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Dear Dr. Jung:

The Healthcare Distribution Alliance (HDA) appreciates this opportunity to provide public comments to the Food and Drug Administration (FDA) regarding the Draft Guidance for Industry: Product Identifier Requirements Under the Drug Supply Chain Security Act—Compliance Policy” Dkt. No. FDA-2017-D-2232 (Draft Guidance).

The Healthcare Distribution Alliance (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.
Though HDA encourages the serialization of all covered products as soon as possible, wholesale distributors also fully support their manufacturer partners. We appreciate FDA’s recognition of the challenges manufacturers face in meeting the serialization requirements of the Drug Supply Chain Security Act (DSCSA) by the November 27, 2017 statutory deadline. HDA believes manufacturers are in the best position to determine when the manufacturing segment will be able to meet the serialization milestone. The Agency’s exercise of enforcement discretion will advance product availability without introducing undue risks into supply chain security.

We also appreciate that FDA announced its intention to exercise enforcement discretion five months in advance of the November 27, 2017 statutory deadline and that the Agency is permitting an opportunity to provide comments.

Wholesale distributors are committed to doing their part to support supply chain security. They supported the DSCSA’s passage and have been diligently working to comply with its mandates. Further, HDA and its members have taken a leadership role in developing educational information, guidelines, and other materials, often for the benefit of the entire supply chain. We believe our work has fostered a greater understanding of the DSCSA’s requirements and supported compliance with them.

We urge FDA to consider the collective DSCSA learnings of stakeholders thus far – that the DSCSA is very complex, that any changes ripple throughout the entire supply chain, and that reaching any milestone takes a long time to implement. Similarly, any late-made DSCSA interpretation that differs from how industry has been implementing and operationalizing the statute is very disruptive. Above all, the DSCSA contemplates a gradual, step-wise approach to achieving unit-level package traceability. The DSCSA codifies a ten-year path, beginning with the exchange of product data, moving to individual package and homogenous case serialization, followed by electronic data exchange, and returns verification; interoperable exchange of information and traceability at the individual package level are achieved only at the very end in 2023.

To that end, we are concerned about several provisions in the Draft Guidance. While we support temporarily easing the serialization burden for manufacturers, to provide this one-year reprieve, the Draft Guidance imposes new, substantial burdens upon the other segments of the supply chain. HDA has significant concerns because the Draft Guidance will substantially constrain the ability of distributors to provide products to trading partners and patients and will increase costs and burdens, without defining a commensurate enhancement of product security. Further, we believe that some elements of the Draft Guidance simply cannot be operationalized at all given existing technology and practices in the pharmaceutical supply chain. In sum, wholesale distributors are significantly challenged by what is supposed to be merely a short-term policy on enforcement discretion.

Below we explain the following concerns as well as the implications of the Draft Guidance for meeting future DSCSA requirements:
I. THE DRAFT GUIDANCE IMPERMISSIBLY SHIFTS DSCSA COMPLIANCE BURDENS, CANNOT BE IMPLEMENTED AND IMPERMISSIBLY ACCELERATES DSCSA STATUTORY DEADLINES

The DSCSA requires manufacturers to serialize products beginning not later than November 27, 2017, and repackagers a year later, by November 27, 2018. However, wholesale distributors may engage in transactions involving unserialized product (e.g., purchases and sales in a change of ownership) until November 27, 2019; dispensers have until 2020. See § 582(c)(2); § 582(d)(2). Depending upon the provisions of FDA’s to-be-issued Guidance on Grandfathering, wholesale distributors and dispensers will also be able to engage in transactions involving unserialized grandfathered product after those dates. See § 582(a)(5); § 582(c)(2); § 582(d)(2). Furthermore, Transaction Information (TI) from sellers will not need to include product identifiers until November 27, 2023.

In this way, the DSCSA creates a step-wise progression that recognizes that products flow continually through the supply chain as inventory is sold, dispensed and replenished. The intent has been, among other things, to allow wholesale distributors two years from the time manufacturers begin to serialize products before they can no longer transact with non-grandfathered, unserialized products. Dispensers have three years. These two and three-year phase-ins were intended to allow time for inventory to turn over as serialized product slowly replaced unserialized products, thereby reducing the amount of unserialized, but otherwise perfectly usable, products that would need to be discarded. These defined, orderly phase-ins also would help prevent potential shortages, assure patients’ continued access to needed medicines, and reduce waste and costs.

The DSCSA’s step-wise implementation allows unserialized products to flow through the supply chain, for a time, without imposing additional burdens on distributors and dispensers. While HDA supports granting manufacturers a one-year period of enforcement discretion to meet their serialization requirements, as discussed below, the Draft Guidance also
creates immense and even insurmountable difficulties for everyone else in the supply chain by shifting operational and compliance burdens from one industry segment to other trading partners. This approach is both contrary to the DSCSA and represents a significant departure from the previous instances in which FDA has extended enforcement discretion for DSCSA deadlines.


The Draft Guidance states:

Trading partners who believe that product may be subject to this compliance policy should take steps to determine that the product was introduced in a transaction into commerce by the manufacturer [between November 27, 2017 and November 27, 2018]… FDA recommends that a trading partner make such a determination for a product without a product identifier based on the following:

- At least one of the transaction information documents that compose the transaction history for the product describes an initial transaction date from the manufacturer that occurs between November 27, 2017 and November 26, 2018; or

- There is other documentary evidence created by a trading partner in the ordinary course of business and containing a product description that matches the package or homogenous case of product that is not labeled with a product identifier. In addition, this other documentary evidence should contain a date from which it can be determined that the product was introduced in a transaction into commerce by the manufacturer between November 27, 2017 and November 26, 2018. Examples of such documents may include, but are not limited to, bills of lading, commercial invoices and shipping invoices.

Draft Guidance at lines 257-270.

For the following six reasons, HDA and its members vigorously object to this documentation requirement for wholesale distributors and their downstream trading partners.

**First, while benefiting manufacturers, the Draft Guidance unfairly and impermissibly shifts compliance burdens to downstream trading partners.** HDA and its members support the exercise of enforcement discretion for manufacturers. However, we are gravely concerned
with how the Draft Guidance shifts the burdens of compliance from manufacturers to wholesale distributors and other downstream trading partners. Serialization is, and was always intended to be, a manufacturer (and repackager) responsibility. The Draft Guidance now eases that burden for manufacturers for one year and threatens enforcement action if wholesale distributors and other downstream trading partners fail to document when the manufacturer introduced serialized product in a transaction into commerce.

The DSCSA has already made significant improvements to supply chain security. At this stage in the DSCSA’s implementation,

- TI and a Transaction Statement (TS), and (until 2023) Transaction History (TH) must be supplied for all DSCSA-covered transactions and products.
- All transactions must be between authorized trading partners who hold appropriate licenses and registrations.
- There must be systems in place for suspect and illegitimate product investigations and notification to trading partners and FDA.
- The level of information available for a particular package allows for lot level traceability.

Amid all these improvements in security, documentation and transparency, the Draft Guidance burdens manufacturers’ downstream trading partners with documentation requests which act as *de facto* requirements that must be implemented to avoid enforcement. Yet, these additional burdens do not appear to further patient safety or supply chain security and, as discussed further below, are also unworkable and unlawful.

Second, absent item-level serialization and TI that includes product identifiers, it is not possible for downstream trading partners to know when a single package entered the supply chain. The fundamental problem with the Draft Guidance’s documentation requirement is that it assumes transaction data can be matched to a particular package in order to determine the day the manufacturer first introduced that package in a transaction into commerce – the *initial transaction* that brought a product into the supply chain. However, this determination is not possible unless and until there is (1) item-level traceability – *i.e.*, all packages serialized – and (2) the systems and data exchange in place that can link the product identifier on each *individual package* to a single, particular transaction and transaction date. Without both item-level serialization and product identifier data, there is no way to know when an individual package was first introduced in a transaction into commerce.

The Draft Guidance’s assumptions regarding a wholesale distributor’s ability to identify the date unserialized packages were introduced in a transaction into commerce by the manufacturer between November 27, 2017 and November 27, 2018 also creates enormous difficulties for unserialized packages already in the supply chain and in wholesale distributor inventory and warehouses as of November 27, 2017. Distinguishing pre-November 27, 2017 unserialized packages from everything else received thereafter would entail changes to existing inventory *and* warehouse receiving practices *right now*. Inventory within warehouses would
have to be subdivided by dates— a physical impossibility. Alternatively, every package in every case on every warehouse shelf now and every package received until November 27, 2017, would have to be individually identified with a date of receipt, which is simply not possible operationally.

At this stage in DSCSA implementation, the statute requires lot level traceability (only) as a stepping-stone to item-level traceability. Though lot level traceability is far superior to what predated the DSCSA, it is limited because manufacturers can send the same lot to a wholesale distributor or other trading partner on different days, leaving the distributor with no way to determine when a specific package was received. The system of item-level serialization and product identifier data in TI that the Draft Guidance presupposes for wholesale distributors and dispensers to avoid enforcement does not exist, is not required to exist, and Congress did not contemplate that it would exist, until 2023.

Third, trading partners downstream from the manufacturer’s initial trading partner do not know when a product was first introduced into commerce because the manufacturer’s initial trading partner does not provide, and is expressly exempted from providing, manufacturer’s initial transaction date in TI or TH between trading partners in subsequent transactions. Currently, and until November 27, 2023, once the manufacturer introduces a product into a transaction, as discussed above, the first buyer will be able to discern from the transaction data it receives from the manufacturer that it purchased a particular lot of the product in a particular transaction on a particular day. Even assuming that a package could, prior to 2023, be matched to its first transaction into commerce, the DSCSA does not require the first purchaser to provide this initial transaction date to any subsequent purchaser in TI or TH.

The statute states explicitly what elements comprise TI that must be passed between trading partners, § 581(26), and initial transaction date of the first transaction is not one of those elements. The date of the transaction between the two immediate trading partners, of course, must be included in TI § 581(26)(G). However, no prior transaction date (e.g., when the seller acquired the product from the manufacturer, repackager or another wholesaler) is included or required to be provided to subsequent purchasers.¹ For example, if a wholesale distributor engages in a transaction to buy a product from a manufacturer on October 1, 2018, the manufacturer’s TI provided to the wholesale distributor would include that date. However, when the wholesale distributor sells that same product, for example, to a dispenser on November 28, 2018, the only transaction date that the wholesale distributor would include in the TI to the dispenser would be November 28, 2018, not October 1, 2018.

¹ We assume and interpret the Draft Guidance as providing enforcement discretion only if subsequent, downstream trading partners are able to document the date on which the manufacturer first introduced the product in a transaction into commerce – the date of the initial transaction must follow the product downstream. Also, we assume that the Draft Guidance is specifying documentation of a manufacturer’s introduction into commerce of a single product, and not the entire lot to which that product belongs, or when it first introduced the lot in a transaction into commerce. However, alternative interpretations are possible.
Further, nothing in the statute requires a seller to include in the TI or TH it passes to a trading partner, the date the manufacturer first sold the product in a transaction into commerce. The DSCSA exhaustively specifies the data that direct purchase wholesale distributors must provide to subsequent purchasers and specifically excludes the initial transaction date:

For purposes of transactions described in sub-clause (I) [direct purchase transactions], [TH] and [TI] shall not be required to include the lot number of the product, the initial transaction date, or the initial shipment date from the manufacturer…”

§ 582(c)(1)(A)(ii)(II) (emphasis supplied). Direct purchase wholesale distributors are wholly exempt from providing initial transaction date (as well as lot numbers) to subsequent purchases.

Further, the result is the same where the transaction scenario contemplates a sale from one wholesale distributor to another wholesale distributor who in turn sells to a dispenser or other trading partner. The direct purchase wholesale distributor is not required to provide to the non-direct wholesale distributor the date it acquired the product from the manufacturer under § 582(c)(1)(A)(ii)(II). The DSCSA also provides that, for subsequent transactions, TH begins with the sale by the direct-purchase wholesale distributor to the non-direct wholesale distributor. § 582(c)(1)(A)(iv). A non-direct wholesale distributor cannot provide to a subsequent trading partner what it never received and which the DSCSA does not require it to receive.

As a result, there is no downstream visibility into the manufacturer’s initial transaction date. No subsequent purchaser is required by law to provide the manufacturer’s initial transaction date to other subsequent purchasers, and, indeed, the law specifically exempts direct purchase wholesalers from providing that information in the TH they pass. There is no way that dispensers and other subsequent downstream purchasers would be able to discern the date on which the manufacturer introduced the product in a transaction into commerce. The information, to the extent it exists at this time, resides with the manufacturer.²

Fourth, the Draft Guidance cannot alter the statutorily prescribed content of TH to require the manufacturer’s initial transaction date in downstream transactions. The Draft Guidance states that “at least one of the [TI] documents that compose the [TH]” should have the initial transaction date. Yet, the manufacturer’s initial transaction date is not required by the DSCSA to be included in TH, either. As discussed above, the direct purchase wholesale distributor is not required to provide the initial transaction date to subsequent purchasers, § 582(c)(1)(A)(ii)(II). If the direct purchase wholesale distributor sells to another wholesale distributor in a second transaction, the TH begins with that direct purchase wholesaler to the non-direct wholesaler transaction. § 582(c)(1)(A)(iv). The TI and TH for that transaction and

² In section II below, HDA expresses its support for the position other organizations endorse that the operative date for grandfathering and/or enforcement discretion should be the date on which the product was packaged and not, as proposed in the Draft Guidance, the date on which the product is first sold. Regardless of the operative date used – sell by, packaged by, or some other – the manufacturer is the best source for lot level information on when its products enter the supply chain.
subsequent transactions do not include, and are not required to include, the date the manufacturer first sold the product into commerce in a transaction with the direct purchase wholesaler.

**Fifth, there is no feasible way to implement what the Draft Guidance proposes, even if the date of a product’s initial introduction in a transaction into commerce is known.** Even assuming that a package’s initial transaction date was “knowable” at this time, we note that there is no way, currently, to introduce this new data element into the electronic data exchange systems that supply chain trading partners are using, such as the Advance Ship Notice (ASN). The 856 electronic data interchange (EDI) transaction set took a year of diligent stakeholder effort to develop after passage of the DSCSA. The 856 communicates TI, TH and TS between individual trading partners, including the current transaction date between two downstream trading partners (e.g., wholesale distributor sale to dispenser); the manufacturer’s initial transaction date is not included.

Adding the initial transaction date means developing and updating a guideline, publishing the guideline, and modifying the existing 856 maps. It also involves intensive efforts by stakeholders to provide and accept the data, and each selling entity must test it across hundreds if not thousands of trading partners. Validation may also be involved, as well as additional changes based on the test results. If trading partners are using portal systems to provide and maintain transaction data, these would also have to be modified. Trying to change existing practices and develop new standards to cover a year-long accommodation would divert important attention and resources from other looming DSCSA deadlines, such as 2019 verification of saleable returns and development of a “vision” for 2023 – a vision that, when realized, will achieve what the Draft Guidance seeks – traceability through item-level serialization supported by product identifier data in TI.

**Sixth, the Draft Guidance cannot impose a de facto requirement.** A Guidance reflects FDA’s current thinking on a topic and is not binding on FDA or the public. See e.g., 82 Fed. Reg. at 30869 (July 3, 2017); Draft Guidance at lines 59-60. However, if the Draft Guidance is finalized as proposed, wholesale distributors and dispensers would risk enforcement action unless they provide, receive and retain the manufacturer’s initial transaction date – information that the DSCSA expressly exempts them from having and providing after the manufacturer’s first transaction into commerce. FDA may not, by guidance, dictate conduct upon pain of enforcement, which is contrary to the statute the Agency is interpreting.

Further, the Draft Guidance imposes these *de facto* requirements without having considered how this new, significant DSCSA interpretation impacts other trading partners. We addressed above that we see no public health or patient safety benefit associated with the Draft Guidance’s documentation provisions. Moreover, the Draft Guidance does not consider how the benefits for manufacturers come at the expense of dispensers and wholesale distributors, such as might have been revealed if a cost-benefit analysis, a small business impact analysis, and/or a Paperwork Reduction Act analysis (and Office of Management and Budget review) had been performed. To our knowledge, these analyses were not undertaken prior to issuance of the Draft Guidance.
B. The Draft Guidance Improperly Accelerates The Date By Which Distributors And Dispensers Can No Longer Transact In Unserialized Products

The Draft Guidance states: “beginning November 27, 2018, wholesale distributors and dispensers who purchase product from a repacker should ensure that they bear product identifiers.” Draft Guidance at lines 205-207. HDA believes this provision is contrary to the DSCSA and should be stricken. As the Draft Guidance correctly points out elsewhere, wholesale distributors and dispensers may engage in transactions with unserialized product before November 27, 2019 and 2020, respectively. See Draft Guidance at lines 196-198 (wholesale distributors); 199-201 (dispensers).

In specifying that wholesale distributors and dispensers “should,” beginning November 27, 2018, confirm product identifiers on product from repackers, the Draft Guidance flatly contradicts § 582(c)(2) and § 582(d)(2). These provisions of the DSCSA do not mandate transacting only with serialized product until 2019 (wholesale distributors) and 2020 (dispensers).

The Draft Guidance also appears to shift repackers’ compliance burdens onto wholesale distributors and dispensers. Under the Draft Guidance, wholesale distributors and dispensers must police repackers. Meeting this expectation would seem to require that distributors and dispensers would have to set up a system for, and conduct, an item-by-item inspection of product packages upon receipt. The DSCSA does not require this type of inspection upon receipt, particularly since wholesale distributors and dispensers are expressly permitted to transact with unserialized product until November 27, 2019 and 2020, respectively.

II. HDA URGES RECONSIDERATION OF FDA’S “INTRODUCED IN A TRANSACTION INTO COMMERCE” INTERPRETATION

Lines 105-110 of the Draft Guidance state:

FDA expects that, under the statute any package or homogenous case of product that is introduced in a transaction into commerce by a manufacturer as of November 27, 2017, must be encoded with a product identifier. For the purpose of this Draft Guidance, we consider a product to be ‘introduced in a transaction into commerce’ when the manufacturer first engages in a transaction involving that product.

HDA interprets this language to mean that a manufacturer cannot transfer ownership of an unserialized product or unserialized homogenous case in any transaction after November 27, 2017 (now 2018).
While we appreciate FDA’s efforts to extend enforcement discretion to manufacturers for serialization, the Draft Guidance creates significant confusion and disruption for the supply chain. HDA and our members agree with the approach long advocated by industry stakeholders, including many manufacturers, that the key to determining when manufacturers must begin serializing packages lies in the phrase “intended to be introduced in a transaction into commerce.” § 582(b)(2)(A) (emphasis supplied). We agree with other stakeholders that a manufacturer “intends” to introduce a product into a transaction into commerce when it packages that product. We urge revision of the Draft Guidance to clarify that the operative date should be the date on which the product is packaged, and not the date it is sold in a transaction. Further, we urge clarification that products packaged on or before November 27, 2018 are deemed to already be in the pharmaceutical distribution supply chain, are eligible for consideration as “grandfathered” under § 582(a)(5) and are, therefore, exempt from the product identifier requirement.

This “packaged by” date interpretation is consistent with FDA’s implementation of other, similar product identifier requirements. The date of manufacture was used to determine compliance with both the Unique Device Identifier (UDI) regulation (21 C.F.R. Part 801, Subpart B), and the Bar Code Rule, 21 C.F.R. 201.25. See 78 Fed. Reg. 58786, 58798 (Sept. 24, 2013). The UDI regulation exempts from its requirements any “finished device manufactured and labeled prior to the compliance date” of the regulation, for up to three years. 21 C.F.R. § 801.30(a)(1). In setting this date, FDA “recognize[d] the precedent set by the earlier bar code label rule” and, for that reason, “the date of manufacture should be used to determine compliance.” 78 Fed. Reg. at 58798 (internal quotations omitted). See also Preamble to Bar Code Rule, 69 Fed. Reg. 9120, 9147 (Feb. 26, 2004).

HDA emphasizes, however, that even if the Agency changes the operative date to the “packaged by” date, instead of the “transacted date,” it is still not possible for downstream trading partners to know when an individual package was introduced in a transaction into commerce. Wholesale distributors and other purchasers face the same technical and other challenges explained earlier in Section I above. Regardless of when a product is deemed to be in the supply chain (packaged by or transacted by), item-level traceability is only possible once a package is serialized and that product identifier is provided in the TI.

III. THE DRAFT GUIDANCE WILL IMPACT THE ABILITY OF DOWNSTREAM TRADING PARTNERS TO MEET OTHER DSCSA DEADLINES AND MAKES ISSUANCE OF THE GRANDFATHERING GUIDANCE ESPECIALLY IMPORTANT

The Draft Guidance states that it affects only the manufacturers’ obligation to affix product identifiers and the inability to verify a product that does not have an identifier. The requirement for repackagers to serialize as of November 27, 2018 still remains in effect. See e.g., Draft Guidance at lines 203-205. We urge FDA to consider the impact on, and the interconnection between, this extension and future DSCSA milestones, such as those effective for repackagers, wholesale distributors and dispensers in 2018, 2019 and 2020, respectively.
There are two immediate, potentially serious effects upon repackagers, wholesale distributors, and dispensers. Most significantly, pushing the serialization date out one year means that the time for unserialized product to move out of the supply chain shortens by one year. In 2018, 2019, and 2020, repackagers, wholesale distributors, and dispensers, respectively, will all have more unserialized product in inventory than originally contemplated. HDA members report that if they are still receiving unserialized products from manufacturers on or about November 27, 2018, past inventory movement experience indicates it is unlikely that all those unserialized products will be sold before November 27, 2019.

In the case of repackagers, extending the manufacturer compliance date is doubly burdensome because repackagers must also begin serializing on November 27, 2018 and, under the Draft Guidance, must also only receive serialized product in transactions after that date.

As discussed, the DSCSA takes a step-wise, gradual approach in which an early action forms the foundation for future actions; moving one milestone for manufacturers will cascade down to other, downstream trading partners and may alter their ability to meet their own DSCSA deadlines. While HDA supports this delay for manufacturers, we caution that FDA may need to move other compliance dates in the future and we may, at a later time, seek further enforcement discretion from the Agency.

One result of the year of enforcement discretion for product serialization is that there will be more unserialized product in the supply chain than was anticipated and it will extend the period in which for unserialized product will be sold and administered. Thus, it becomes even more urgent to clarify in the anticipated grandfathering guidance that trading partners may continue to sell unserialized product already in inventory. Failing to address – and permit – the sale or the administration of unserialized products already in the supply chain could significantly disrupt the flow of otherwise safe and effective medicines to patients, create shortages, and result in inefficient and costly burdens on the supply chain.

FDA seems to recognize the importance of grandfathering as it concludes the Draft Guidance by stating at the very end that, at a future time, it will address the relationship between the Draft Guidance and grandfathered product. Draft Guidance at lines 299-301. HDA endorses the Agency’s apparent recognition of the need for addressing the relationship between the two guidances.

* * * * *

In sum, HDA and its wholesale distributor members support the one-year period of enforcement discretion to allow manufacturers more time to accomplish serialization, a critical step toward item-level traceability. However, we do not support shifting burdens and compliance obligations to downstream trading partners who face potential enforcement action if they cannot document and provide information that is essentially unknowable at this time and
that the law expressly exempts from having to be provided and traced. To that end, HDA requests that the following immediately be stricken from the Draft Guidance:

- Section III.B.4, lines 250-270; and
- The sentence beginning on line 205, “Consequently, beginning November 27, 2018, wholesale distributors and dispensers who purchase products from a repackager should ensure that they bear identifiers.”

To avoid any ambiguity, including the real risk that regulators/inspectors will use the Draft Guidance in their licensure and enforcement decisions, we urge FDA to make these changes as swiftly as possible or otherwise issue a public clarification.

HDA also urges revision of the Draft Guidance so that the operative date for serialization is the date on which the product is packaged, and not the date it is sold in a transaction.

HDA thanks FDA for the opportunity to provide input to the Agency as it develops revisions to the Final Guidance. Should you have any questions about these comments, please feel free to contact me at 703-885-0240 or aducca@hda.org.

Sincerely,

Anita T. Duca
Senior Vice President, Regulatory Affairs