



Healthcare Distribution Alliance

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Re: Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act; Public Meeting; Request for Comments, 86 Fed. Reg. 57435 (Oct. 15, 2021), Docket No. FDA-2021-N-1004

Dear Dr. Jung:

The Healthcare Distribution Alliance (HDA) thanks the Food and Drug Administration (FDA) for this opportunity to submit comments regarding the Agency's public meeting on November 16, 2021 and subsequent request for comments. Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act; Public Meeting; Request for Comments, 86 Fed. Reg. 57435 (Oct. 15, 2021). We greatly appreciate the ongoing dialogue with the Agency on implementation of the Drug Supply Chain Security Act (DSCSA).

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.

The purpose of the public meeting, in substantive part, was to provide a forum for discussion of "enhanced drug distribution security at the package level" and the FDA's recently issued Draft Guidance, *Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act* (EDDS Draft Guidance). We previously submitted extensive comments to the EDDS

Draft Guidance, available [here](https://www.regulations.gov/comment/FDA-2020-D-2024-0017), <https://www.regulations.gov/comment/FDA-2020-D-2024-0017> (referred to hereafter as “HDA EDDS Draft Guidance Comment” or “prior EDDS comments”). In those comments, we expressed grave concerns regarding many aspects of the EDDS Draft Guidance. In brief, HDA noted that EDDS Draft Guidance (i) does not clearly articulate the essential requirements for 2023 compliance, (ii) is inconsistent (in many respects) with the requirements set forth in the DSCSA, and (iii) is inconsistent (in other respects) with compliance characteristics that the supply chain has been implementing.

In our view, the EDDS Draft Guidance seems to set out a vision for a “system” that does not exist, is not being built, is not required by the statute, and cannot be built in time to meet the 2023 deadlines even if it were statutorily mandated. For those and other reasons, we urged the Agency to withdraw the EDDS Draft Guidance.

We appreciate that the Agency has attempted to clarify the EDDS Draft Guidance in oral statements and presentations given at the October 5, 2021, Small Business and Industry Assistance (SBIA) conference, at HDA’s own Traceability Conference on November 1, 2021, and at the November 16, 2021 public meeting. However, and after considered discussion with HDA’s members and other stakeholders, HDA continues to be of the view that the vision FDA appears to have for “enhanced drug distribution security at the package level” is inconsistent with the DSCSA and, as a result, is not what the industry is working to implement for compliance with the DSCSA’s 2023 requirements. Accordingly, HDA reluctantly renews its request for the Agency to withdraw the EDDS Draft Guidance.

In our comments below, we address the following:

- The need for grandfathering of products and homogenous cases that were placed into the supply chain before November 27, 2023 without their product identifiers included in Transaction Information (TI).
- The “enhanced system,” “system structure” and “communication hub” referenced by the Agency in the EDDS Draft Guidance and presentations.
- The compliance risks and barriers to implementation that arise from the EDDS Draft Guidance and the Agency presentations regarding it and the “enhanced system.”
- Potential application of FDA’s Good Manufacturing Practices (GMP) regulations to wholesale distributors and dispensers.
- Responses to tracing requests from trading partners.
- Using the “same system” for both verification and provision of transaction data.
- Product “status.”
- Inference, aggregation and scanning on inbound receipt.
- Resource and labor constraints and challenges.

1. Grandfathering Product In The Supply Chain On November 27, 2023

We wish to elaborate upon an upcoming “grandfathering” challenge involving covered products bearing DSCSA-mandated product identifiers that are sold and purchased after November 27, 2023, where the product’s identifier was not included in transaction data provided/received prior to November 27, 2023. This concern was discussed as early as 2017 in FDA public meetings and it was raised anew, with heightened urgency, at our Traceability Seminar and at FDA’s public meeting. This grandfathering issue is analogous to the transition that occurred in 2016-2018 when products

and homogenous cases with identifiers were in the supply chain alongside products and homogenous cases that did not have identifiers.

From the perspective of wholesale distributors, the articulation of the concern is straightforward:

- On November 27, 2023, TI for each product transaction must include “the product identifier at the package level for each package included in the transaction.” § 582(g)(1)(B).
- HDA understands that its wholesale distributor members intend, for each downstream product transaction (that is, a sale to a customer), to scan the product identifier on each package (or homogenous case if a sealed case is sold). The scan will then populate the TI with the product identifier(s) that will then be included in the transaction data provided to the distributor’s customer.
- Prior to sale to the downstream customer, the wholesale distributor will also check the scanned identifier against the data *it received from the seller* to ensure that it received transaction data from the seller for that package (or sealed homogenous case). In addition to assuring receipt of the package or sealed homogenous case and its data, this confirmation will also help ensure that the wholesale distributor will be able to respond to an appropriate tracing request. Additionally, should the package or sealed homogenous case be returned, the wholesale distributor will be able to associate the product identifier(s) to the transaction data of the original sale as required by § 582(g)(1)(F).
- However, sellers are not required to include product identifiers in TI prior to November 27, 2023. This means that the wholesale distributor, when preparing to ship a product to a dispenser/customer, will not be able to match its outbound product identifier with inbound received data, resulting in a mismatch and an internal error.
- Given the expiration dating on products and rates of inventory turnover, wholesale distributors expect that the problem will persist into 2025.

This period of time where the identifiers on some products and homogenous cases can be matched to inbound, received TI, and some cannot, is a simple artifact of product expiration dating, rates of inventory turnover, and the DSCSA’s staggered implementation, rather than due to a true problem with the product or its identifier. Similar issues arose as products and cases bearing identifiers were slowly introduced into commerce and there were, simultaneously in the supply chain, products and homogeneous cases both with and without product identifiers. In September 2018, FDA issued a grandfathering policy clarifying the status of products and homogenous cases packaged before November 27, 2018 and already in the supply chain after that date that did not bear identifiers:

A package or homogenous case of product that is not labeled with a product identifier shall be grandfathered where there is documentation that it was packaged by a manufacturer or repackaged by a repackager before November 27, 2018. For example, if a package or homogenous case of product not labeled with a product identifier is accompanied by transaction information or a transaction history that includes a sale before November 27, 2018, that trading partner can reasonably conclude the product was packaged by a manufacturer or repackaged by a repackager before that date.

If the transaction information or transaction history does not include a sale before November 27, 2018, and absent other indicia that a product may be suspect or illegitimate, the transaction statement is one indication that the product was in the

pharmaceutical distribution supply chain before that date. Furthermore, since manufacturers and repackagers retain packaging date information in the ordinary course of business, they should provide the packaging date to any trading partner who owns the product if they request it.

Guidance for Industry, [Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier](#) (Sept. 2018) (internal footnotes omitted) at page 5.

We believe this flexibility and grandfathering are appropriate for all other product identifier-related DSCSA requirements. We hope to see grandfathering extended to packages and homogenous cases in the supply chain before November 27, 2023, that, though they bear a product identifier, will have been purchased and sold prior to November 27, 2023, without that product identifier included in TI. This exercise of enforcement discretion will be necessary so that needed medicines can continue to move through the supply chain without compromising supply chain security and patient safety.

To minimize supply disruptions during this transition, HDA's wholesale distributors are trying to onboard their manufacturer suppliers as soon as possible and are urging their suppliers to begin providing product identifiers in their TI data months before the November 27, 2023, deadline. In this way, by the time the requirement is in effect, a significant part of a wholesale distributor's inventory will be capable of being matched with inbound TI product identifiers. This, in turn, means that once wholesale distributors begin scanning product identifiers on outbound sales and including those identifiers in the TI they generate for their customers, they will have those product and case identifiers in their transaction data repositories for seamless matching and documentation of changes of ownership. Wholesale distributors will also be able, at the item level, to associate a returned product to the TI that accompanied that product when the wholesale distributor first sold that product to the dispenser that initiated the return.

However, and as discussed further below and in our EDDS Draft Guidance Comment, the effort to establish and stabilize the EPCIS¹-enabled connections between wholesale distributors and their manufacturer suppliers that will support the transmission of the product identifier within the TI has been moving very slowly. There will unquestionably be products, potentially a significant number of products, in wholesale distributors' inventory on November 27, 2023, that were lawfully transacted but not accompanied by product identifiers in the TI provided.

We believe a good starting point for addressing this transition is the language quoted above from the September 2018 Grandfathering Guidance. A trading partner should be able to sell a product or sealed homogenous case where it did not receive product identifiers for the product or sealed homogenous case at the time of the transaction, so long as there are no other indicia that the product or case is suspect or illegitimate.

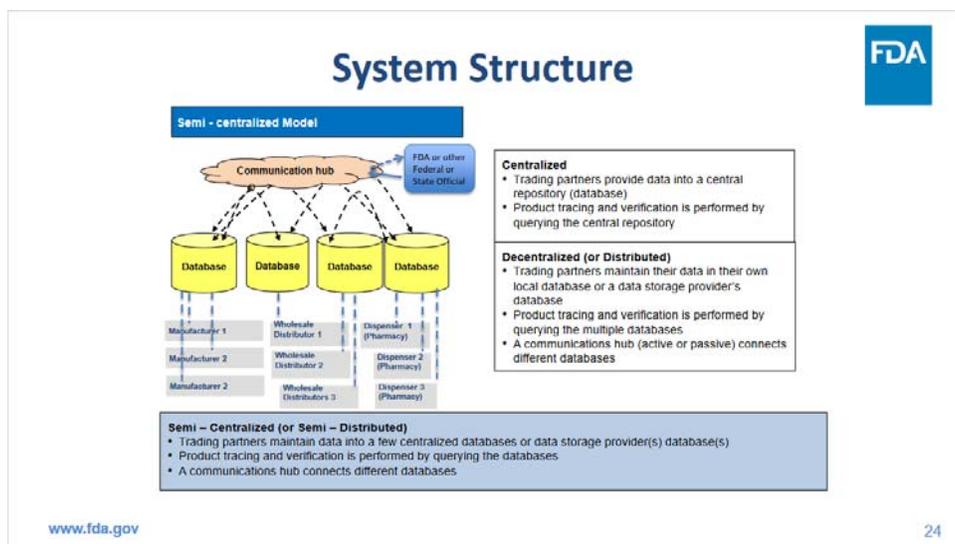
We welcome the opportunity to engage with FDA and other stakeholders on this important issue.

¹ Electronic Product Code Information Services (EPCIS) is a GS1 standard that enables trading partners to share information about the physical movement and status of products as they travel throughout the supply chain.

2. Continuing Concerns About The “Enhanced System,” “System Structure” And The “Communication Hub”

a. An “Ecosystem” Not “A System” Or “The System”

FDA has recently presented its concept of “System Structure” for 2023 and noted that it recognizes industry has moved to a “semi-centralized” and/or “decentralized” model. We believe the following slide on “System Structure” first appeared at the [October 5 SBIA webinar](#) as slide 22 and was presented at the November 16 public meeting [on slide 24 of the posted meeting materials](#).



FDA presented a similar slide at the HDA traceability seminar.

We appreciate FDA’s recognition that the industry is not implementing a centralized system in which all trading partners send their transaction data to a centralized repository. At times, the Agency also has appeared to orally acknowledge what actually exists – an **ecosystem in which thousands of individual companies privately own and maintain systems for the holding of their own transaction data**. Moreover, even a single company may not have all its transaction data in one data repository. For instance, many dispensers will look to their suppliers to hold and maintain their transaction data. As many dispensers purchase from multiple suppliers, these dispensers will likely have their transaction data similarly residing in multiple repositories.

Even with different data repositories in a decentralized “ecosystem of systems,” DSCSA-compliant interoperability will still be achieved in 2023. As we stated in our Comment on the EDDS Draft Guidance on page 12, “With each trading partner using EPCIS under a common, international, GS1 standard, these different systems become interoperable in that they are able, in a **business-to-business**, trading partner-to-trading partner connection, to electronically share standardized data sets, enabling the sending and receiving of TS and TI (with product identifiers) and, which will, in turn, enable traceability” (emphasis in original).

However, we believe that slide 24 and other slides and FDA statements continue to support or to signal an expectation of a single “system” for 2023 that does not exist and is not being built. For instance, FDA presented the following slide on November 16, October 5, and in other presentations:

The slide features the FDA logo in the top right corner. The main title is "The Drug Supply Chain Security Act DSCSA" in a large, bold, blue font. Below the title is a bulleted list of four points. At the bottom left is the URL "www.fda.gov" and at the bottom right is the number "9".

- Enacted November 27, 2013
- Outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the U.S.
- Enhances ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful
- Improves detection and removal of potentially dangerous drugs from the drug supply chain

FDA presents a 2023 end-state showing “an electronic, interoperable **system** to identify and trace certain prescription drugs as they are distributed in the U.S.” (emphasis supplied). Slide 32 contains similar language, describing that, by November 27, 2023, there will be an “electronic” “interoperable” “System across the pharmaceutical distribution supply chain.”



As has been explained numerous times in comments and presentations to the Agency by many stakeholders, there is **no** single “system.” We appreciate that the Agency has stated more guidance is forthcoming² that may elaborate further upon what it means by a “system.” However, thus far, these Agency statements and presentations have not illuminated the EDDS Draft Guidance. Moreover, unfortunately, this circumstance also perpetuates confusion and anxiety about what

² As stakeholders have also pointed out, at this late stage, any guidance that fundamentally differs from what industry has adopted and implemented is likely to cause even greater consternation and delay. Any further divergence or distractions will imperil the industry’s ability to meet 2023 requirements at all – as is evident from how long it is taking to establish the necessary EPCIS connections between manufacturers and wholesalers. Without those connections, there will be no electronic, interoperable data to exchange, and no data to respond to tracing requests.

“system” FDA believes exists and whether the Agency deems the enormous and costly effort industry is undertaking as compliant with 2023 requirements.

We note further that the Agency’s repeated statements of the “system” or “enhanced system” are not in fact what the DSCSA states. Section 582(g)(1) refers to “enhanced drug distribution **security**” (emphasis supplied) **not** “enhanced **system**.”

b. The Functionalities That Seem To Be Expected Are Not The Reality Now And Are Not Achievable By 2023

Slide 9 from the November public meeting (above) is concerning for other reasons. Slide 9 states that the enhanced “electronic, interoperable system” will “**identify and trace** certain prescription drugs **as they are distributed in the U.S.**” (emphasis supplied). The Agency seems to be saying that the “system” will be able to track a drug as it moves through the supply chain, with, presumably, some arrangement for ongoing access to transaction data by regulators and/or trading partners as drugs are purchased and sold. While we may have misinterpreted the Agency’s intent, we want to be clear that this is not, in any way, what the DSCSA requires and is not what industry is building. There is no effort underway to build this kind of active or real-time surveillance system that can “identify” and “trace” or track product as it is “distributed” through the U.S. supply chain.³

Tracing, as contemplated in the DSCSA, is a retrospective act done to identify who owned a drug and who a drug was sold to. It does not track where a drug is. Indeed, the DSCSA does not require trading partners to record changes in a drug’s physical location at all; only changes in ownership must be reflected in transaction data.

Additionally, at times the Agency has presented functionalities of the “enhanced system” as something that will be achieved in a post-2023 future state. Slides 17 and 20 from the November meeting, for instance, use this type of phrasing. Numerous stakeholders have emphasized previously in oral and written comments that this perpetual projection beyond what is necessary for 2023 compliance is harming the efforts to meet 2023 deadlines at all.⁴

Even if the attributes of this “enhanced system” were required for 2023 compliance, and we do not believe they are, they are not achievable in the time we have left. As we have previously reported to FDA, it is taking four to ten weeks for a wholesale distributor to establish and stabilize the EPCIS connection with a single manufacturer supplier – and a wholesale distributor typically has hundreds of manufacturer suppliers. And then, wholesale distributors must begin establishing the connections with dispenser customers in order to be able to provide TI that includes product identifiers.⁵

At this late stage, discussions of post-2023 possibilities are distractions that imperil the ability of industry to do what **is** required. If stakeholders are going to meet the requirements that become effective on November 27, 2023, we must remain focused on being able to interoperably exchange transaction data with product identifiers. Without this fundamental building block, neither the tracing

³ A related point, that the DSCSA does not require or provide for continual reporting of a drug’s “status,” is discussed further below.

⁴ HDA raised this point in comments to Dkt. No. FDA-2020-N-1862, 86 Fed. Reg. 15685 (March 24, 2021), as recently as June 2021.

⁵ We believe that many dispenser customers will rely upon their wholesale distributor or service provider to electronically provide TI data into a portal which the dispenser can access, without the need for establishing the point-to-point electronic connection that EPCIS requires.

necessary for compliance nor any post-2023 “nice-to-haves” (that trading partners may choose to voluntarily build) can be implemented.

The presentations and slides continue a concern HDA and other stakeholders raised with the EDDS Draft Guidance – a fundamental misalignment between what the Agency is describing and what industry is doing. When presenting at the public meeting, Dr. Bernstein of the American Pharmacists Association (APhA) reiterated that, while the single, enhanced system was something the Agency at one time envisioned, it does not reflect current reality. She urged the Agency to pivot and acknowledge what industry is actually building for 2023 and that it is compliant.

c. Industry Is Building A Decentralized System And There Is No “Communication Hub”

Returning to the System Structure concept (slide 24 from the November public meeting and slide 22 at the October SBIA webinar) identified above, the Agency recognizes that industry is not contemplating a “centralized system.” Beyond this recognition, however, the “System Structure” FDA describes on slide 24 becomes muddled. There appears, incorrectly, to be no discernible difference between the “decentralized” and “semi-centralized” systems except in the number of databases where transaction data reside.

Slide 24 does not reflect the truly “decentralized” system that industry is building and implementing for 2023 compliance. As stated above and in HDA’s EDDS Draft Guidance Comment, in the decentralized system, each trading partner owns and controls its transaction data and, in response to appropriate tracing requests, will provide the TI and Transaction Statement (TS) or other information. This is not what slide 24 represents graphically.

Rather, slide 24 shows that both the “decentralized” and “semi-centralized” systems have a “communication hub” that links government regulators to each trading partner’s transaction data repository (whether its own or one the trading partner’s data service/storage provider maintains). FDA referred to this “communication hub” in presentations at the October 5 SBIA webinar, HDA’s traceability seminar, and the November public meeting.

We have speculated that the “communication hub” and Slide 24 assume that there will be an expansion of the Verification Router Service (VRS) from product identifier verification to also support communication of tracing requests and provision of responses. The VRS is useful and functional for verification of product identifiers and the experience of creating it has been enormously helpful in informing the effort underway to meet 2023 requirements. As we explained on pages 13-15 of our Comment on the EDDS Draft Guidance, however, the VRS cannot be the “enhanced system” envisioned in the EDDS Draft Guidance. Nor can it serve as the “communication hub” to communicate tracing requests and responses. The VRS does not, and was not foundationally designed to, support interoperable tracing or data exchange.

While there is no specific reference to such a hub in the EDDS Draft Guidance, lines 201-202 do state, “The enhanced system should allow FDA and other Federal and State officials to communicate with trading partners’ individual systems and receive relevant information upon request.” The “communication hub” depicted in the slides is, possibly, intended as a representation of what is suggested in the EDDS Draft Guidance – an electronic interface that connects all regulators to all proprietary databases and that supports sending, receiving, and responding to government-initiated tracing requests.

But this is supposition. FDA has not explained what this communication hub is, or who is building it, funding it or maintaining it. If this is intended as a system-to-system connection, as the graphic appears to indicate, we believe it represents an unprecedented federal encroachment into the proprietary, highly confidential, and highly secure systems of regulated industry – and, as such, has no basis or support in the DSCSA.⁶ Nothing in the DSCSA’s requirement that TI and TS be exchanged in a secure, interoperable, electronic manner in accordance with standards (§ 582(g)(1)(A)) suggests that regulators and/or law enforcement should have direct and unfettered access to a trading partner’s proprietary transaction data.

What is known of the “hub” comes solely from the FDA oral presentations. It seems the Agency is assuming that there is a technology that will allow federal and state regulators to establish a system-to-system connection with the transaction data repository of each DSCSA trading partner in the U.S. pharmaceutical supply chain. We are aware of no such interface being built; there are no standards under development to support this messaging function of sending, responding to, and receiving tracing requests. We agree that a tracing request message between regulator and industry could be standardized. However, wholesale distributors rigorously protect this highly confidential data, and ***even internally within their own companies severely restrict who may access it***. We join with others who do not support a regulator’s direct access to internal trading partner data repositories or communications systems.⁷

The communication hub references reinforce our concerns that the Agency is contemplating some system and functionality that does not exist, is not being built, is not required by the law, and, even if it were required, could not be built by 2023.

3. The Agency’s Draft Guidance, Recommendations And Statements Have Serious Consequences For Regulated Industry

a. Compliance Risks

In our prior EDDS comments, and again in oral testimony at the public meeting on November 16, HDA emphasized that regulated industry rightfully takes FDA guidances very seriously. “State inspectors, auditors, trading partners, and even other FDA personnel often treat FDA guidances as legally binding (or at least highly authoritative) and any entity that does not follow them is often deemed to be out of compliance.” HDA EDDS Draft Guidance Comment at page 22. It is the experience of some HDA members that state regulators look to and follow FDA guidances even though a guidance states it is “draft” or is “non-binding” or contains only “recommendations.”

Having heard FDA’s presentations and participated in the public meeting, we continue to be “especially concerned that state regulatory authorities will delay or deny licensure because wholesale distributors and other trading partners are not participating in the ‘enhanced system’ with the functionalities described in the Draft Guidance – a system that does not exist and which the DSCSA does not require.” HDA EDDS Draft Guidance Comment at page 22; see *also* pages 10-13. Our

⁶ We note that setting forth expectations for 2023 DSCSA compliance through PowerPoint and other presentations would also not be compliant with the Administrative Procedure Act (APA), the Agency’s Good Guidance Practices regulation, and similar requirements applicable to the Agency’s regulatory or guidance developments.

⁷ See, e.g., page 37 of November 16 meeting materials and the presentation by the Pharmaceutical Distribution Security Alliance (PDSA) (“The ‘enhanced system’ for 2023 should not be viewed as a single system, technology, or asset but as a network of independent, but interoperable, trading partner systems and processes” and “Access to DSCSA data should not be viewed as direct access to data, but rather an interoperable protocol to request data and respond with data, intermediated by a business-by-business gatekeeping function”).

statement at the November 16 public meeting further emphasized that state regulators will read the EDDS Draft Guidance and expect that wholesale distributors will implement it as written and may condition licensure upon compliance with it.

Indeed, our concerns are greater even than before. We note, for example, in the National Association of Boards of Pharmacy (NABP) presentation during the FDA public meeting, that the presenter included a slide that stated, “How will regulators request transaction information from trading partners within the secure, electronic interoperable system?” NABP oral presentations have also discussed “the enhanced system.” We are concerned that state inspectors and licensure officials may conclude that a wholesale distributor should have a “communication hub” (or have access to one) that gives the regulator direct access to the trading partner’s transaction data repository and that the wholesale distributor or other pharmacy trading partner should be able (presumably by way of this communication hub) to identify and trace a prescription drug as it is distributed in the U.S. We are also concerned that regulators might take enforcement action, deny licensure, and otherwise deem a trading partner to be out of compliance if it does not have a “communication hub” and is not otherwise part of the “enhanced system” that allows the regulator “one-button,” direct access to the trading partner’s transaction data. As discussed above, the communication hub does not exist, is not required and is not being built.

b. Impeding Implementation of EPCIS

As we explained in our comment to the EDDS Draft Guidance at page 16, Congress provided the roadmap for achieving 2023 interoperability in the definition of product identifier in § 581 and the requirements for transaction data exchange in § 582(h). These sections require supply chain-wide alignment on common standards for product identifiers and data exchange, with the implementation of these common standards across trading partners enabling and achieving interoperability. In the absence of any guidance from FDA since 2014,⁸ this is precisely what trading partners have done – trading partners read and interpreted § 581 and § 582 and worked with GS1 to develop and implement standards for the product identifier⁹ and for transaction data exchange using EPCIS to achieve the interoperability at the package level mandated in § 582(g)(1). When fully implemented, EPCIS is expected to enable seamless, stable, consistent, compatible, interoperable, electronic connections between trading partners throughout the pharmaceutical supply chain.

⁸ The 2014 Draft Guidance, “DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information,” recognized EPCIS as a compliant method for meeting the initial DSCSA requirements for electronic transaction data.

⁹ It is for this reason that we continue to object to FDA’s view that the human readable portion of product identifier must include the product’s NDC number and that inclusion of the GTIN is optional. See *Product Identifiers under the Drug Supply Chain Security Act - Questions and Answers* (June 2021). Congress was explicit that the product identifier must conform to the standards of an international standards development organization – which is fundamental to achieving interoperability. See § 581(14) (product identifier must conform to international standards). Under the international standard for the product identifier established by GS1, the human readable portion is an accurate interpretation of the machine readable, two-dimensional data matrix barcode which, in turn, requires a serialized GTIN. Inclusion of the GTIN in the human readable portion of the product identifier is not optional – the product does not conform to the international standards for the product identifier that the DSCSA requires and Congress mandated for interoperability if the GTIN is omitted. Moreover, and has been discussed exhaustively with the Agency, including only the NDC in the human readable portion of the product identifier poses insurmountable traceability problems because unlike a serialized GTIN, a serialized NDC is not unique. If the product identifier in the machine-readable barcode cannot be scanned, and only the NDC is in the human readable portion of the barcode, it will not be possible to uniquely identify and trace, verify, or associate the product. We continue to believe that FDA’s Product Identifier Q&A Final Guidance is contrary to the plain language of the DSCSA and, therefore, is unlawful.

Having had the benefit of comments stakeholders submitted on the EDDS Draft Guidance, it was hoped that the Agency would use other recent opportunities, such as the public meeting and presentations, to acknowledge EPCIS and confirm that this international standard satisfies the DSCSA's 2023 statutory requirements. We greatly appreciate FDA's statement that more guidance is coming. However, the unfortunate reality is that the EDDS Draft Guidance and the Agency's subsequent statements about the "enhanced system" and "communication hub" are engendering significant confusion.

The communication hub and enhanced system the Agency continues to mention but not explain clearly appear **so** different from what industry is implementing that some trading partners believe that something other than EPCIS is coming to help them meet 2023 requirements. Such trading partners are concluding that they should defer investment in, and commitment to, EPCIS to avoid the expenditure of time and money on something that is not what FDA describes and seems to expect. HDA's members have observed this reticence in their dealings with trading partners and we heard similar statements from trading partners at our November Traceability Seminar. The Agency's continuing statements about a "communication hub" and "the enhanced system," without acknowledging that EPCIS is a compliant building block for electronic, interoperable data exchange, means that some trading partners believe they should ignore development and implementation of EPCIS and wait for this hub or enhanced system to materialize.

As has been stated previously, to our knowledge there is nothing else being developed or built. If trading partners do not commit to and implement EPCIS, it will be impossible for them to provide, receive, and maintain transaction data that includes product identifiers by November 27, 2023.¹⁰ If product identifiers are not included in TI, trading partners will not be able to trace, by product identifier, the prescriptions drugs they purchased and sold.

4. Potential Application Of Validation And Good Manufacturing Practices To Wholesale Distributors And Dispensers

The applicability of FDA's current Good Manufacturing Practices (GMPs) (21 C.F.R. Parts 210 and 211) (and the attendant data quality requirements) to DSCSA transaction data has been raised previously. Moreover, at least one presenter at the public meeting raised the issue of whether these requirements apply to wholesale distributors and dispensers and FDA probed the issue in its questions to dispensers.

In actuality, the question of whether GMPs apply to wholesale distributors and dispensers long predates the DSCSA and has been unequivocally answered for over forty years. In the promulgation of the GMP regulations in 1978, FDA specifically addressed whether those requirements applied to wholesale distributors and pharmacies and stated that they did not:

Section 501(a)(2)(B) of the act provides that a drug shall be deemed to be adulterated if "the methods used in, or the facilities or controls used for its manufacture, processing, packing, or holding do not conform to current good manufacturing practice..." This section, through operation of section 301(k) of the act, applies to wholesalers, retailers, pharmacies, and hospitals, as well as manufacturers. ***However, the CGMP regulations set forth in part 211 apply only to establishments engaged in the preparation of a drug product. Therefore,***

¹⁰ As explained in footnote 5, some dispensers will likely rely upon their supplying wholesale distributor or service provider to maintain their transaction data and will not need to establish the point-to-point connection EPCIS requires.

these regulations do not apply to the wholesalers, retailers, pharmacies, and hospitals that are traditional to those establishments.

43 Fed. Reg. 45014, 45027 (Sept. 29, 1978) (emphasis supplied).

The Agency reiterated this position in its promulgation of the Prescription Drug Marketing Act (PDMA) regulations in 1990 (55 Fed. Reg. 38,012, (Sept. 14, 1990)). Twice, the Agency referred back to the GMP rulemaking and 43 Fed. Reg. at 45027 quoted above:

CGMP regulations do not apply to the traditional activities of wholesale drug distributors (see 43 FR 45027), whereas these guidelines are expressly applicable to the traditional activities of wholesale drug distributors.

...

Several comments object to the reference to ‘current good manufacturing practices’ in the introductory paragraph to proposed § 205.50. The comments asserted that the agency lacks the authority to impose such requirements on wholesale drug distributors.

...

FDA agrees that it may be confusing to refer, in § 205.50, to “current good manufacturing practices.” The provision has been revised accordingly.

...

FDA has previously stated that the CGMP regulations set forth in 21 CFR Part 211 do not apply to wholesalers engaging in activities that are traditional to those establishments (see 43 FR 45027) ... FDA intends, in the near future, to issue a guideline under § 10.90 of its procedural guidelines... describing acceptable current good manufacturing practices for wholesalers that reflect the approach taken in this rule.

55 Fed. Reg. at 38014, 38019 (internal parentheticals omitted) (emphasis supplied).

21 C.F.R. Parts 210 and 211 (and the guidance implementing them) have never been applied to wholesale distributors. Merely because the GMP regulations are applied to manufacturers and repackagers in no way means that they must be extended to wholesale distributors. FDA specifically rejected this interpretation in 1978 and it has remained in place ever since.

If FDA intends to apply GMP requirements to wholesale distributors and/or dispensers, it may only do so by promulgating a new requirement as it did the original requirement applicable to manufacturers and repackagers – by notice and comment rulemaking.¹¹ Imposition of GMPs upon whole classes of trading partners not previously covered, where the Agency has been clear for so long that they do not apply, would be an enormous undertaking that would engender huge system and process changes for wholesale distributors and dispensers and likely hundreds of millions of dollars in investment. This would unquestionably be an “economically significant” rule and would trigger the full panoply of APA and other rulemaking requirements (e.g., notice and publication of proposed and final rule, opportunity for comment, Regulatory Flexibility Act analysis, Federalism analysis, Paperwork Reduction Act, etc.).

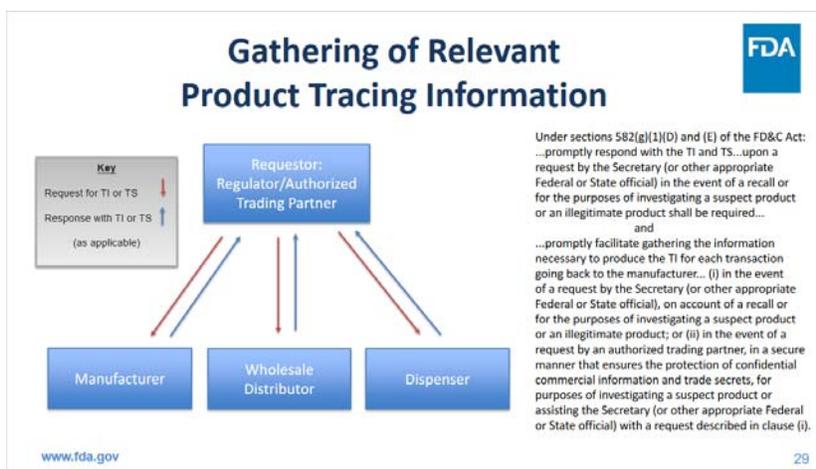
¹¹ “The [Administrative Procedure Act] establishes the procedures federal administrative agencies use for ‘rule making,’ defined as the process of ‘formulating, amending, or repealing a rule.’” *Perez v. Mortg. Bankers Ass’n*, 575 U.S. 92, 95 (2015) (citing 5 U.S.C. § 551(5)). The APA “mandate[s] that agencies use the same procedures when they amend or repeal a rule as they used to issue the rule in the first instance” *Perez*, 575 U.S. at 101.

In our comments on the EDDS Draft Guidance, we objected to the instances where the Draft Guidance states that trading partner systems and processes should be validated. HDA EDDS Draft Guidance Comments at pages 33-34. “Validation,” as we noted, has a very specific meaning under the FDC Act and implementing regulations; manufacturers and repackagers must validate systems and processes in order to be in compliance with GMP requirements. We asked that the references to “validated” and “validation” be stricken from the Draft Guidance and repeat that request here. If FDA seeks to impose GMPs upon wholesale distributors and dispensers, including requirements that these trading partners validate their DSCSA-related transaction data systems and processes, this will only be lawful and valid if done through notice-and-comment rulemaking and in conformance with other legal requirements applicable to promulgation of regulations.

5. Responses to Tracing Requests from Trading Partners

HDA extensively discussed tracing requests and responses under § 582(g)(1)(D) and § 582(g)(1)(E) of the DSCSA in its Comments to the EDDS Draft Guidance at pages 23-28. As we explained, sections (D) and (E) are not the same and the differences are material to an understanding of what they require of a government or trading partner requester and of a trading partner responding to a tracing request. (HDA EDDS Draft Guidance Comment at page 25.) We recognize and greatly appreciate that FDA has, in its more recent presentations, acknowledged that tracing requests and responses are dictated by the two separate provisions of § 582(g)(1)(D) and § 582(g)(1)(E).

Though we appreciate the Agency’s recent efforts to distinguish (D) from (E), we note that slide 29 from the November public meeting continues to combine together “Regulator/Authorized Trading Partner” as initiators of tracing requests:



This graphic shows tracing requests and responses as always being for TI and TS. This is incorrect – only regulators may seek TI and TS pursuant to § 582(g)(1)(D). Section 582(g)(1)(E) specifies the responding trading partner must provide “information,” not TI and TS. Further, the circumstances in which regulators may request TI and TS under (D) and in which trading partners may request information under (E) are not the same, even though slide 29 graphically suggests that they are.

We recognize that sections (D) and (E) are complex and trying to simplify them for communicative ease can be desirable. However, such summaries may also continue to perpetuate confusion and misinterpretation of these distinct provisions and we urge that (D) and (E) be separately presented and addressed wherever possible. The failure to note the DSCSA's distinction between (D) and (E) tracing requests and responses is one of the most serious shortcomings of the EDDS Draft Guidance.

On a related point, in [its comment to the EDDS Draft Guidance](#) the Pharmaceutical Research & Manufacturers of America (PhRMA) stated that FDA should “not permit redaction of transaction information directly relevant to a trading partner and its role in the supply chain when responding to a request from an authorized trading partner” (footnote omitted) under § 582(g)(1)(e)(ii). At the public meeting, PhRMA reiterated that a responding trading partner should not be permitted to redact TI due to confidentiality. Respectfully, we disagree with this interpretation of the DSCSA.

The DSCSA expressly provides that a trading partner response to a tracing request under § 582(g)(1)(E)(ii) is comprised of “information,” **not TI**. This distinction is critical from the standpoint of legal rules for construction of statutes. If Congress had intended for the responding trading partner to provide all TI and TS in its possession (as PhRMA argues), it would have said so, as it did in § 582(g)(1)(D) and would not have included the express protections for confidential information in § 582(g)(1)(E)(ii).¹²

Moreover, the obligation for a wholesale distributor to provide “information” rather than TI is legally compelled by the DSCSA because Congress expressly limited who wholesale distributors can share TI and TS with. Under § 582(c)(1)(A)(v)(II) (footnotes added):

A wholesale distributor shall ... “maintain the confidentiality of the [TI] (including any lot level information consistent with the requirements of this section), [TH, and TS] for a product in a manner that prohibits disclosure to any person other than the Secretary or other appropriate Federal or State official, except to comply with clauses (ii) and (iii),¹³ and, as applicable, pursuant to an agreement under subparagraph (D).

Subparagraph D, entitled **Trading partner agreements**, provides that, beginning November 27, 2019, “a wholesale distributor may disclose the transaction information, including lot level information, transaction history, or transaction statement of a product to the subsequent purchaser of the product, **pursuant to a written agreement between such wholesale distributor and such subsequent purchaser**. Nothing in this subparagraph shall be construed to limit the applicability of subparagraphs (A) through (C).”¹⁴ § 582(c)(1)(D) (emphasis supplied).

¹² See HDA EDDS Comment at pages 26-27. “If Congress had intended for an (E) response to be or include TI, it would have said so, as it did in other parts of the DSCSA. Where a trading partner **is** required to produce TI (rather than “information”), Congress and the law are very clear. Including language in one place in the DSCSA and not in another is presumed also to be the deliberate decision of Congress.” Citations to applicable law include *Russello v. United States*, 464 U.S. 16, 23 (1983) (“Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion”) (internal quotations and citations omitted); *Am. Methyl Corp. v. E.P.A.*, 749 F.2d 826, 835–36 (D.C. Cir. 1984) (the “mention of one thing implies exclusion of another thing” is a “common sense observation ... frequently invoked by the Supreme Court in construing statutes”) (internal citations and footnotes omitted).

¹³ Clauses (ii) and (ii) set out the requirements for a wholesale distributor to provide TI and TS to its downstream customer with each transaction of covered products.

¹⁴ Subparagraphs (A) through (C) refer to the provision (and protection) of transaction data in transactions, requests for information by government officials, and returns.

Thus, in responding to a tracing request initiated by a trading partner on its own behalf, a wholesale distributor can **only** provide information and **is legally prohibited from providing TI and TS**. A wholesale distributor may only provide TI and TS to another trading partner if permitted in an agreement with its **subsequent** customer, or if the wholesale distributor transacted the product subject to the request with that requesting trading partner. HDA elaborated upon this issue at pages 26-27 of its EDDS Draft Guidance Comment and Mr. Scott Mooney (McKesson) further explained the issue at the public meeting. We appreciate FDA's acknowledgement at the public meeting of the limitation § 582(c)(1)(A)(v)(II) imposes upon wholesale distributor responses to tracing requests initiated by trading partners.

We also do not agree with the PhRMA representative's assertion that a trading partner responding to a § 582(g)(1)(e)(ii) tracing request who did not provide all the transaction data without limitation would be contrary to the intent of the Partnership for DSCSA Governance (PDG) Blueprint. The PDG Blueprint, of course, does not supersede a wholesale distributor's legal obligations to protect the confidentiality of transaction data under § 582(c)(1)(A)(v)(II). Moreover, we do not read the PDG Blueprint as contemplating such a response, even if it were legally permissible (which it is not).

6. Using the Same "System" for Verification and Providing Transaction Data

We believe that FDA stated at the public meeting that trading partners should be using the same system for both verification and providing transaction data. If this was indeed expressed, we have two comments upon it. First, insofar as verification is concerned, using the same system for verification of saleable returns and for storing transaction data is consistent with previous comments HDA (*e.g.*, HDA EDDS Draft Guidance Comment at 33) and with the PDG Blueprint, both of which provide that a wholesale distributor may verify its saleable returns against "replicate" data – that is, the transaction data the wholesale distributor received directly from the manufacturer. Wholesale distributors must, of course, also confirm that the product is otherwise appropriate for return to inventory and resale, including that it is intact, not expired, and not subject to a recall or other similar action by the manufacturer).¹⁵

Another possible interpretation is that FDA intended to state that DSCSA systems and processes, including those involving verification and provision and maintenance of transaction data, were expected to be fully integrated internally. As we discussed in our EDDS Draft Guidance comments at pages 34-35, we do not believe that the DSCSA requires that all of a trading partner's DSCSA systems be integrated with one another for 2023 compliance.

Trading partners already have business processes in place to conduct many of the activities the DSCSA requires; some predate the DSCSA, such as processes for conducting supplier and customer due diligence and for identifying and notifying customers who purchased recalled product. Newer interoperable processes, such as verification of saleable returns and exchange of transaction data in standard EPCIS file formats have proceeded without any greater integration into existing systems. We do agree that a trading partner's systems should enable the sharing and use of information (such as not returning a product to inventory that is under a recall), but these different

¹⁵ For clarification, verification against replicate data is only appropriate when a wholesale distributor purchased a product directly from a manufacturer, the wholesale distributor sold the product to a dispenser, and that product has now been returned to the same wholesale distributor. After associating the returned product with the TI in its possession, the wholesale distributor then can verify the product identifier against the data it directly received from the manufacturer. Only after completing these steps may the wholesale distributor return that product to inventory for resale.

internal systems and processes are not typically “integrated” into a single “system” and do not need to be to assure patient well-being, supply chain security and DSCSA compliance.

7. Product “Status”

We thank FDA for the acknowledgement during the public meeting that the DSCSA does not mandate the capture or reporting of a product’s status as it moves through the supply chain. This issue of product “status” was also thoroughly vetted during and following a public meeting in August 2017 and does not need to be further revisited.¹⁶ As discussed above, neither does the DSCSA build or contemplate or require an active surveillance system that tracks products as they move through the supply chain.

Nor can the DSCSA’s requirements for interoperable product identifier and transaction data exchange be extended to achieve visibility into company inventory levels across the supply chain. Even if FDA or another trading partner was entitled to direct access to a wholesale distributor’s DSCSA transaction data (and, as discussed above and in comments, they are not), how much unsold product a wholesale distributor has in inventory is not captured by the DSCSA *at all*. HDA and their wholesale distributor members deeply appreciate how COVID-19 has brought product shortages, warehouse management, and allocation practices into sharp focus – but these serious matters are wholly outside the DSCSA. With all that must be done to achieve 2023 compliance, focusing on such matters is distracting, unhelpful and completely beyond the DSCSA’s scope.

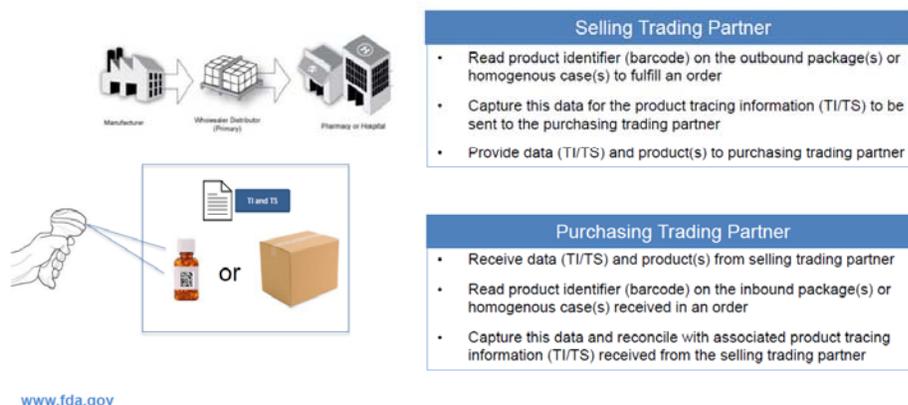
8. Inference, Aggregation and Scanning on Inbound Receipt

The EDDS Draft Guidance provided that trading partners would be able to rely upon aggregation and inference and would not need to open up every larger unit but could infer the contents within that unit based upon the data received from the seller. FDA’s presentations have continued to support the use of aggregation and inference. In our Comments on the EDDS Draft Guidance, we thanked FDA for its acknowledgement of the importance of aggregation and inference and we do so again.

However, slide 27 from the November public meeting suggests that all products or cases must be scanned on inbound and the captured data reconciled against the TI data received:

¹⁶ HDA and others submitted extensive comments on the issue. See HDA Comments on Enhanced Drug Distribution Security Under the Drug Supply Chain Security Act; Public Meetings; Request for Comments, Dkt. No. FDA-2017-N-3857, September 22, 2017, available here <https://www.regulations.gov/comment/FDA-2017-N-3857-0007>.

Enhanced Product Tracing: Reconciliation of Data and Product



Selling Trading Partner

- Read product identifier (barcode) on the outbound package(s) or homogenous case(s) to fulfill an order
- Capture this data for the product tracing information (TI/TS) to be sent to the purchasing trading partner
- Provide data (TI/TS) and product(s) to purchasing trading partner

Purchasing Trading Partner

- Receive data (TI/TS) and product(s) from selling trading partner
- Read product identifier (barcode) on the inbound package(s) or homogenous case(s) received in an order
- Capture this data and reconcile with associated product tracing information (TI/TS) received from the selling trading partner

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FDA reiterated this point in previous presentations and similar points are made in the EDDS Draft Guidance.

HDA extensively addressed our many concerns with this apparent reconciliation expectation in its Comments on the EDDS Draft Guidance at pages 30-32. Mr. Scott Mooney (McKesson), Ms. Maryann Nelson (Cardinal Health), Mr. Brad Pine (Smith Drug), Mr. Matt Sample (AmerisourceBergen) and Dr. Ilisa Bernstein (APhA) also discussed the burden and impracticality of a trading partner scanning all product on inbound receipt to match it with received TI. Whether receiving homogenous cases or homogenous pallets, as wholesale distributors explained, they intend to rely upon aggregation and inference, and do not have the space or resources to open every sealed container and scan each product contained within upon receipt.

Nor is such an effort necessary to protect patient safety and secure the supply chain. HDA members who spoke at the meeting have stated they intend to perform spot checks on inbound packages to confirm receipt of corresponding TI.¹⁷ More importantly, rigorous reconciliation will occur on outbound sale when a wholesale distributor will scan the product identifiers on all packages (or the product identifier on sealed homogenous cases if whole cases are sold) to generate TI for the customer that includes all the product identifiers for all products in the transaction and to assure that the wholesale distributor received inbound TI (with the corresponding product identifiers) from the manufacturer.

To go beyond these intended business processes, and require, at receiving, reconciliation against received TI of each package and each unit within a larger container (whether each package within a case or each case on a pallet) cannot be done given the physical limitations of warehouses – there is simply not enough room to open up every homogenous case and pallet received, scan the barcodes, and check each scan against the TI received from the manufacturer. Additionally, given the time it would take to accomplish this reconciliation of every inbound package, case and pallet, we believe the ability of wholesale distributors to continue just-in-time delivery of needed medicines to dispensers and patients would be compromised.

¹⁷ Though not addressed previously, it is likely that in contrast to sealed homogenous cases and pallets, a wholesale distributor would scan, on receipt, all packages within a non-homogenous container, such as different products repackaged into a larger tote or case.

Nor do we see any security or patient safety benefit to what amounts to wholly duplicative and wasteful effort when all packages and/or homogenous cases will be scanned on outbound so wholesale distributors can satisfy their own requirements to include product identifiers in TI provided to downstream customers. Moreover, scanning on inbound is likely to be so burdensome and cumbersome, it will significantly slow the delivery of medicines to patients who have an immediate need for them.

9. Resource and Labor Constraints

Last, we note also that well-documented labor shortages are impacting American employers, including pharmaceutical wholesale distributors. These challenges are concerning both for their impact on current operations and because hiring and training must increase for wholesale distributors to be able to meet 2023 requirements. Ms. Maryann Nelson (Cardinal Health) noted in her presentation that outbound scanning is estimated to increase expected labor needs by a minimum of 12-15 percent based on recent time studies and that a single average distribution center with a 50-person night crew would need to hire six more people to support outbound scanning. This is another reason why also performing duplicative scanning of every package on inbound would be so burdensome – having to do so is likely to at least double the number of employees who would have to be hired for scanning activities. HDA's members are very concerned that the employee pool is currently too small to support all that the EDDS Draft Guidance would seem to contemplate, particularly when, as noted above, the inbound scanning offers no additional security benefit.

Resource constraints also are impacting other parts of DSCSA implementation – one reason that wholesale distributors are so concerned about the pace of manufacturer adoption of EPCIS is that there is a relatively small number of persons who are sufficiently knowledgeable to advise on EPCIS implementation. As the 2023 deadline approaches, we believe the slow adopters who have been deferring their investment and waiting, will realize that there is no other “system” coming. They will then face the prospect of being out of compliance unless they *immediately* begin establishing EPCIS connections with their trading partners and confirm whether their data are sufficiently organized so that they can include product identifiers in the transaction data they provide. These latecomers could need additional resources to get into compliance swiftly and will find that the relatively small number of specialized industry experts are already fully committed and will not be available to help them. We are running not just out of time, but out of people.

* * *

We thank FDA for this opportunity to further engage with the Agency on DSCSA implementation. If you have any questions, please contact me at 703-885-0240 or aducca@hda.org.

Sincerely,



Anita T. Ducca
Senior Vice President, Regulatory Affairs