subsequent purchasers, with reference, as necessary, to reliable master data. Manufacturers and repackers that are creating the first transaction information for the product they are introducing into commerce should use their respective NDC number. Subsequent trading partners should use the same NDC number and the same configuration that is on the transaction information they received from the product’s previous owner. Repackers, however, should provide the NDC number that they have assigned to the repackaged product.

6. Number of Containers; Lines 271-277 state:

The number of containers is the quantity of individual saleable units of a product of the same lot number included in a transaction. If more than one lot number is associated with the products received in a transaction, the products should be grouped by lot number, and the number of containers for each group of lot numbers should be reflected on the transaction information provided to the subsequent purchaser.
Comment and suggested revision:

Lines 271-277 should be modified to reflect the fact that wholesale distributors do not need to provide lot numbers in TI when the product was purchased directly from the manufacturers. See § 582(c)(1)(A)(ii)(II). Therefore, for these types of transactions, wholesale distributors do not have to group products by lot number nor identify the number of containers in each group by lot number.

Therefore, lines 271-277 should be revised as follows:

The number of containers is the quantity of individual saleable units of a product of the same lot number included in a transaction. If more than one lot number is associated with the products received in a transaction, the products should be grouped by lot number, and the number of containers for each group of lot numbers should be reflected on the transaction information provided to the subsequent purchaser. However, for purposes of transactions described in section 582(c)(1)(A)(ii)(II), wholesale distributors who purchase directly from a manufacturer do not have to comply with this requirement because they do not need to provide product lot numbers in TI.

7. Transaction Date; Lines 295-302 state:

For the purposes of this guidance, the date of the transaction is the date on which ownership of the product involved in the transaction is transferred between trading partners. If that date is specified in a contract between the trading partners, FDA recommends using the contractually specified date as the date of the transaction. Otherwise, FDA recommends that trading partners use the product’s shipment date as the date of the transaction.

Comment:

HDA believes that this interpretation of the Transaction Date, while likely appropriate for many, if not most purchases/shipments, may not necessarily be appropriate for all. With the tens of thousands of product orders and shipments made each day, circumstances can, and do, arise where a date other than the date specified in a contract between the trading partners, or a shipment date, would be appropriate, such as in the case of emergencies, shortages and other circumstances.

As HDA noted in our comments to the Agency provided on June 9, 2014,8 we believe trading partners should have the flexibility to determine commercially appropriate transaction dates, as appropriate. We suggest the following revision to Lines 295-302:

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For the purposes of this guidance, the date of the transaction is the date on which ownership of the product involved in the transaction is transferred between trading partners. If that date is specified in a contract between the trading partners, FDA recommends using the contractually specified date as the date of the transaction. Otherwise, FDA recommends that trading partners use any commercially reasonable and supportable transaction date including, but not limited to, the date of invoicing or the product’s shipment date as the date of the transaction.

8. Business Name and Address, Section V.A.9.-V.A.10.; Lines 310-332 state:

In Lines 310-332, the Draft Guidance “recommends” that trading partners use “the address of the facility from which the product is being shipped” and “the address of the facility to which the product is being shipped” (emphasis supplied). However, the DSCSA indicates that TI must include the business name and address of the person “from whom ownership is being transferred” and “to whom ownership is being transferred.” § 581(26)(I),(J) (emphasis supplied).

Comment and suggested revision:

HDA believes the Draft Guidance’s recommendations to provide addresses from where and to which a product is being shipped are flatly contrary to the DSCSA and should be changed, immediately. The statute’s whole structure and emphasis on product traceability is predicated upon changes in ownership, not changes in possession. The statute is clear and unambiguous:

The term “transaction information” means—

…
(I) the business name and address of the person from whom ownership is being transferred; and
(J) the business name and address of the person to whom ownership is being transferred.

§ 581(26)(I),(J) (emphasis supplied).

By its express terms, TI must include the name and address of product owners, not those who are in physical possession of the product. Indeed, ownership is foundational to the DSCSA — those that are engaged in accepting and transferring direct ownership of products are “trading partners” under the law (§ 581(23)), and all traceability requirements in § 582 are triggered by trading partners engaged in a “transaction,” which is defined as “the transfer of product between persons in which a change of ownership occurs.” § 581(24)(A) (emphasis supplied). Product movements that involve changes of physical possession but not ownership are singled out in the law and do not trigger traceability requirements, such as the activities of third-party logistics providers (3PLs) that provide logistics services and take physical possession of product but do not take ownership of product. See § 581(22) (definition of 3PL); § 581(23)(B) (definition of trading partner who is a 3PL).
Which business addresses should be included in TI has been a concern since 2014 and the supply chain sought clarification from FDA on this issue. Manufacturers and wholesale distributors relied upon the statute’s plain language when drafting the HDA 2014 ASN Guidelines\(^9\) which provide for the identification of corporate headquarters as the entity transferring or receiving ownership of a product. The location of the corporate entity which obtains or transfers ownership is not necessarily the same as the physical “ship to” or “ship from” location. The widely used Transaction Scenarios also reflect this business reality. In the last three years, we believe most TI exchanged between trading partners has provided corporate ownership information, not ship to and ship from locations.

Trading partners may and sometimes do make the individual business decisions to provide shipping location information if/when it is determined as important and/or relevant to efficient, secure operations. “Ship to” and “ship from” locations are not, however, required under the DSCSA and are not a component of TI.

The Draft Guidance poses enormous difficulties and enforcement risks for trading partners. FDA’s “recommendation” could easily be interpreted as a mandate by licensure and inspectional authorities, forcing trading partners to immediately divert resources from other vital DSCSA implementation and looming compliance dates to try to reconfigure and test existing data exchange systems. And, such efforts are likely to be discarded when trading partners move to EPCIS to exchange transaction data for 2023 and beyond.

We urge FDA to immediately revise Lines 313-332 of the Draft Guidance as follows to allow for trading partners to make their own business decisions regarding what addresses to provide in TI.

Lines 313-320:

FDA understands that a trading partner transferring ownership of a product may have multiple options regarding which address to provide in the transaction information (e.g., headquarters or corporate address, billing address, shipping address). FDA views this as business decision between trading partners; however, FDA recommends using the address of the facility from which the product is being shipped as the business address of the trading partner that is transferring ownership of the product. However, if the product is shipped from a third-party logistics provider’s facility, the business address of the trading partner that is transferring ownership of the product should be used, and not the address of the third-party logistics provider.

Lines 325-332:

FDU understands that a trading partner to whom ownership is being transferred may have multiple options regarding which address to provide in the transaction information (e.g., headquarters or corporate address, billing address, shipping address). FDA views this as a business decision between trading partners. However, FDA recommends using the address of the facility to which the product is being shipped as the business address of the trading partner that is receiving ownership of the product. However, if the product is shipped to a third-party logistics provider’s facility, the business address of the trading partner that is receiving ownership of the product should be used, and not the address of the third-party logistics provider.

Even if the DSCSA contemplates “ship to” and “ship from” locations in TI, and we do not believe it does, expectations regarding their inclusion in TI would have been meaningful during the discussions of the ASN revisions several years ago. An expectation of their inclusion in TI now imposes very significant burdens and costs upon trading partners.

9. **Transaction History, Section V.B.; Lines 337-378 state:**

Section V.B. of the Draft Guidance provides FDA’s recommendations on standardization of TH. Given the length of this section, we do not quote it here but reprint it only once below with our suggested edits.

**Comment and suggested revision:**

Section V.B., which ostensibly addresses standardizing TH, continues and worsens the same problems observed in Section V.A. Specifically, this section repeatedly characterizes TH as a physical “document” that must be separate from TI, follows a single product and is updated and added to as the product moves through the supply chain. Section V.A. also assumes TH information can be added above or below other information and that documents can be physically arranged in a reverse chronological fashion. Yet, most such records are electronic now, and all TI must be provided electronically by 2023. In our revisions below, we recommend deletion of all references to receiving, sending and holding documents, how those documents should be added to, and their organization by reverse chronological date.10

Further, TH sunsets in 2023. Given the other very pressing DSCSA priorities, we see little benefit in expending scarce supply chain resources on standardizing TH that will have little utility in the future when every product is serialized, all transactions include serialized product data, and all trading partners must hold these data and swiftly retrieve it upon receiving an appropriate request.

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10 We recognize that TH is defined as a statement in “paper or electronic form.” § 581(25). However, as of November 27, 2017, manufacturers must be providing transaction data electronically. § 582(b)(1)(C). Ultimately, all transaction data must be exchanged electronically. § 582(g)(1).
Additionally, we believe the Draft Guidance is being unnecessarily prescriptive in its insistence that TH be separate from TI. HDA’s members and others in the supply chain have long assumed, and built business practices and implementation systems upon the assumption, that the static information provided in TI (e.g., product name, strength and dosage form, NDC) that does not change does not need to be duplicated in TH.

We raise a particular concern with line 370, which states that the TH the trading partner provides should include, for each prior transaction, “the number of containers.” We believe the Draft Guidance is stating that if a trading partner purchased five units, and sells one, it should be able to identify and must include within TH that that single unit being sold was purchased with four other units. However, this level of traceability will not be possible until 2023 when all products and homogenous cases are serialized and the serialized data are passed in TI. Without serialization and serialized data, it is impossible to associate a single product container with the transaction in which it was acquired.

Identification of “number of containers” should always be in reference to the number of containers in the current transaction and not the number of containers received in the prior transaction. It is illogical, unnecessary and inaccurate if a wholesale distributor informs a purchaser as to the number of containers it received from the manufacturer. Such information is often deemed confidential commercial information. We do not believe that TH should include – nor can it include – the number of initial containers the wholesale distributor received from the manufacturer.

We recommend the following changes to V.B., Lines 337-378:

For each transaction, the transaction information should remain separate from the transaction history. The transaction history is defined in section 581(25) of the FD&C Act as a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product. In general, the transaction history for a product should include be a compilation of the transaction information for each prior transaction involving that product. The recommendations in this section do not preclude a trading partner from providing more information than is described. Information present in the product’s transaction information (e.g., proprietary or established name, strength, dosage form, NDC) does not have to be repeated in the transaction history.

A trading partner should provide the transaction history for a product in one of the following two ways:

1. The trading partner can assemble compile the transaction information documents that it received from the product’s previous owner for each prior transaction involving the product. The transaction information documents should be arranged in reverse chronological order by transaction date.

For certain transactions involving wholesale distributors, the lot number and transaction and shipment dates from the manufacturer are not required to be included
in the transaction information (see section VI of this guidance). Consequently, some of the transaction information documents that make up the transaction history for a product might not contain this information. In these situations, the trading partner should not add the information that is omitted from the transaction information documents for prior transactions. The trading partner should instead assemble compile the transaction information documents that it received from the product’s previous owner(s) and provide this information to the subsequent purchaser as the transaction history.

2. The trading partner may create a new single document or file for the transaction history based on the transaction data documentation it has received from the product’s previous owner. The product information for the current transaction (i.e., the proprietary or established name, strength, dosage form, NDC number, number of containers, container size, lot number of the product) should be provided in the transaction information for that sale at the top of the document. If this information does not change from transaction to transaction, it can be stated once, in the transaction information history. Below the product information, the trading partner should provide the following information for each prior transaction: the number of containers, the business name and address of the person that transferred ownership, the business name and address of the person that accepted ownership and the date of the transaction, and date of the shipment (if more than 24 hours after the date of the transaction). This information should be provided in reverse chronological order by transaction date.

When creating or assembling transaction history, if a trading partner transcribes information from that chooses to create this new single document should ensure that the transaction data information from documentation received from the product’s previous owner(s), it should ensure that the information is accurately transcribed.

10. Transaction Statement; Lines 404–412 state:

The transaction statement that a trading partner provides to a subsequent purchaser should identify the trading partner as the entity transferring ownership and indicate that the trading partner is in compliance with section 581(27)(A)–(G) of the FD&C Act. A trading partner may indicate that it is in compliance by reproducing that section, word-for-word, in the transaction statements that it provides to subsequent purchasers. Alternatively, a trading partner may indicate that it is in compliance with section 581(27)(A)–(G) by including the following sentence as the transaction statement that it provides to subsequent purchasers: “For this transaction, [Insert name of trading partner transferring ownership] is in compliance with section 581(27)(A)–(G) of the Federal Food, Drug, and Cosmetic Act.”
Comment and suggested revision:

We thank FDA for acknowledging the use of an abbreviated TS in Lines 404-412 of the Draft Guidance. There is some variation in the abbreviated TS currently in use. For instance, to conserve data/storage space, the ASN Guidelines provide for the following, which is widely used in transaction data trading partners exchange: “Seller has complied with each applicable subsection of FDCA Sec. 581(27)(A)–(G).” Given the difficulties in changing current transaction data practices, we suggest that the Draft Guidance be slightly revised to provide more flexibility to the supply chain. Further, because the trading partner transferring ownership, that is, the seller, is identified in the current TI for the transaction, we believe that the seller’s name may be omitted from the TS.

In light of the foregoing, we suggest revising Lines 409-412 as follows:

Alternatively, a trading partner may indicate that it is in compliance with section 581(27)(A)-(G) by including the following, or similar, sentence as the transaction statement that it provides to subsequent purchasers: “For this transaction, Seller [Insert name of trading partner transferring ownership] is in compliance with section 581(27)(A)-(G) of the FDCA Federal Food, Drug, and Cosmetic Act.”

We believe that a single, standardized abbreviated TS that the Draft Guidance envisions could be incorporated into future EPCIS standards development for 2023.

11. Direct Purchase Statement; Lines 433-438 state:

For this purpose, FDA recommends that wholesale distributors that conduct a direct purchase use the following language in the direct purchase statement that they provide to subsequent purchasers: “[insert name of wholesale distributor that made a direct purchase] purchased this product directly from the manufacturer, exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer.”

Comment and suggested revision:

We thank FDA for this suggested language. As with the abbreviated TS discussed above, there is some variation in the direct purchase statements currently in use. Again, to conserve data/storage space, the ASN Guidelines provide for the following, which is widely used in transaction data trading partners exchange: “As indicated below, product was purchased directly from the manufacturer, manufacturer’s exclusive distributor or repackager who purchased directly from a manufacturer.”

Given the difficulties in changing current transaction data practices, we suggest that the Draft Guidance be slightly revised to provide more flexibility to the supply chain in the provision of the direct purchase statement. Consistent with our recommendation regarding TS, because the
wholesale distributor that made the direct purchase is identified in the current TI for the transaction, we believe that its name may be omitted from the direct purchase statement.

We urge revising Lines 433-438 as follows:

For this purpose, FDA recommends that wholesale distributors that conduct a direct purchase use the following, or similar, language in the direct purchase statement that they provide to subsequent purchasers: “As indicated below, product was purchased directly from the manufacturer, manufacturer’s exclusive distributor or repackager who purchased directly from a manufacturer.” “[insert name of wholesale distributor that made a direct purchase] purchased this product directly from the manufacturer, exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer.”

To the extent FDA believes a different format is appropriate, we believe such discussions could be incorporated into future EPCIS standards development for 2023.

HDA also believes that the direct purchase statement in situations where a wholesale distributor is transferring ownership of a product it purchased from another wholesale distributor (lines 445–451) should be addressed. We recommend amending lines 445–451 in a manner similar to our recommendation for lines 443–438 above.

12. Clerical Errors and Other Discrepancies; Lines 454-463 state:

FDA recognizes that clerical errors and other discrepancies in product tracing information may occur. If a wholesale distributor, dispenser, or repackager purchases product and identifies a potential clerical error or other discrepancy in the product tracing information it has received, that trading partner should resolve the error or discrepancy as quickly as possible. This may include immediately contacting the trading partner that provided the product tracing information to resolve the issue. If the error or discrepancy cannot be resolved and the product is determined to be a suspect or illegitimate product, trading partners must follow steps for verification of product, including, if applicable, quarantine and investigation.

Comment and suggested revision:

FDA appears to be acknowledging that errors and discrepancies do not automatically render a product suspect. This is a very helpful clarification that HDA supports. We suggest that the words “data” be added to clarify that this provision applies “clerical or data errors and other discrepancies.”

The Draft Guidance would be revised to read as follows:

FDA recognizes that clerical or data errors, as well as and other discrepancies in product tracing information may occur. If a wholesale distributor, dispenser, or
repackager purchases product and identifies a potential clerical, **data** error or other discrepancy in the product tracing information it has received, that trading partner should resolve the error or discrepancy as quickly as possible. This may include immediately contacting the trading partner that provided the product tracing information to resolve the issue. If the error or discrepancy cannot be resolved and the product is determined to be a suspect or illegitimate product, trading partners must follow steps for verification of product, including, if applicable, quarantine and investigation.

13. **Part VI, DOCUMENTATION PRACTICES, pages 14-19.**

HDA has many significant concerns with Part VI of the Draft Guidance. As explained further below, Part VI, if finalized as proposed, would seriously impact existing business processes, inventory management and production, as well as upend data exchange practices between trading partners that have been in place for over three years. We do not believe that business and data processes can be aligned with the Draft Guidance without imperiling 2019 and 2023 DSCSA readiness. The provisions in Part VI regarding TH are particularly troubling because they would necessitate changing current business operations which, in turn, would require altering and/or increasing physical warehousing space, changing receiving processes, and changing repackaging lines, at enormous time and expense – all for a requirement that sunsets in 2023. Some of the Draft Guidance’s provisions regarding TI and TS might be useful for further consideration as part of 2023 development, but not if expected to be applied to current transactions.

Earlier, we urged that the Draft Guidance be withdrawn in its entirety and be reissued with the intention of stimulating discussion of 2023 development. If FDA elects not to do so, we recommend numerous changes to Part VI as described below.

A global change we suggest is the wording of the obligation regarding TH provided throughout Part VI. See, e.g., Lines 505-507, 522-24, etc. The provision states: “The transaction history, which must include all of the information specified in section 581(25) of the FD&C Act for each prior transaction…” (emphasis supplied). The assertion that TH must include all of the information specified in § 581(25) seems awkward because the definition of TH in § 581(25) does not specify elements of information as the definitions of TI and TS do. Section 581(25) simply defines TH as the TI going back to the manufacturer. For this reason, we suggest deleting the “all of” language in the TH provisions throughout Part VI.

14. **Product Tracing Information a Manufacturer Must Provide; Lines 500-510 state:**

The manufacturer must provide the following:

- The transaction information, which must include all of the information specified in section 581(26) of the FD&C Act, including the lot number of the product,
transaction date, and shipment date, if more than 24 hours after the date of the transaction.

- The transaction history, which must include all of the information specified in section 581(25) of the FD&C Act for each prior transaction going back to the manufacturer, including the lot number of the product, transaction date, and shipment date.

- The transaction statement, as defined in section 581(27)(A)-(G) of the FD&C Act (see section V.C).

**Comment and suggested revision:**

Because the manufacturer is usually making the first sale into the supply chain, neither TH nor aspects of TS would seem applicable. In the case of TH, there would not be any for the manufacturer to provide (and no responsibility for a customer to receive) because the manufacturer is making the first sale into the supply chain. If there is TH, presumably because it is not the product’s first transaction into the supply chain, the manufacturer would not be a manufacturer under the DSCSA for purposes of that transaction.

Similarly, we note that certain elements of the TS are also not relevant or applicable to a manufacturer’s first sale. Specifically, it does not make sense for the originating manufacturer to attest to § 581(27)(B) and (C) which, respectively, are attestations that the seller received the product from an authorized person and received TI and TS from the prior owner.

We recommend that Lines 500-510 be revised as follows to clarify these issues:

The manufacturer must provide the following:

- The transaction information, which must include all of the information specified in section 581(26) of the FD&C Act, including the lot number of the product, transaction date, and shipment date, if more than 24 hours after the date of the transaction.

- The transaction history, which must include all of the information specified in section 581(25) of the FD&C Act for each prior transaction going back to the manufacturer, including the lot number of the product, transaction date, and shipment date, **if the entity is not functioning as a manufacturer (as defined in section 581(10)) for purposes of the transaction. However, when the manufacturer is functioning as a manufacturer for the purposes of a transaction, the manufacturer is generating the initial transaction information, and thus there is no transaction history to be provided.**

- The transaction statement, as defined in section 581(27)(A)-(G) of the FD&C Act (see section V.C). **If the manufacturer is first introducing a product in**
a transaction to a repackager, distributor, or dispenser, the required transaction statement may omit section 581(27)(B) (that it received product from an authorized person) and (C) (that it received transaction information and a statement from the prior owner), as these elements are not relevant to a manufacturer’s first sale of a product.

15. **Product Tracing Information a Repackager Must Provide; Lines 515-527 state:**

The repackager must provide the following:

- The transaction information, which must include all of the information specified in section 581(26) of the FD&C Act, including the lot number of the product, transaction date, and shipment date, if more than 24 hours after the date of the transaction.

- The transaction history, which must include all of the information specified in section 581(25) of the FD&C Act for each prior transaction going back to the manufacturer, including the lot number of the product, transaction date, and shipment date.

- The transaction statement, as defined in section 581(27)(A)-(G) of the FD&C Act (see section V.C).

**Comment and suggested revision:**

HDA disagrees with the Draft Guidance to the extent that it would require a repackager that purchased product directly from the manufacturer to provide to its subsequent customer the TH associated with its initial purchase from the manufacturer. The supply chain has taken the position for over three years that, with respect to traceability requirements, the DSCSA effectively treats direct purchase repackagers (as well as exclusive distributors, addressed further below) as the manufacturer for purposes of initiating TI and TH, and the direct purchaser repackager need not provide TH reflecting its initial purchase from the manufacturer.

HDA has explained and consistently maintained this position since 2014 in its Transaction Scenarios, made available to industry, FDA and the public. HDA addressed this and other related issues in an October 1, 2014 letter to the Agency and in previously submitted comments. Both the letter and comments are attached and incorporated here by reference.

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We believe this interpretation comports with §582(c)(1)(A)(ii), which creates the “direct purchase” option and affords a wholesale distributor’s direct purchases from a direct purchase repackager or exclusive distributor the same status as those directly from the manufacturer – all three purchases qualify for a direct purchase option with abbreviated TI and TH obligations when the wholesale distributor resells the product. Under this provision, the manufacturer, the manufacturer’s exclusive distributor and the manufacturer’s direct purchase repackager are treated identically in terms of the abbreviated TI and TH the direct purchase wholesale distributor is permitted to provide to its customer in subsequent transactions. It then logically follows that what the manufacturer must provide to its wholesale distributor customer is the same as what the direct purchase repackager (or, as discussed below, the manufacturer’s exclusive distributor) must provide to its wholesale distributor customer.

Beginning TH with the direct purchase repackager’s first sale, rather than back to the initial manufacturer, is consistent with FDA’s historical regulation of repackagers as manufacturers 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 must have processes in place so that the repackaged product can be linked back to the original manufacturer, traditionally done through manufacturing and other records. Furthermore, pursuant to § 582(e)(2)(A)(iv), a repackager must be able to associate the product identifier it affixes or imprints to the repackaged product with the product identifier the original manufacturer assigned.

TH follows a product but, once the manufacturer’s original product is repackaged, it no longer exists as a product. The repackaged product bears a new label, is assigned a new NDC, new GTIN, and new product identifier, and appears in a new packaging size and configuration. The manufacturer’s original product cannot be sold, returned, validated, verified or reconstituted; the manufacturer’s old containers and packaging must be securely disposed of pursuant to appropriate procedures. Repackagers and manufacturers will likely arrange privately for decommissioning of the manufacturer’s product identifiers. We do not see the logic in having TH for a product that no longer exists. As noted above, existing processes enable a repackager to link its repackaged product to the original manufacturer, but this information cannot logically be incorporated into TH.

The business and process implications for direct purchase repackagers – if they are not treated as a manufacturer for purposes of the TH requirement and have to provide manufacturer transaction and shipment dates – are especially severe. Repackagers receive products from manufacturers and organize and segregate them by lot and NDC as a control so that they only repack products with the same NDC from the same lot. However, manufacturers often send the same lot of product in multiple shipments to the repackager. In order to be able to know a product’s transaction and shipment date for inclusion in TH, the repackager would have to begin segregating inventory by transaction/shipment date as well as lot and NDC, requiring dramatic changes to current inventory systems and repackaging operations with a heavy reliance upon manual labor. Logistically and operationally, it would be impossible for direct purchase repackagers to continue operations as they do today, in the physical space they have today, if they must provide TH on repackaged product back to the manufacturer’s original sale.
Data from a direct purchase repackager containing TH back to the manufacturer would also be confusing to a customer, particularly with respect to NDC number, lot number, and container size, each of which changes during the repackaging process. TH going back to the manufacturer would need to reflect the manufacturer’s NDC number, lot number and original container size (e.g., 100-count bottle) whereas the repackager’s TI would reflect a different NDC number, lot number, and packaging configuration (e.g., 10-count bottle). Competing and inconsistent information between the TH for the acquisition of the product and TI for the sale of the new product would be confusing, and make it more difficult for trading partners, including pharmacies and other dispensers, to identify whether transaction data are accurate. As discussed above, we also see little utility to it given that the original manufacturer’s package no longer exists.

Even assuming direct purchase repackagers could completely change how they receive and segregate product for repackaging (and we do not believe they can), alignment with the Draft Guidance would also require trying to change the content and format of the transaction data direct purchase repackagers have been providing to their wholesale distributor customers for over three years. Attempting these changes would severely burden the supply chain and divert scarce resources from 2019 verification and 2023 enhanced drug distribution security implementation.

Recalling that transaction data must be both provided and received, increasing the amount of and changing the data that must be provided in TH has a significant, and very negative, downstream impact as well. Systems, EDI transactions, trading partner connections, and portals were all designed three or more years ago to accommodate certain pieces of information in a certain number of fields. If a repackager were to change the data that it provides to include TH back to the manufacturer, its customer will not be able to receive that data without reconfiguring its system to accommodate the new data.

Where transaction data are provided via a portal, the impact upon wholesale distributors and dispensers is especially severe. Tens of thousands of dispensers rely upon portals built and maintained by their wholesale distributor suppliers to receive and store transaction data. HDA members report that the portals they provide for their dispensing customers cannot accommodate new data fields for TH without reconfiguring the entire platform.

Yet, these many changes to operations and data, and all this increased complexity and cost, and this diversion of effort from 2019 and 2023 implementation, would be solely to try to align with the Draft Guidance’s interpretation of DSCSA TH requirements – which sunset in 2023 by operation of law. § 582(k)(1). For the foregoing reasons, we recommend the following changes to Lines 522-524.

- The transaction information, which must include all of the information specified in section 581(26) of the FD&C Act, including the lot number of the product, transaction date, and shipment date, if more than 24 hours after the date of the transaction.

- The transaction history which must include all of the information specified in section 581(25) of the FD&C Act for each prior transaction going back to the
manufacturer, including the lot number of the product, transaction date, and shipment date. However, a repackager that repackaged product it purchased directly from the manufacturer is not required to provide TH back to the manufacturer.

- The transaction statement, as defined in section 581(27)(A)-(G) of the FD&C Act (see section V.C).

16. **Product Tracing Information an Exclusive Distributor Must Provide; HDA recommends a new section**

Part VI.C. treats an exclusive distributor as a wholesale distributor for purposes of product tracing information it must provide to a subsequent purchaser. While recognizing that an exclusive distributor is defined as a wholesale distributor (§ 581(6)), for the same reasons provided above regarding direct purchase repackagers, we believe that an exclusive distributor is more akin to a manufacturer than a wholesale distributor for purposes of assessing transaction data requirements as it stands in the shoes of the manufacturer and is the entity solely responsible for the introduction of the product into the supply chain. As such, HDA disagrees with the Draft Guidance to the extent that it would require an exclusive distributor to provide TH reflecting its initial purchase from the manufacturer.

With respect to provision of product tracing information, the supply chain has taken the position since the DSCSA’s enactment that the exclusive distributor need not provide TH that reflects its purchase of the product from the manufacturer when it transfers ownership to its customer. HDA explained this position in its Transaction Scenarios, made available to industry, FDA, and the public and expanded upon this interpretation in our October 1, 2014 letter to FDA and in previously submitted comments.12

As with the discussion above regarding direct purchase repackagers, we believe this interpretation comports with §582(c)(1)(A)(ii), which affords a wholesale distributor’s direct purchases from a direct purchase repackager or exclusive distributor the same status as those directly from the manufacturer and permits the subsequent wholesale distributor customer to provide abbreviated TI and TH when it resells the product.

We see the DSCSA as seeking to maintain current, secure supply chain relationships and practices until individual product serialization occurs, trading partners begin providing serialized data, and TH requirements eventually sunset. To that end, the manufacturer’s exclusive distributor is closely analogous to an authorized distributor of record (ADR) under the Prescription Drug Marketing Act (PDMA), §503(e), who was exempt from providing a pedigree identifying each prior

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purchase or sale of the drug. Further, under FDA’s articulation of its enforcement policy following the RxUSA case, a wholesale distributor that purchased from an ADR could start its pedigree with the ADR (that is, it did not have to provide pedigree back to the manufacturer).  

We believe further that there is little value to the TH that an exclusive distributor would provide. As we discussed in point 9, much of the static information about the product (name of product, NDC, dosage form/strength) is represented in the current TI the exclusive distributor would provide to its customer and would not need to be duplicated in TH. If treated as a distributor for purposes of its sale to a subsequent direct purchase wholesaler, the exclusive distributor would be exempt from providing the manufacturer’s transaction and shipment date or lot number. In fact, if treated as a manufacturer, an exclusive distributor would actually provide more information to its direct purchase wholesale distributor customer as it would have to provide the product’s lot number.

While we believe it is better to withdraw the Draft Guidance in its entirety, should FDA choose to re-issue the Draft Guidance, we suggest adding a new section describing what transaction data an exclusive distributor must provide. The new section should more closely align the obligations of exclusive distributors with the obligations of manufacturers and direct purchase repackagers, rather than with the obligations of wholesale distributors. We propose a new section to the Draft Guidance as follows:

**Product Tracing Information That an Exclusive Distributor Must Provide to a Subsequent Purchaser**

For the purposes of determining traceability obligations, the exclusive distributor acts as a manufacturer to the extent that it is an entity designated by the manufacturer to introduce the product into commerce. An exclusive distributor must provide the following product tracing information when it sells to a subsequent purchaser a product it purchased directly from the manufacturer:

- The transaction information, which must include all of the information specified in section 581(26) of the FD&C Act, including the lot number of the product, transaction date, and shipment date, if more than 24 hours after the date of the transaction.

- The exclusive distributor is not required to provide TH to its subsequent purchasers.

- The transaction statement, as applicable, as defined in section 581(27)(A)-(G) of the FD&C Act (see section V.C).

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While the obligations imposed upon exclusive distributors under the Draft Guidance would require modest changes to current systems, as explained in point 17 below, the impacts upon direct purchase wholesale distributors purchasing from exclusive distributors would be devastating.

17. Transactions Involving a Direct Purchase by Wholesale Distributors; Part C.1., Lines 536-552 state:

1. **What Product Tracing Information Must a Wholesale Distributor or an Exclusive Distributor Provide to a Subsequent Purchaser for Product That Was Purchased Directly From the Manufacturer?**

The wholesale distributor or exclusive distributor must provide the following:

- The transaction information, which must include all of the information specified in section 581(26) of the FD&C Act except the lot number of the product and the initial transaction and shipment dates from the manufacturer.

- The transaction history, which must include all of the information specified in section 581(25) of the FD&C Act for each prior transaction going back to the manufacturer except the lot number of the product and the initial transaction and shipment dates from the manufacturer.

- The transaction statement, as defined in section 581(27)(A)-(G) and which must also include a direct purchase statement (see section V.C).

**Comment and suggested revision:**

As discussed in point 16 above, we believe the better interpretation of the DSCSA, and now widely implemented in the supply chain, is that the manufacturer’s exclusive distributor is a manufacturer for purposes of providing transaction data and the exclusive distributor should provide to the subsequent purchaser the same TI that a manufacturer would, and no TH. Consequently, the references in Part C.1., Lines 536-552 regarding the information the exclusive distributor should provide as a wholesaler should be stricken.

HDA otherwise generally agrees with the presentation of the transaction data that a direct purchase wholesale distributor provides to a subsequent purchaser in Part C.1., Lines 540-552. However, we believe elements of this section would benefit from clarification.

We believe that Lines 542-544 should not reference that TI need not include initial transaction and shipment dates from the manufacturer. Information regarding the wholesale distributor’s initial purchase from the manufacturer are elements of TH and should not be reflected in, and are not relevant to, the current TI it is providing to a subsequent purchaser. Initial transaction
dates and shipment dates from the manufacturer would be provided, when required, in TH. We recommend this language be deleted.

Also, as discussed in points 9 and 16 above, we strongly believe that TH should not have to duplicate what is already represented in TI for the current transaction or information about the product that does not change throughout the transaction. Of the ten TI elements, product name, strength and dosage form, NDC, container size, number of containers,\(^{14}\) transaction date, date of shipment (if more than 24 hours), and business name and address of seller and buyer, are all represented in the current TI for the transaction and/or do not change through all transactions of the product. Further, direct purchase wholesale distributors are exempt from having to provide lot number, the date on which it purchased the product from the manufacturer, and the date the product was shipped from the manufacturer. § 582(c)(1)(A)(ii)(II). Consequently, the only TH that the direct purchase wholesale distributor must provide to its subsequent purchaser is the business name and business address of the manufacturer that sold it the product. We believe the Draft Guidance also suggests direct purchase wholesale distributors are obligated to provide more data in TH than is legally required.

We, therefore, recommend the following changes to Lines 536-552:

1. *What Product Tracing Information Must a Wholesale Distributor or an Exclusive Distributor Provide to a Subsequent Purchaser for Product That Was Purchased Directly From the Manufacturer?*

The wholesale distributor or exclusive distributor must provide the following:

- The transaction information, which must include all of the information specified in section 581(26) of the FD&C Act except the lot number of the product and the initial transaction and shipment dates from the manufacturer.

- The transaction history, which must include all of the information specified in section 581(25) of the FD&C Act for each prior transaction going back to the manufacturer except the lot number of the product and the initial transaction and shipment dates from the manufacturer. **However, the transaction history does not need to repeat information if it is already represented in the current transaction information that the wholesale distributor provides to its subsequent trading partner, such as the product’s proprietary or established name, strength and dosage form, NDC number, and container size.**

\(^{14}\) As discussed in point 6, we do not believe that a wholesale distributor or other direct purchaser from the manufacturer should (or even could) include the number of containers it received from the manufacturer. We believe “number of containers” refers to the number of containers in the current shipment that the wholesale distributor or other direct purchaser from the manufacturer sells to its downstream customer; this number does need to be provided in TH as it is reflected in current TI.
18. Transactions Involving a Direct Purchase by Wholesale Distributors from the Manufacturer’s Exclusive Distributor or Direct Purchase Repackager; Part C.2., Lines 554-573 state:

2. What Product Tracing Information Must a Wholesale Distributor Provide to a Subsequent Purchaser for Product That Was Purchased Directly From the Manufacturer’s Exclusive Distributor or From a Repackager That Purchased Directly From the Manufacturer?

The wholesale distributor must provide the following:

- The transaction information, which must include all of the information specified in section 581(26) of the FD&C Act except the lot number of the product.

- The transaction history, which must include all of the information specified in section 581(25) of the FD&C Act for each prior transaction going back to the manufacturer except the lot number of the product and the initial transaction and shipment dates from the manufacturer. The transaction history should include the transaction date, shipment date, and the business name and address of the trading partner from whom the wholesale distributor received ownership (either the manufacturer’s exclusive distributor or the repackager who purchased directly from the manufacturer).

- The transaction statement, as defined in section 581(27)(A)-(G) and which must also include a direct purchase statement (see section V.C).

Comment and suggested revision:

We disagree with the Draft Guidance’s conclusion that wholesale distributors selling product that was purchased from a manufacturer’s exclusive distributor or direct purchase repackager must provide TH reflecting the exclusive distributor’s or direct purchase repackager’s initial purchase from the manufacturer. As discussed above and extensively in our 2014 comments and letter to the Agency, we believe that the transaction history a wholesale distributor provides a subsequent customer should be the same regardless of whether the wholesale distributor purchased the product directly from the manufacturer, the manufacturer’s exclusive distributor or the manufacturer’s direct purchase repackager.

Requiring a wholesale distributor that purchased from an exclusive distributor or direct purchase repackager to provide TH back to the manufacturer is at odds with the direct purchase option in § 582(c)(1)(A)(ii). Section 582(c)(1)(A)(ii) treats a wholesale distributor’s subsequent sale
to a customer the same regardless of whether it purchased the product from the manufacturer, or purchased the product from the manufacturer’s exclusive distributor or direct purchase repackager. We believe the intent of this provision in the DSCSA was to recognize that a wholesale distributor’s purchase from the manufacturer’s exclusive distributor or direct purchase repackager shares the same qualities of security, accountability, and credibility as the wholesale distributor’s purchases direct from the manufacturer. Certainly, § 582(c)(1)(A)(ii) makes no distinction among the three types of purchases. The widely used Transaction Scenarios, made publicly available, including to FDA in 2014, took the same position that, where a wholesale distributor purchased directly from the manufacturer, the manufacturer’s exclusive distributor or the manufacturer’s direct purchase repackager, TH was first provided with the wholesale distributor’s sale to its customer and reflected its acquisition of product from the manufacturer, exclusive distributor or direct purchase repackager.

The interpretation set forth in the Draft Guidance – that TH must include data going back to the initial purchase from the manufacturer – in fact burdens direct purchase wholesale distributors more than wholesale distributors that are not purchasing from entities that directly purchased from the manufacturer.

As Lines 590-592 make clear, in subsequent transactions of a product after a direct purchase, a secondary wholesale distributor need only provide to its customer TH back to the initial wholesale distributor and does not have to provide TH going back to the manufacturer’s first sale. It is illogical to burden a wholesale distributor who directly purchased from an exclusive distributor or direct purchase repackager by requiring it to trace the product back to the original manufacturer while, in contrast, its customers need only trace back TH to the direct purchase wholesale distributor from whom they purchased the product. We do not believe the DSCSA should be interpreted as permitting a non-direct purchase wholesale distributor to provide a more abbreviated TH than a direct purchase wholesale distributor.

To align with the Draft Guidance, a wholesale distributor would have to segregate and identify each shipment of product delivered in order to link those units to their transaction and shipment dates; without this segregation of every incoming shipment by delivery date, a wholesale distributor would not be able to generate appropriate TH when subsequently selling the units. For wholesale distributors, current business operations are not conducted in this manner, at all.

Significant warehousing practices would have to change and systems would have to be developed so that hundreds, thousands or tens of thousands of products from exclusive distributors and direct purchase repackagers could be manually segregated and matched to incoming TI, every day. In the absence of serialization, aggregation, and not yet developed data exchange methods, warehouses would have to be physically expanded and reconfigured, at great expense and disruption during construction, for enormous manual sorting and matching operations. There is simply no way such a system could be implemented in the typical warehouse without severely impacting the steady, rapid flow of pharmaceuticals to dispensers.

We believe that the DSCSA is best read as maintaining current, primary business operations as much as possible during the statute’s complex, 10-year implementation. The Draft Guidance is at odds with that reading of the DSCSA and would add dramatic and costly business changes to the
very significant effort necessary to realize the DSCSA’s mandate of full traceability by 2023. And all this would have to be done to comply with an interpretation of a requirement that sunsets in 2023.

As discussed previously, in addition to the profoundly disruptive changes to warehouse and receiving operations, trading partners will also have to change the transaction data that has been provided between trading partners over the last three years. Supply chain stakeholders would have to halt 2019 and 2023 efforts and try to determine how to track product at a shipment level when receiving processes cannot and have never identified product shipment dates or transaction dates once products enter warehouses. At this point we believe that diverting resources to attempt to align current business and data exchange practices with the Draft Guidance would likely delay the supply chain’s ability to meet the serialized data and other 2019 and 2023 electronic exchange deadlines.

Also, to reiterate a theme in point 15 above, the Draft Guidance imposes significant burdens upon those who would have to receive the additional TH. The systems, EDI transactions, and portals trading partners currently use, and have used for the last three years, were not designed for a whole other, secondary, level of TH. Many direct purchase wholesale distributor customers are retail pharmacies that have elected to receive their transaction data through portals that the wholesale distributor maintains. HDA members report that currently none has a portal that can accommodate more fields for TH going back to the manufacturer. All these modes of providing transaction data would have to be reconfigured.

We oppose undertaking such an enormous effort, particularly when TH sunsets in 2023. Accordingly, we recommend the following changes to Lines 559-573.

The wholesale distributor must provide the following:

- The transaction information, which must include all of the information specified in section 581(26) of the FD&C Act except the lot number of the product.

- The transaction history, which must include all of the information specified in section 581(25) of the FD&C Act for each prior transaction going back to the manufacturer’s exclusive distributor or repackager that purchased directly from the manufacturer except the lot number of the product and the initial transaction and shipment dates from the manufacturer’s exclusive distributor or repackager that purchased directly from the manufacturer. The transaction history should include the transaction date, shipment date, and the business name and address of the trading partner from whom the wholesale distributor received ownership (either the manufacturer’s exclusive distributor or the repackager who purchased directly from the manufacturer). However, the transaction history does not need to repeat information if it is already represented in the current transaction information that the wholesale distributor provides to its subsequent trading partner, such as the product’s proprietary or established name, strength and dosage form, NDC number, and container size.
The transaction statement, as defined in section 581(27)(A)-(G) and which must also include a direct purchase statement (see section V.C).

19. **Drop Shipments to Dispensers; Lines 605-617 state:**

In drop shipment situations, section 582(f) of the FD&C Act allows wholesale distributors that do not physically handle or store product to be exempt from certain provisions of section 582 of the FD&C Act, provided that the manufacturer, repackager, or other wholesale distributor that distributes the product provides the contact information of the wholesale distributor on whose behalf the product was distributed. In these situations, [the] contact information of the wholesale distributor on whose behalf the product was distributed must be included on the transaction information and transaction history provided to the dispenser, and should consist of the wholesale distributor’s business name, address, and email address and/or phone number.

If a wholesale distributor and the trading partner that conducts the drop shipment directly to the dispenser do not exercise the exemption under 582(f), the wholesale distributor should provide the product tracing information to the dispenser as required under section 582(c).

**Comment and suggested revision:**

We appreciate FDA’s effort in the Draft Guidance to interpret “contact information” to mean that the manufacturer, repackager or other wholesale distributor should provide to the dispenser the wholesale distributor/product owner’s business name, address, and email and/or phone number. However, we believe that this is a matter where FDA interpretation is unnecessary and the issue is best left for trading partners to resolve as a business matter. HDA members report that in the last three years, wholesale distributors have worked with their trading partners to agree upon suitable contact information and it has become customary to not provide addresses, emails, and phone numbers with drop shipments. Providing an individual name and contact information is more burdensome than helpful; uncertainty will also arise over what address to provide, *e.g.*, corporate office, distribution center, etc. In the experience of trading partners, since 2015, providing only the wholesale distributor’s name has been sufficient in drop shipment transaction data.

Further, we believe Lines 605-617 could better reflect the limited role that a wholesale distributor has in typical drop shipment situations, and could be more closely aligned with § 582(f), the drop shipment section.

We recommend the following changes to Lines 605-617.

In drop shipment situations, under section 582(f) of the FD&C Act, the manufacturer, repackager, or other wholesale distributor that distributes the
product on behalf of a wholesale distributor must provide to the dispenser customer the transaction information, transaction history (if any), and transaction statement, and exempts allows wholesale distributors (on whose behalf the drop shipment is made) that do not physically handle or store product to be exempt from having to provide transaction data to the dispenser customer and from certain other provisions of section 582 of the FD&C Act. The, provided that the manufacturer, repackager, or other wholesale distributor that distributes the product must provides the contact information of the wholesale distributor on whose behalf the product was distributed. In these situations, the contact information of the wholesale distributor on whose behalf the product was distributed must be included on in the transaction information and transaction history (if any) provided to the dispenser, and should consist of the wholesale distributor’s business name, address, and email address and/or phone number.

If a wholesale distributor and the trading partner that conducts the drop shipment directly to the dispenser do not exercise the exemption under 582(f), the wholesale distributor should provide the product tracing information to the dispenser as required under section 582(c).

20. Grandfathering, Section VI.F.; Lines 620-662:

Given the length of this discussion, we do not quote Section VI.F. here but reprint it only once below with our suggested, substantial edits.

Comment and suggested revision:

Section VI.F. describes FDA expectations for product tracing requirements for products that entered the supply chain prior to January 1, 2015. As first discussed in point 1 above, we believe there are excellent arguments in support of deleting Section VI.F. entirely. First, it is highly unlikely that many pharmaceuticals that entered the supply chain over three years ago remain in saleable inventory. In our experience, wholesale distributor inventory typically turns over within a matter of days or weeks. Even relatively slow-moving products typically do not remain in saleable inventory for years. Wholesale distributors often return unsold products that are close to expiry date to the manufacturer (or the manufacturer’s agent) for credit. Similarly, dispensers generally are unlikely to dispense or administer such older drugs and frequently return them to their supplier for credit or arrange for their disposition.

Second, we believe the Agency has better and more thoughtfully addressed the treatment of grandfathered product – in this case, product already in the supply chain without product identifiers – in the Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier.15

In sum, we believe that § 582(a)(5)(B) has sufficiently guided the supply chain through the sell-down of pre-2015 inventory and that Section VI.F. is unnecessary and needlessly complicates transactions that occurred long ago. HDA recommends, as the preferred action, that FDA delete the entirety of the grandfathering discussion in Part IV.F., Lines 620-662. If Part IV.F. is not deleted entirely, we recommend that the section align more closely with § 582(a)(5)(B).

Section 582(a)(5)(B) of the FD&C Act addresses the tracing requirements for products that entered the pharmaceutical distribution supply chain before January 1, 2015 (pre-2015 products). The section exempts authorized trading partners from the requirement to provide transaction information for pre-2015 products under sections 582(b)(1)(A)(i), (c)(1)(A)(ii), (d)(1)(A)(ii), and (e)(1)(A)(ii) of the FD&C Act. It also requires that the transaction history for a pre-2015 product begin with the product’s owner on January 1, 2015 (initial owner). In addition, section 582(a)(5)(B)(iii) exempts the initial owner of pre-2015 product from asserting in a transaction statement that it received transaction information and a transaction statement from the prior owner of the product. FDA recommends that trading partners follow the practices set forth below when providing product tracing information for pre-2015 products.

1. Transaction Information

Pursuant to section 582(a)(5)(B)(i), authorized trading partners shall be exempt from providing transaction information as required under section 582 for pre-2015 products. A trading partner should inform subsequent purchasers that the transaction involves pre-2015 product and that the trading partner is exempt from providing transaction information for such product pursuant to section 582(a)(5)(B)(i) of the FD&C Act. FDA recognizes that some trading partners will provide transaction information to subsequent purchasers of pre-2015 product even though they are exempt from doing so under section 582(a)(5)(B)(i), in the interest of supply chain security. In these situations, FDA recommends that the trading partner inform subsequent purchasers that the transaction information is for a pre-2015 product.

2. Transaction History Omitting Certain Elements

Pursuant to section 582(a)(5)(B)(ii), the transaction history for pre-2015 product may begin with the owner of such product on January 1, 2015, that an initial owner provides to a subsequent purchaser of pre-2015 product (second owner) starts with the initial owner. For all transactions after the initial owner-second owner transaction, the transaction history that is provided to a subsequent purchaser of pre-2015 product should go back to the product’s initial owner.
3. Transaction Statement

Pursuant to section 582(a)(5)(B)(iii), the owners of such product on January 1, 2015 shall be exempt from asserting receipt of transaction information and transaction statement from the prior owner as required under section 582. An initial owner is required to provide a transaction statement to a subsequent purchaser but, pursuant to section 582(a)(5)(B)(iii) of the FD&C Act, is not required to assert in that transaction statement that the initial owner “received transaction information and a transaction statement from the prior owner of the product, as required under section 582.” Although this statement described in section 581(27)(C) of the FD&C Act may, as a result, be absent from a transaction statement received from the initial owner, the absence of this statement will not prevent a trading partner that purchases pre-2015 product from the initial owner from having received the transaction information and transaction statement that is required under section 582. When this trading partner transfers ownership of the product to a subsequent purchaser, it must provide a transaction statement that includes the statement set forth in section 581(27)(C).

* * *

HDA thanks FDA for this opportunity to comments and suggestions on FDA’s Draft Guidance. If you have any questions, please contact me at 703-885-0240 or at aducca@hda.org.

Sincerely,

Anita T. Ducca
Senior Vice President, Regulatory Affairs

Attachments