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BY ELECTRONIC FILING

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Dear Doctor Jung:


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.

We thank FDA for the Agency’s efforts to provide guidance to industry about Drug Supply Chain Security Act (DSCSA) implementation and in the Q&A format. However, both the timing and the content of the Draft Q&A are creating serious difficulties and confusion among manufacturers, repackagers and wholesale distributors, particularly regarding the National Drug Code (NDC) and expiration dating as presented in both the machine readable and human readable product identifier.
Manufacturers and repackagers have spent hundreds of millions of dollars and years of work to meet the product identifier requirements of the DSCSA by November 27, 2018. Among other things, manufacturers and repackagers have:

- Purchased equipment and software to serialize product,
- Integrated serialization into existing packaging lines,
- Developed new standard operating procedures,
- Programmed new software,
- Tested and then validated the changes to packaging and labeling operations,
- Created new artwork for labels, labeling and packaging,
- Purchased new labels, labeling and packaging, and,
- Submitted new labels to FDA.

Additionally, wholesale distributors have devoted enormous resources to supporting their suppliers’ costly efforts to assure that machine readable product identifiers can be scanned and read.

Consequently, the release of the Draft Q&A two months before the November 27, 2018 product identifier deadline has caused considerable consternation for trading partners who believed they had accomplished this element of DSCSA implementation (often months or years ago) and now must weigh the significant risks and costs of changing their labeling and packaging operations, again (and potentially a third time, if the Q&A is finalized with changes).

Unfortunately, the assertion that the Q&A is in draft and not binding offers no remedy. As the Agency would expect, industry takes even draft guidances very seriously, viewing them as "safe harbors"; any deviation from a draft guidance is undertaken very cautiously. We expect that inspectors and auditors with state and other authorities may similarly treat the Draft Guidance as highly authoritative. Indeed, FDA cites to draft guidance to support the Draft Q&A guidance (see footnote 24 of the Draft Q&A).

Our comments below focus primarily upon Q&A 3, 4 and 5 where we believe the greatest confusion and concerns arise. We explain how the Draft Q&A is misaligned with industry practice, creates significant uncertainty, and potentially severely hampers systems development for 2019 verification of saleable returns and 2023 electronic interoperability. We conclude with suggested editorial changes to Q&A 3, 4 and 5. We have suggestions regarding other parts of the Draft Q&A that are addressed separately.

I. **HDA SUPPORTS THE INCLUSION OF CLEAR INFORMATION ON DRUG PACKAGES FOR PATIENT SAFETY AND HEALTHCARE PRACTITIONER USE**

We emphasize at the outset that we wholly support the paramount need of healthcare professionals and patients to be able to properly identify drug products. HDA and its members recognize that the NDC is critical to healthcare practitioners’ ordering, dispensing, and reimbursement
practices and that pharmacy operations are built around, and are dependent upon the NDC. Similarly, a clear and unambiguous expiration date is critical to assuring that patients receive safe, potent medicines. Expiration dates also are vitally important to trading partners’ inventory management.

We therefore are committed to assuring that healthcare professionals have the information they need. As discussed below, we believe the NDC should appear on drug packages – but not in the human readable interpretation of the machine readable product identifier. We further believe that FDA should not, at this time, direct the precise format of expiration dating but should allow manufacturers and repackagers to determine the best means for its unambiguous presentation.

II. THE GTIN, AND NOT THE NDC, IS FUNDAMENTAL TO SUPPLY CHAIN SECURITY PROCESSES AND DSCSA IMPLEMENTATION

The chief difficulty of the Draft Q&A arises in that, in its efforts to assure that healthcare providers have an NDC on a drug package, it instructs that the NDC should be included in the human readable portion of the product identifier when manufacturers and repackagers have already implemented costly product serialization without the NDC in the human readable interpretation. Rather than NDCs, industry uses Global Trade Identification Numbers or GTINs to uniquely identify each product at the trade item level. GTINs are built in accordance with GS1 global standards; GS1 is an international standards-setting organization. GTINs are used throughout the world to uniquely identify products. In the U.S., a drug’s NDC is embedded within the GTIN. The GTIN allows a high degree of specificity that is very important to supply chain operations, with unique GTINs assigned for an individual package, bundle and case.

Unlike a GTIN, the NDC number for a drug package, a bundle, and a case are usually all the same because the NDC assigned to these different trade item configurations is typically not differentiated. This differentiation is critical to manufacturers, repackagers and wholesale distributors who all buy, sell and distribute products (and manage the associated data) in larger units – bundles, cases and pallets – and the NDC does not uniquely identify products at these levels. The utility of the GTIN to distinguish between a product, a bundle and a case, which the NDC cannot do, is graphically illustrated in the attachments included at the end of this letter.

The GTIN, not the NDC, underpins all of industry’s DSCSA serialization implementation to date. Unlike the NDC, the GTIN complies with GS1 global standards and is a vital component in achieving DSCSA compliance and interoperability as discussed below. The GTIN is fundamental to the supply chain security and integrity the DSCSA is intended to address.

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1 For example, for a 30-count bottle of a single drug, that product typically has the same NDC for the individual bottle, for those 8 bottles shrink-wrapped in a bundle, and for a case of 18 bundles (with a total of 144 individual bottles in a single case). In contrast, a unique GTIN is assigned to the bottle, to the bundle of 8 bottles and to the case of 18 bundles/144 individual bottles. The GTIN enables unique identification of a drug at every packaging level, including what the product is (name, strength, dosage form, etc.), what type of packaging it is, and what is the saleable quantity.
III. THE DRAFT Q&A SHOULD NOT EQUIVOCATE ON THE CONTENT AND FORMAT OF THE MACHINE READABLE BARCODE

The DSCSA requires that products bear a product identifier by November 27, 2018. “The term ‘product identifier’ means a standardized graphic that includes, in both human readable form and on a machine readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier [SNI], lot number, and expiration date of the product.” § 581(14). Uncertainty has long persisted regarding whether FDA deems as DSCSA-compliant a product identifier that includes an NDC as part of a serialized GTIN where that GTIN accords with the international standards of GS1.2

Having neither received nor perceived any objection from FDA, having received the Agency’s seeming tacit support,3 and further deeming there to be no other alternative that would satisfy the DSCSA, industry has coalesced around use of a GS1-compliant machine readable product identifier. That machine readable product identifier is comprised of a serialized GTIN, with an embedded NDC number, plus lot number and expiration date that are formatted in accordance with GS1 global standards and encoded to be machine readable in a GS1 data carrier, the GS1 2D DataMatrix.4

Given that we are aware of no other applicable international standard for the product identifier other than those of GS1, the Draft Q&A could, but does not, use the opportunity to endorse these GS1 global standards and industry’s widespread adoption of them. In fact, with its emphasis upon the NDC and that the SNI is the serialized NDC (see, e.g., Lines 268-274), the Draft Q&A appears to be tacitly endorsing an alternative interpretation, where a serialized NDC is embedded in some unidentified machine readable 2D data matrix barcode (see, e.g., Lines 251-253). If this is FDA’s intent, it is deeply disruptive. This is not what industry has implemented and the problems to such an approach are fundamentally at odds with the DSCSA’s requirements.

First, the serialized GTIN (with NDC embedded in it), lot and expiration encoded in the 2D DataMatrix complies with GS1 global standards, thereby satisfying the DSCSA’s requirements.

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2 Industry alerted FDA to the importance of the GTIN at least as early as the April 5-6, 2016 public meeting on Proposed Pilot Projects, and in follow-up comments to that meeting. (HDA’s comments are available here.) Additionally, multiple organizations put forth this view to FDA and the need for guidance on product identifier standards at the October 14, 2016 Public Meeting and in comments filed thereafter. HDA’s comments to that docket, Dkt. No. FDA-2016-2673, are available here. Given its importance and the cost and complexity, discussions and concerns regarding the format and content of the product identifier have preoccupied the supply chain almost since the passage of the DSCSA.

3 In its Guidance for Industry, Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages (March 2010) (SNI Guidance), FDA proposed an SNI that would comport with GS1 global standards, though that Guidance pre-dated the DSCSA and did not address the standards for a machine readable product identifier.

4 We use the term “2D DataMatrix” here as this is the GS1 term for the machine readable product identifier.
There is no international standard for the NDC, nor one for its serialization. Serializing the NDC would, therefore, not comply with any international standards as the DSCSA requires.

Second, while we recognize that the SNI “is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters”, the SNI must also “uniquely identify each package or homogenous case.” § 581(20). Given what HDA understands of packaging and serialization operations within manufacturers and repackers, it cannot be assumed that a serial number assigned to an NDC alone would result in a unique identification of the product. We believe that the logic of the serialization systems typically numbers each packaging level based on the GTIN rather than the NDC because the GTIN uniquely identifies the trade unit. It is possible that a serialized NDC for a product, bundle and case would all bear the same serialized NDC, whereas the serialized GTIN for a product, bundle and case would each be unique.

Last, and most critically, the DSCSA requires that the standards for the interoperable, electronic exchange of data (required for 2023) “comply with a form and format developed by a widely recognized international standards development organization.” § 582(a)(2)(A). Electronic Product Code Information Services or EPCIS is a widely used standard established by GS1 that enables the interoperable, electronic exchange of data. HDA’s wholesale distributor members (and, we believe, their trading partners) continue to believe that EPCIS is the only standard currently in use that can support the DSCSA’s requirement for electronic, interoperable exchange.5

Every model for data exchange currently being considered for 2023 uses EPCIS. The GTIN is a required data element for EPCIS. It will not be possible to achieve 2023 electronic interoperability, regardless of the particular technology or technologies used, without the serialized GTIN and the 2D DataMatrix it is encoded in.6

We note also that attempting to undo the serialization work that industry has committed to, invested in, and implemented would severely burden the supply chain and divert scarce resources from 2019 verification and 2023 traceability and electronic interoperability. Trying to change the linchpin on which industry has built serialization significantly imperils 2019 and 2023 readiness.

For the foregoing reasons, we believe that an NDC, embedded in a serialized GTIN, satisfies the letter and spirit of the DSCSA. The serialized GTIN uniquely identifies a product, comports with

5 FDA has similarly recognized EPCIS as an acceptable method for DSCSA data exchange, going back as far as the November 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.

6 We note also that verification systems, such as those tested in the HDA pilots and the Verification Router Service, are all built upon verification of the elements encoded in the 2D DataMatrix – serialized GTIN, lot, and expiration date. The NDC is, of course, embedded within the serialized GTIN being verified. Verification is not, and has never been, predicated upon verification of a less precise “serialized NDC.” This is not how products are being serialized under the DSCSA and an NDC and serial number alone may not accurately identify the product because the NDC is not unique as to different trade items levels for the same drug package, which could result in an incorrect verification.
the standards of an international standard-setting body, and enables electronic interoperability and data exchange. A serialized NDC does not.

IV. THE HUMAN READABLE INTERPRETATION SHOULD MIRROR THE MACHINE READABLE AND THE NDC SHOULD BE PRESENTED ELSEWHERE

We do not believe the NDC should be shown in the human readable interpretation, except as a part of the GTIN. Manufacturers and repackagers have already configured their complex packaging, serialization, and labeling systems to follow GS1 global standards for the human readable interpretation of the 2D DataMatrix, which provides, logically, for mirroring the 2D DataMatrix in its human readable interpretation. As the GS1-compliant serialized GTIN is what was encoded in the 2D DataMatrix, manufacturers and repackagers should provide a human readable version of that same number on the product label, and should not provide or be expected to provide the NDC there.

As noted above, the serialized GTIN, lot and expiration together uniquely identify the product at the trade unit level (unlike a serialized NDC). In the event that there is a problem with the machine readable 2D DataMatrix, the human readable interpretation may be of limited value if the GTIN is omitted. If the machine readable product identifier cannot be scanned, the GTIN in the human readable interpretation is necessary in order to be able to perform verification and traceability processes.

Nevertheless, we appreciate the concern of FDA and healthcare practitioners that, though the NDC is present in the GTIN, it can be difficult to decipher for those who are unfamiliar with it. We therefore recommend that the NDC be placed elsewhere on the drug package, and not in the human readable interpretation of the 2D DataMatrix.

We acknowledge and thank FDA for the statement in Lines 297-298 of the Draft Q&A: “If the NDC is on the label in its FDA-assigned 3-segment format, a company may also voluntarily affix or imprint the associated GTIN on the label.” However, we understand that many trading partners were confused by this language.

We recommend that Q&A 3, 4 and 5 be revised to state specifically and expressly that manufacturers and repackagers should provide the GTIN in the human readable interpretation of GS1’s 2D DataMatrix and that the NDC should appear elsewhere on the product label, somewhere distinct from (and, if possible, not near) the human readable interpretation or the machine readable 2D DataMatrix. We also support use of abbreviations and movement away from AIs in the human readable interpretation so that dispensers can more easily identify the discrete data elements within the GS1 product identifier, including the GTIN. Manufacturers and repackagers should

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7 GS1 General Specifications 4.15.1 is available here.

8 AIs or “Application Identifiers” are numeric signals that denote when one sequence ends and another begins. So, for instance, in the product identifier, AI17 would denote the beginning of the expiration date and AI10 would denote the end of the expiration date and the beginning of the lot number.
have the flexibility to decide how to present this human readable interpretation and the NDC given space limitations.

We suggest clarifying language in Section VI further below.

V. **PRESENTATION OF THE EXPIRATION DATE IN HUMAN READABLE FORMAT**

In the Draft Guidance at Lines 277-282, FDA recommends that the human readable interpretation of the 2D DataMatrix bar code represent the expiration date as follows:

- YYYY-MM-DD with non-zero day if using only numbers, or
- YYYY-MMM-DD if using alpha for month

If space is a problem, human-readable may include only a year and month,
- YYYY-MM if using only numbers, or
- YYYY-MMM if using alpha for month

There is no consensus within pharmaceutical industry as to how to present the expiration date. Practices vary between the U.S. and other countries and even within a single manufacturer or repackager.

Because expiration dating is so complex and implicates every supply chain entity as well as patient safety and inventory management practices, we do not believe that setting out FDA’s expectation in a draft Q&A, two months before the statutory deadline, is the appropriate process for so important of an issue. If FDA seeks to bring consistency to expiration dating presentation – which we wholly support – we believe the process should involve the solicitation of comment, consideration of alignment with or departure from the common expiration date formats used domestically and internationally, and the involvement of GS1 as a sector-neutral, standard-setting body.

In the meantime, we recommend that the Draft Q&A be revised. HDA defers to the well-informed views of manufacturers and repackagers regarding the best methods for the human readable presentation of the applicable expiration date. We suggest that whatever the format, the expiration date in the human readable interpretation should be consistent with what is encoded in the machine readable product identifier and be unambiguous and easily understood.

VI. **REVISED Q&A 3, 4 AND 5**

Below we set out our suggested editorial changes to the Draft Q&A. Suggested deletions are in red *strikeout* and additions in blue bold. Footnotes are omitted.
3. How should machine-readable formats include the product identifier required by the DSCSA?

The product identifier must be included in a 2-dimensional (2D) data matrix barcode when affixed to or imprinted on a package and in a linear barcode or 2D data matrix barcode when affixed to or imprinted on a homogenous case.

“The term ‘product identifier’ means a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.” § 581(14) of the FD&C Act. A “standardized numerical identifier” or SNI is “a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code [NDC] that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.” § 581(20) of the FD&C Act. These data elements of the product identifier “shall be included in a 2-dimensional data matrix barcode when affixed to, or imprinted upon, a package” and “shall be included in a linear or 2-dimensional data matrix barcode when affixed to, or imprinted upon, a homogenous case.” § 582(a)(9)(i)-(ii) of the FD&C Act.

FDA recognizes GS1 as an international standard setting body that has a standard for embedding a product’s NDC into a Global Trade Identification Number or GTIN. To comply with the DSCSA’s requirements for a machine-readable product identifier and to enable future electronic and interoperability, FDA recommends that a product’s GTIN (which includes its NDC) plus a serial number, lot number and expiration date be encoded into the GS1 two-dimensional (2D) DataMatrix bar code, also referred to as the 2D DataMatrix.

FDA recognizes the above format as compliant with the DSCSA.

4. How should the human-readable portion of the product identifier required by the DSCSA be formatted to appear on the drug package label?

In order to maximize the usefulness of the human readable product identifier, it should follow the machine-readable bar code format as closely as possible while still assuring that it is unambiguous and usable. To aid healthcare practitioners and other supply chain trading partners that may need to use product information, such as checking the expiration date or recording the NDC and lot number into a patient record, in the human-readable portion interpretation of the product identifier, FDA
recommends that the human-readable product identifier appear in the following, or a similar, unambiguous format:

- **NDC**
- **GTIN**: [insert product’s NDCGTIN]
- **SERIAL**: [insert product’s serial number]
- **LOT**: [insert product’s lot number]
- **EXP**: [insert product’s expiration date]

The NDC and serial number are the two components of the Standardized Numerical Identifier (SNI) as defined in section 581(20) of the FD&C Act. The Product Identifier requires the SNI, lot number, and expiration date. The drug package label must include the product identifier information (i.e., the NDC, serial number, lot number, and expiration date) in both the human-readable form and the machine-readable, 2D data matrix barcode format. FDA recognizes that variations may exist in how to abbreviate the human-readable portion of the label for the NDCGTIN, serial number, lot number, and expiration date. For example, “No.” may be used instead of “number,” or may not be listed at all.

FDA recognizes that there currently is no recognized and accepted standard for the presentation of expiration date. FDA recommends that the human-readable expiration date on the drug package label be presented so that it is unambiguous. **One option is to** include a year, month, and non-zero day in YYYY-MM-DD format if using only numerical characters or in YYYY-MM-DD if using alphabetical characters to represent the month. If there are space limitations on the drug package, the human-readable text may include only a year and month, expressed as YYYY-MM if using only numerical characters or YYYY-MMM if using alphabetical characters to represent the month. FDA recommends using a hyphen or a space to separate the portions of the expiration date. FDA recognizes that other unambiguous presentations of the expiration date are possible.

FDA recognizes the above formats as compliant with the DSCSA.

5. **Where do I put the NDC?** Can the GS1 Global Trade Identification Number (GTIN) be used in place of the NDC to comply with the requirements for a human-readable NDC as part of the product identifier?

No. The product identifier on the product label must contain the NDC. The NDC is currently a 10 or 11-digit number, in its FDA-assigned 3-segment format, that identifies the labeler, product, and trade package size.

FDA recommends, and it is the industry practice, **While industry’s practice is to embed the NDC in use a GTIN that may incorporate the digits of the NDC in accordance with GS1 global standards. However, the GTIN typically contains additional digits and is not in the 3-segment format by which the NDC is defined in**
FDA regulations. Moreover, FDA is concerned that use of the GTIN alone in the human-readable portion of the product identifier could lead to improper identification of the NDC and drug product. Therefore, the NDC should also appear if the NDC is on the label in its FDA-assigned 3-segment format. The NDC may appear near the linear bar code, if present, or elsewhere on the drug label as space allows. A company may also voluntarily affix or imprint the associated GTIN on the label.

We note that a manufacturer or repackager may choose to utilize a GTIN to encode the NDC number in the machine-readable portion of the product identifier (2D data matrix barcode).

VII. OTHER COMMENTS

a. Draft Q&A 7

Draft Question 7 asks if the 2D DataMatrix should be near the human readable portion of the product identifier. Draft Answer 7 says “yes,” noting that the machine readable bar code and human readable information should be near or next to one another “[i]f space permits.” Draft Q&A at Lines 313-316. HDA supports Q&A 7 and appreciates FDA’s recognition that placing the two presentations of the product identifier near one another will aid in their use and identification given that other bar codes may be on the label as well. We note, however, that if there is not adequate space around the 2D DataMatrix bar code, it cannot be read by a scanner. We suggest adding the following to Lines 316-17:

If space permits, the data matrix barcode should be affixed or imprinted near or next to the human-readable portion of the product identifier on a package. However, there should be sufficient blank space around the machine-readable bar code so that it can be read by a scanner.

b. Draft Q&A 13

Q&A 13 addresses how manufacturers and repackagers should submit a package label change to FDA that is solely for the purpose of incorporating the product identifier of an already approved drug. We suggest changing Q&A 13 to include labels affixed to both packages and cases as case labels are submitted to FDA as part of FDA-approved product labeling and will be bearing DSCSA-mandated product identifiers.

c. Draft Q&A 14

Answer 14 addresses when a manufacturer or repackager might have to provide product identifier information to FDA. Lines 413 – 417 state as follows (with footnotes omitted):
FDA may request information from a manufacturer or repackager in the event of a recall or to investigate a suspect or illegitimate product. In this circumstance, the manufacturer or repackager must provide the applicable transaction information, which includes the NDC number and lot number, as well as the transaction history and transaction statement for the product.

First, we note that the formatting in Lines 413 – 427 suggest that this is a block quote from another document but no document is cited. Second, as to the information a repackager or manufacturer could provide to FDA, we note that “transaction history” sunsets in 2023 per § 582(k)(1). Also, manufacturers, as the originator of a transaction have no transaction history to provide. Furthermore, repackagers who have purchased product directly from a manufacturer do not have any transaction history, either. They would provide the transaction information and transaction statement associated with their sale to their customer.  

We therefore recommend clarifying the phrase “transaction history and” in Line 416 of the Draft Q&A, so that the line would read, instead,

In this circumstance, the manufacturer or repackager must provide the applicable transaction information, which includes the NDC number and lot number, as well as the transaction history, as applicable, and transaction statement for the product.

d. Table at Line 495

We found aspects of the Table beginning at Line 495 confusing in several respects. First, we note that in column 1, fifth row, “each case contains 5 pre-filled syringes” should be changed to “each carton case contains 5 pre-filled syringes.”

We are uncertain how the fourth row is supposed to be different from the fifth row. We ask that FDA clarify what the example is supposed to convey.

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In sum, the human readable interpretation is vital to healthcare practitioner operations and supply chain processes when the machine readable product identifier cannot be read. But the Draft Q&A was issued eight weeks before the November 27, 2018 deadline, does not align with the well-known, universally-adopted, GS1 global-standards-based practice in place for years, and impacts potentially millions of individual packages and homogenous cases packaged by thousands of manufacturers and repackagers. To implement the Draft Q&A, manufacturers and repackagers would, among other things, have to:

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9 We have previously addressed with FDA the transaction data that we believe a direct purchase repackager provides to its customer. See, e.g., HDA comment on Standardization of Data and Documentation Practices for Product Tracing; Draft Guidance for Industry available here; HDA comment on DSCSA May 18-19, 2014 Workshop available here.
- Redo serialization-related standard operating procedures,
- Reprogram software,
- Re-test and re-validate the changes to packaging and labeling operations,
- Create new artwork for labels, labeling and packaging,
- Purchase new labels, labeling and packaging and potentially dispose of old stock, and,
- Re-submit new labels to FDA.

It will take months of work and staff hours to accomplish the above and regulated industry will incur real and substantial costs – recognizing that the Draft Q&A could change again if and when it is finalized. Further, implementing such changes to serialization and labeling now would unquestionably divert scarce industry resources from developing 2019 verification and 2023 electronic interoperability systems and processes and may imperil timely achievement of those critical supply chain security milestones.

We urge the Agency to clarify the intent and scope of the Draft Q&A as quickly as possible to eliminate the confusion it has engendered and to avoid the risks of not being aligned with the Draft Q&A, and the enormous costs that would have to be incurred to align with it.

* * *

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

Sincerely,

Anita T. Ducca
Senior Vice President, Regulatory Affairs

Attachments
Identifying a Product

What does using a GTIN provide?

Example of different packaging levels

- Enables unique identification of a drug at every packaging level, including: what the product is, what type of packaging is it, and what is the saleable quantity.

- GTIN is a globally universally acceptable identifier, throughout all other major industries, and is the underpin of the current work done for DSCSA.
Identifying a Product

What does using a NDC provide?

- Allows identification of a drug, but not the unique packaging level, or quantity.
- Currently a supply chain challenge as various packaging can not be uniquely identified with an accepted standard.