GS1 US Comment
to the

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

regarding

Standards for the Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format – Request for Comment

Docket No. FDA-2014-N-0200

GS1 US appreciates the opportunity to provide this comment to the United States Food and Drug Administration (FDA) regarding standards for the interoperable exchange of information for tracing human, finished and/or prescription drugs, in paper or electronic format.

GS1 US commends the FDA for its commitment and on-going efforts to improve the security of the nation’s drug supply chain. We agree that the ability to track and trace finished prescription drugs plays a significant role in providing transparency and accountability in the pharmaceutical supply chain, and we look forward to supporting the FDA as it works to implement the new requirements in the Drug Supply Chain Security Act (DSCSA).
# CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHO IS GS1 US?</td>
<td>3</td>
</tr>
<tr>
<td>QUESTION 1</td>
<td>4</td>
</tr>
<tr>
<td>QUESTION 2</td>
<td>6</td>
</tr>
<tr>
<td>QUESTION 3</td>
<td>7</td>
</tr>
<tr>
<td>QUESTION 4</td>
<td>7</td>
</tr>
<tr>
<td>QUESTION 5</td>
<td>8</td>
</tr>
<tr>
<td>QUESTION 6</td>
<td>8</td>
</tr>
<tr>
<td>QUESTION 7</td>
<td>9</td>
</tr>
<tr>
<td>QUESTION 8</td>
<td>10</td>
</tr>
<tr>
<td>QUESTION 9</td>
<td>11</td>
</tr>
<tr>
<td>QUESTION 10</td>
<td>11</td>
</tr>
<tr>
<td>QUESTION 11</td>
<td>12</td>
</tr>
<tr>
<td>QUESTION 12</td>
<td>12</td>
</tr>
<tr>
<td>QUESTION 13</td>
<td>13</td>
</tr>
</tbody>
</table>
**WHO IS GS1 US?**

GS1 US is a not-for-profit member organization established over 35 years ago by the grocery industry to administer and manage Universal Product Codes, also known as U.P.C.’s. The U.P.C. remains one of the most successful standards in history – with billions of barcodes scanned daily worldwide. This method of identifying products and capturing product data has evolved into what is now known as the GS1 System, the world’s most widely used supply chain standards, which include:

- globally-unique numbering formats (identification numbers) for identifying supply chain objects;
- barcodes and radio frequency identification (RFID) for capturing identification numbers; and
- data synchronization and electronic information exchange for sharing data.

GS1 US brings industry communities together to solve supply chain problems through the adoption and implementation of GS1 Standards. More than 300,000 businesses in 25 industries rely on GS1 US for trading partner collaboration and for maximizing the cost-effectiveness, speed, visibility, security and sustainability of their business processes using GS1 Standards. GS1 US also manages the United Nations Standard Products and Services Code® (UNSPSC®). Some of the world’s largest corporations participate in our boards and work groups, motivated by the knowledge that GS1 Standards help their companies reduce costs and increase both the visibility and security of their supply chains.

GS1 US is not:

- a software provider
- a hardware provider
- a commercial solutions provider
- a technology company
- a trade organization
- a government agency

GS1 US is a local member organization of GS1®, a global information standards organization that has been recognized as a voluntary, consensus standards body pursuant to OMB Circular A-119. GS1 has been accredited by the FDA as an Issuing Agency for the assignment of UDIs in the context of the U.S. FDA Unique Device Identification System, and GS1 US serves as the first point of contact for the FDA. In addition, GS1 US works with and actively supports numerous federal government entities, including:

- Department of Agriculture (USDA)
- Department of Commerce (DOC)
- Department of Defense (DOD)
- Department of Homeland Security (DHS)
- Department of Justice (DOJ)
- Department of State
- Department of the Treasury (DOT)
- Department of Veteran Affairs (VA)
- Commodity Futures Trading Commission (CFTC)
- Consumer Product Safety Commission (CPSC)
- Customs & Border Protection (CBP)
- Environmental Protection Agency (EPA)
- Federal Communications Commission (FCC)
- Federal Deposit Insurance Corporation (FDIC)
- Federal Trade Commission (FTC)
- Food and Drug Administration (FDA)
- National Aeronautics & Space Administration (NASA)
- Securities & Exchange Commission (SEC)
- United States Postal Service (USPS)
- National Institute of Standards & Technology (NIST)
- United States Congress
- United States Trade Representative (USTR)
QUESTION 1

NOTE: For clarity, our response presents the first two parts of Question 1 in reverse order.

1a. What practices, processes, or systems, either paper-based or electronic, do supply chain stakeholders use to exchange information?

Trading partners that use the GS1 System predominantly use Electronic Data Interchange (EDI) to exchange transaction information. EDI enables the computer-to-computer exchange of business transactions between companies using a standard format. Two common EDI supply chain transactions are Purchase Order and Advance Ship Notice. Supply chain stakeholders can exchange EDI transactions using traditional means [i.e., proprietary systems, Value Added Networks (VANS), and AS2], or using Extensible Markup Language (XML) to exchange transactions over the Internet. The U.S. pharmaceutical supply chain predominantly uses the ASC X12 EDI standard (discussed further below).

Although EDI is predominantly used, GS1 US is aware of two other approaches. Pharmaceutical dispensers typically use distributor-provided systems and Enterprise Resource Planning (ERP) systems to exchange transaction information. Such systems generally use distributor item numbers, which are then mapped to National Drug Codes (NDCs). In addition, there is also some use of portals across industry to exchange information.

NOTE ABOUT EPCIS: The evolution of state pedigree requirements over the past decade prompted supply chain stakeholders to pursue the use of the Electronic Product Code Information Services (EPCIS) for pedigree and traceability information. EPCIS enables supply chain partners to capture event information about objects as they move through the supply chain (e.g., shipped; received; etc.), and to share that information with their trading partners. EPCIS enables the exchange of information about supply chain events (e.g., Packing, Shipping, Receiving, Dispensing, etc.) using a standard format. Prior to the passage of the DSCSA, the pharmaceutical industry had been long at work with GS1 and GS1 US developing an EPCIS-based approach to pedigree and traceability pursuant to the requirements of the California regulation. An implementation guideline for forward logistics was released in February 2013, various pilots were initiated, and development continues to align with the new requirements of the DSCSA (including all permutations of Transaction Information, Transaction History and Transaction Statement). Because this approach represents current thinking about how to best meet serialization and traceability requirements in the pharmaceutical supply chain, this Comment will also present information related to this approach and its ongoing development and progress.

1b. What types of information about transactions do you exchange?

EDI: EDI is used to exchange information about supply chain transactions. The actual information exchanged depends on the specific transaction. In the context of this Request for Comment, the most applicable transaction is the Advance Ship Notice (also known as the ASN). The Advance Ship Notice transaction is used to communicate the contents of a shipment of goods, as well as other information relating to shipment. Typical information exchanged in an Advance Ship Notice include order information, product description, packaging, marking, carrier information, and packing configuration within the transportation mechanism.

EPCIS: EPCIS is used to exchange information about supply chain events. The data elements captured and recorded for each EPCIS event are grouped into five dimensions: who, what, when, where, and why. Table 1 presents the data elements recorded for each event:
Although the table above presents the basic data elements, the EPCIS standard enables extending event data in each direction.

1c. Are the practices, processes, or systems based on a standard?

EDI: The U.S. pharmaceutical supply chain predominantly uses the ASC X12 EDI standard. (The ASC X12 transaction for Advance Ship Notice is Transaction 856 – Ship Notice/Manifest.) ASC X12, chartered by American National Standards Institute (ANSI) in 1979, develops EDI standards for national and global markets. ASC X12 standards streamline business transactions using a common, uniform business language, and facilitate electronic interchange of business transactions such as order placement and processing, shipping and receiving, invoicing, etc. Members include standards experts from healthcare, insurance, transportation, finance, government, supply chain and other industries. GS1 US works through the U.S. National Bodies to develop ANSI, ISO and ISO/IEC standards which support the implementation of the GS1 System and incorporate key aspects of the GS1 General Specifications. GS1 US, as was its predecessor the Uniform Code Council, has had a close relationship with ASC X12 and the development of EDI standards since the mid 1980’s. GS1 US has held various roles with ASC X12 over the years, and currently chairs the X12M Supply Chain subcommittee. (X12M is the ASC X12 EDI supply chain transaction set which includes the 856 Ship Notice/Manifest subcommittee discussed above.)

EPCIS: EPCIS is a global GS1 Standard (published in 2007) for capturing and communicating data about the movement and status of objects in the supply chain. The EPCIS standard defines a data-sharing interface that enables supply chain partners to capture and communicate data about the movement and status of objects in the supply chain. The EPCIS specification provides technical standards, as well as a standardized set of service operations and associated data elements. The EPCIS standard also incorporates data standards [known as the Core Business Vocabulary (CBV)] for how to populate EPCIS data elements. The CBV provides lists of acceptable values for how to express what business process was operating on an object and the status of the object upon exiting the process. It includes syntaxes, vocabularies, and element values (with definitions). The CBV offers a pre-defined vocabulary for a large set of business events and scenarios. In addition, GS1 Global continues its on-going work at the global level to develop various EPCIS architectures (e.g., centralized; decentralized; etc.) to support global requirements, and to develop security, choreographies and checking services for event-based traceability.
EPCIS is a flexible standard that can be leveraged for a wide variety of business needs. There are numerous options for how the standards can be implemented in order to accommodate different applications and environments. In preparation for state pedigree requirements (most notably, California), members of the U.S. pharmaceutical industry (including leading manufacturers, wholesalers, retail pharmacies, healthcare providers, government agencies and industry associations) worked together to determine how the standards can best be applied to support pedigree and track and trace. These efforts resulted in the publication of the GS1 Healthcare US Implementation Guideline: Applying GS1 Standards to U.S. Pharmaceutical Supply Chain Business Processes to Support Pedigree and Track & Trace (R1.0) (hereinafter referred to as the “GS1 Healthcare US Rx Guideline”) in February 2013. This implementation guideline defines each event and data element recommended to support serialization, pedigree and track and trace, and shows industry members how to apply the standards to their own business processes. Pilots based on this guideline are underway. Work to accommodate DSCSA requirements using the EPCIS solution continues. A revision that addresses DSCSA Lot-Level Management as well as Item-Level Tracing (including all permutations of Transaction Information, Transaction History and Transaction Statement) is expected to be published in the Spring of 2014.

1d. Are they interoperable with other systems that supply chain stakeholders may be using?

The extent to which systems are interoperable depends on the extent to which they are aligned vis-à-vis standards. For example, systems supporting some supply chain and pharmacy practices utilize National Drug Codes (NDCs) to identify drugs. Conversely, point-of-sale systems use UPC barcodes, which encode Global Trade Item Numbers® (GTIN®). However, because GS1 Standards enable members of the pharmaceutical supply chain to integrate NDCs into their GTINs, those systems have a certain degree of interoperability.

EDI: X12 EDI is interoperable with other systems that supply chain stakeholders may be using to the extent that those systems are aligned with the same standards.

EPCIS: EPCIS solutions (like those based on the GS1 Healthcare US Rx Guideline) are interoperable with other systems that supply chain stakeholders use to the extent that those systems are aligned with the same standards (i.e., GS1 Standards).

QUESTION 2

2a. What practices, processes or systems, either paper-based or electronic, do supply chain stakeholders use to exchange information related to prior transactions?

There are very few (and very limited) transactions that include prior transactions. GS1 US is aware of two types of transactions that may fall into this category: (1) paper-based solutions used to comply with Prescription Drug Marketing Act (PDMA) and (2) paper-based solutions used to comply with state pedigree requirements. However, as paper-based solutions, they are not optimal and do not go all the way back to the manufacturer.

EPCIS: With regard to the EPCIS model being released and pursued by U.S pharmaceutical industry, there has been movement in this area. R1.0 of the GS1 Healthcare US Rx Guideline was developed around item-level serialization requirements provided by industry to satisfy California pedigree regulations. With the passage of the DSCSA, industry has been developing R1.1 of the guideline to align with DSCSA requirements. Specifically, R1.1 will include a new means to share Lot-Level Management data to satisfy DSCSA lot-level requirements (including permutations that support direct purchase, drop ship, etc.). In addition, R1.1 will update all of the R1.0 events
(which were originally developed around California requirements) to align with the DSCSA requirements for item-level traceability commencing in 2023 (including all permutations of Transaction Information, Transaction History and Transaction Statement). With these updates, R1.1 would support the exchange of information about prior transactions (i.e., in the Transaction History). R1.1 is expected to be released in the Spring of 2014.

2b. Are the practices, processes, or systems based on a standard?

The paper-based solutions used to comply with PDMA and state pedigree requirements are not standardized.

**EPCIS:** EPCIS is a global GS1 Standard for capturing and communicating data about the movement and status of objects in the supply chain.  (*See Question 1c above for more detail.*)

2c. Are they interoperable with other systems that supply chain stakeholders may be using?

Paper-based solutions used to comply with PDMA and state pedigree requirements are not interoperable.

**EPCIS:** EPCIS solutions (like those based on the GS1 Healthcare US Rx Guideline) are interoperable with other systems that supply chain stakeholders use to the extent that those systems are aligned with the same standards (i.e., GS1 Standards).  (*See Question 1c above for more detail.*)

**QUESTION 3**

Do the practices, processes, or systems that supply chain stakeholders use to exchange transaction information or transaction histories include or have the ability to include lot level data?

**EDI:** ASC X12 Transaction 856 – Ship Notice/Manifest can hold lot-level data. The practice is to include lot-level data in ASN transactions between manufacturers and distributors. The inclusion of lot-level data in transactions with providers is also supported. There are efforts underway to allow for the inclusion of Transaction History in these transactions.

**EPCIS:** The current version of the GS1 Healthcare US Rx Guideline (R1.0) includes lot-level data. In addition, R1.1 of the GS1 Healthcare US Rx Guideline will include a new means to share Lot-Level Management data to satisfy DSCSA lot-level requirements (including all permutations that support direct purchase, drop ship, etc., as well as Transaction Information, Transaction History and Transaction Statement). GS1 US expects publication of R1.1 in the Spring of 2014.

**QUESTION 4**

If you are currently using paper means to exchange transaction information or history, when do you plan to move to an electronic format?

N/A
QUESTION 5

5a. Are there challenges to adopting and using a system, in paper or electronic format, for the interoperable exchange of transaction information or history?

Lot-Level Management and Item-Level Traceability are collaborative supply chain solutions which require trading partners to share and exchange data. The primary challenge to any collaborative supply chain solution is ensuring that the data can be shared and understood. Paper formats present the largest challenges as they are not machine-ready, and therefore not searchable or interoperable with other systems. In terms of challenges related to electronic format, supply chain stakeholders and systems can have different ways of identifying products (e.g., manufacturer catalog number; distributor item numbers; NDC; etc), different ways of identifying parties and locations, and different approaches to defining data elements (e.g., date format; address format; etc.). These types of variations present a key challenge to adopting and using a system for the interoperable exchange of transaction information and history because they inhibit the ability to share and process data. The GS1 Healthcare US Rx Guideline provides a solution to industry by providing standardized data, standardized marking practices (GS1 DataMatrix) and standardized information sharing practices and events to address DSCSA requirements. An additional challenge is to determine how interoperable trading partner systems are to handle exceptions (e.g., overages, underages, data errors, etc.) when they occur.

5b. How can these challenges be addressed?

In order to meet this challenge and ensure that transaction information and histories can be shared and understood across the supply chain, paper systems need to be replaced with electronic approaches and data exchange needs to be standardized. Data exchange can be standardized by specifying (1) what data needs to be recorded and (2) how that data should be expressed (e.g., acceptable values; permissible format; etc.). Standardizing what data needs to be recorded helps trading partners collect and store data efficiently. Standardizing how that data should be expressed helps all systems to recognize and process data. GS1 US and the industry have also been working on how interoperable trading partner systems can manage exceptions. This body of work continues at both the lot-level and serialized item-level, and is slated to be published in R2.0 of the GS1 Healthcare US Rx Guideline.

QUESTION 6

Are there practices, processes, or systems that supply chain stakeholders can use now to exchange the information in the transaction statement required by the DSCSA?

The information required in the Transaction Statement is new, and is not a part of any current system. However, it might be possible to modify current systems in order to support Transaction Statement requirements:

EDI: The most applicable EDI transaction is the Advance Ship Notice or ASN (e.g., ASC X12 Transaction 856 – Ship Notice/Manifest). Although this transaction only communicates information about the current transaction between current trading partners (no prior transactions), it may be possible to alter the ASN to also include the information required in the Transaction Statement. The Healthcare Distribution Management Association (HDMA) is currently working to develop the ASN to align with DSCSA lot-level requirements, including the Transaction Statement and Transaction History.

EPCIS: With the passage of the DSCSA, industry has been developing R1.1 of the GS1 Healthcare US Rx Guideline to align with DSCSA requirements. Specifically, R1.1 will include a new means to share Lot-Level
Standards for the Interoperable Exchange of Information for Tracing Human, Finished, Prescription Drugs, in Paper or Electronic Format

Management data to satisfy DSCSA lot-level requirements (including permutations that support direct purchase, drop ship, etc.). In addition, R1.1 will update all of the R1.0 events (which were originally developed around California requirements) to align with the DSCSA requirements for item-level traceability commencing in 2023 (including all permutations of Transaction Information, Transaction History and Transaction Statement). R1.1 is expected to be released in the Spring of 2014.

QUESTION 7

7a. Are there challenges to providing the transaction statement to supply chain stakeholders in either paper or electronic form?

GS1 US notes two challenges regarding the Transaction Statement. The first challenge is that not all of the assertions in the Transaction Statement as currently written may apply to all stakeholders in all circumstances (e.g., grandfather exemptions for existing inventories; manufacturer assertions regarding “prior owners”; etc.). It is unclear how stakeholders are expected to respond to Transaction Statement assertions when they do not apply to the transaction. The second challenge is data storage issues resulting from the current form of the Transaction Statement. Both the length of the statement and the use of seven assertions which must be individually affirmed can present real challenges for data storage, especially considering that the Transaction Statement must be recorded for each transaction.

7b. How can these challenges be addressed?

As a preliminary matter, GS1 US understands that the Transaction Statement is a legal statement to which certain constraints and requirements may apply. The recommendations below are intended to respond to the challenges described above from a standards perspective. We defer to the experts on the legal requirements.

Challenges related to the lack of universal applicability of all assertions in the Transaction Statement may be addressed by either revising the language or providing additional instruction about how to respond to negative assertions and assertions that do not apply. Challenges related to the form and length of the Transaction Statement may be addressed by changing how the assertions are affirmed. It is unlikely that a stakeholder would respond with an affirmative answer to only some of the assertions in the Transaction Statement. Because of that, it may be possible to respond to the data storage issues by employing a single affirmation approach wherein the seven individual assertions are affirmed together as a group. This approach is routinely used on the Internet where Terms of Use, Disclaimers, and other statements are presented as one paragraph/field and the user clicks on one box to affirm the entire statement.

From a standards perspective, this could be accomplished by creating an attribute that enables a trading partner to indicate that they affirm all of the assertions in the Transaction Statement with respect to all of the information in the current transaction. Use of an affirmation attribute is a common approach in standards work. For example, Green Dot is a European network of industry-funded systems for recycling consumer good packaging materials wherein manufacturers contribute to the cost of recovery and recycling in order to satisfy the European Packaging & Packaging Waste Directive. Green Dot participation is indicated in transactions through the use of a Green Dot attribute, which is selected by trading partner to indicate that they affirm all of the required Green Dot assertions with respect to all of the information in the current transaction. To use this approach for the DSCSA Transaction Statement, the FDA would need to approve the use of a single affirmation approach, approve the use of a Boolean yes/no indicator, and publish a standard Transaction Statement to be associated with the attribute. The GS1 US Rx Guideline R1.1 includes the exact text of the Transaction Statement from the DSCSA Law and provides a single
attribute whereby a trading partner indicates their affirmation of the statement with regard to the associated shipping event or document. The attribute, definition or quoted statement will be adjusted based on FDA guidance.

**QUESTION 8**

Are there standards or current practices that you would recommend for FDA to consider as a model for providing any or all of the transaction information, transaction history, or transaction statement to other supply chain stakeholders?

GS1 US recommends that the FDA consider the EPCIS model embodied in the GS1 Healthcare US Rx Guideline. Prior to the passage of the DSCSA, the evolution of state pedigree requirements over the past decade prompted supply chain stakeholders to pursue the use of the EPCIS for traceability information. In fact, the pharmaceutical industry has been long at work with GS1 US developing an EPCIS-based approach to traceability.

In preparation for state pedigree requirements, members of the U.S. pharmaceutical industry (including leading manufacturers, wholesalers, retail pharmacies, healthcare providers, government agencies and industry associations) have been working together to determine how EPCIS standards can best be applied to support pedigree and track and trace. To support testing and analysis, they created a computerized model of the U.S. pharmaceutical supply chain that simulates forward logistics and reverse logistics processes using GS1 Standards for product serialization and visibility. (That model is known as the Industry Reference Model for the U.S. Pharmaceutical Industry.) The GS1 Healthcare US Rx Guideline R1.0 records all of the decisions points from the Reference Model, defining each event and data element needed to support serialization, pedigree and track and trace, and showing industry members how to apply the standards to their own business processes. R1.0 of the guideline represents a tremendous amount of effort to understand the chronologies and define the process. The implementation side of that work continues as manufacturers work on item-level labeling, and all trading partners work on managing the volume of item-level data.

Development of the EPCIS solution is on-going. R1.0 of the GS1 Healthcare US Rx Guideline was developed around item-level serialization requirements provided by the industry to satisfy California pedigree regulations. With the passage of the DSCSA, industry has developed R1.1 of the guideline to align with DSCSA requirements. R1.1 will include a new means to share Lot-Level Management data to satisfy DSCSA lot-level requirements (including permutations that support direct purchase, drop ship, etc., as well as Transaction Information, Transaction History and Transaction Statement). In addition, R1.1 will update all of the R1.0 events (which were originally developed around California serialization requirements) to align with the DSCSA requirements for item-level traceability commencing in 2023. The revisions work for R1.1 to accommodate DSCSA requirements was able to leverage the existing chronologies and therefore was a streamlined experience. Work for R2.0 is also underway. R2.0 continues the effort to build out the solution by examining exceptions processing and additional events. As with most collaborative supply chain solutions, 10% of the effort is to get the process to work, and 90% of the effort is exceptions processing. Therefore, there is much work that lies ahead. Nonetheless, the EPCIS model embodied in the GS1 Healthcare US Rx Guideline represents current thinking about how to best meet Lot-Level Management and Item-Level Traceability requirements in the pharmaceutical supply chain.

GS1 continues its on-going work at the global level to develop various EPCIS architectures to support global requirements (e.g., centralized; decentralized; etc.), and to develop security, choreographies and checking services for event-based traceability. This work promotes a standards-based approach that helps provide a level of interoperability between what is done in the U.S. and globally. With implementation of EPCIS growing in number and momentum around the world, the EPCIS approach would align with global efforts and help facilitate overseas
pharmaceutical manufacturers in complying with the DQSA. GS1 US recommends that the FDA consider this model and leverage the work that has already been done as a jumpstart for implementing the ultimate vision of the DSCSA for traceability in the pharmaceutical supply chain.

QUESTION 9
Are there other technologies, systems, or solutions available now that would enable the interoperable exchange of transaction information, transaction history, or transaction statements?

GS1 US does not know of any technology, system or solution available today that can enable the interoperable exchange of DSCSA Transaction Information, Transaction History, and Transaction Statement as currently deployed. All current solutions need to be amended in some form to meet the exact requirements of this law. Although many of the data elements in the Transaction Information and the Transaction History are currently supported, the information required in the Transaction Statement is new, and is not a part of any current system. GS1 US notes the following efforts are underway:

EDI: The Healthcare Distribution Management Association (HDMA) is currently working to develop the ASN to align with DSCSA lot-level requirements.

EPCIS: GS1 US has been working with industry to align the GS1 Healthcare US Rx Guideline with DSCSA requirements. This next release of the guideline (R1.1) will include a new means to share Lot-Level Management data to satisfy DSCSA lot-level requirements (including permutations that support direct purchase, drop ship, etc.), and will update all of the R1.0 events to align with the DSCSA requirements for item-level traceability. R1.1 includes all permutations of Transaction Information, Transaction History and Transaction Statement, and is expected to be released this Spring.

Even with these changes, all systems need to be optimized to support the vision of traceability expressed in the DSCSA, especially paper-based systems which must be converted to automated approaches.

QUESTION 10
Are there current practices, processes, or systems that could be used to exchange information between supply chain stakeholders and FDA with respect to providing, receiving, and terminating a notification that an illegitimate product is found in distribution?

GS1 US is not aware of any current practice, process or system that could be used to exchange information between supply chain stakeholders and the FDA for this purpose. However, there is a recall notification process used by the FDA to notify stakeholders. This process is effective and should be leveraged going forward to avoid supply chain participants needing to go to a website to learn about suspect/illegitimate products.
QUESTION 11

11a. Are there current practices, processes, or systems that could be used to exchange information between supply chain stakeholders or with FDA to respond to requests to verify the lot number, expiration date, and other indices of identity assigned to a product by the manufacturer or repackager (i.e., requests for verification of suspect product)?

GS1 US is not aware of any current practice, process or system that could be used to exchange information between supply chain stakeholders and the FDA to respond to requests for verification of a suspect product. There is no standardized electronic process to verify the lot number, expiration date, and other indices of identity assigned to a product, and there are on-going issues about how to automate this process. Today, this is predominantly a manual process using phone calls between the FDA and the stakeholder. However, GS1 Global continues its on-going work to develop security, choreographies and checking services for event-based traceability. The checking services may be of particular value in this area.

11b. Are these practices, processes, or systems effective?

The current process of personal contact from the FDA is effective in that it initiates a conversation with the stakeholder rather just a database response. However, this approach does not provide for party authentication to legitimize the caller (i.e., is this really the FDA?) and the responder (i.e., is this a legitimate person who is authorized to speak on behalf of the stakeholder?). Because of that, this approach raises concerns about information security and brand protection.

11c. If not, please provide recommendations to improve these practices, processes, or systems.

This would be an excellent topic for an FDA workshop with the industry.

QUESTION 12

Are there current practices, processes, or systems that could be used for providing information in response to requests from FDA or other appropriate Federal or State officials in the event of a recall or for the purpose of investigating a suspect or illegitimate product?

The pharmaceutical supply chain does not currently have a standardized, automated recall process, but there are a number of recall databases and services in existence. Nonetheless, EPCIS can provide an excellent platform for sharing information in such circumstances because all data is automated, standardized and searchable. For example, EPCIS includes the standardized “disposition” attribute “Recalled,” and a standardized format for exchanging information between stakeholders and the FDA (i.e., the EPCIS + US DSCSA Extension). (EPCIS is not totally in place across industry today. However, once adoption becomes more widespread, EPCIS would be an excellent system to support this need.)
QUESTION 13

13a. Are there other considerations related to standards for the interoperable exchange of information for tracing of human, finished, prescription drugs that have not been addressed by the previous questions?

From an information management point of view, there are three prerequisites that need to be satisfied to achieve interoperability among systems used by supply chain participants:

1: Supply chain partners must identify products and locations using a standardized product identification and standardized location identification method.

2: Supply chain partners must use standardized data capture methods in order to capture the standardized identification in a common way – like barcodes and/or EPC/RFID\(^1\) tags.

3: Once supply chain partners are using a common language to identify and capture product data, the information must be shared in a standardized format, ensuring data completeness and accuracy.

To meet those requirements for interoperability, the following three areas should be standardized:

- **Identification Standards**
  An identification standard specifies the format of an identifier and the rules for creating new identifiers. Identification standards ensure that identifiers are globally unique, and that each supply chain object, party and location has one and only one identifier. In addition, identification standards ensure that information systems are capable of processing and storing an identifier regardless of who assigned it.

  Standard methods of identification for supply chain objects (e.g., products; totes; cases; pallets; etc.), as well as supply chain parties and locations, are the backbone of a track and trace system. In addition, they are the foundation for data and interface standards.

- **Data Standards**
  Data standards define the content and meaning of track and trace data, so that one trading partner can understand data that it receives from another trading partner. Data standards include file formats, schema definitions, data dictionaries, etc.

- **Interface Standards**
  Interface standards define how trading partner systems interact with each other to exchange track and trace data. Interface standards include messaging protocols, web service definitions, etc.

---

\(^1\) EPC/RFID stands for “Electronic Product Code / Radio Frequency Identification.”
GS1 US encourages the FDA to apply this high-level perspective about what is needed to support interoperability as it works to implement the DSCSA and the vision of traceability in the pharmaceutical supply chain. Consider the GS1 System as an example: The GS1 System includes the data standards, interface standards and identification standards discussed above as part of an integrated suite of global standards for identifying, capturing, and sharing information regarding products, locations, assets and services. Table 2 (below) summarizes some of the GS1 Standards related to track and trace.

Table 2: Overview of GS1 Standards to Support Track & Trace

<table>
<thead>
<tr>
<th>GS1 Standards Supporting Track &amp; Trace</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification</td>
</tr>
<tr>
<td>trade items</td>
</tr>
<tr>
<td>locations &amp; trading partners</td>
</tr>
<tr>
<td>logistics units</td>
</tr>
<tr>
<td>individual assets</td>
</tr>
<tr>
<td>returnable assets</td>
</tr>
<tr>
<td>Data</td>
</tr>
<tr>
<td>Global Data Dictionary</td>
</tr>
<tr>
<td>Item Business Msg Std</td>
</tr>
<tr>
<td>Party Business Msg Std</td>
</tr>
<tr>
<td>Transactional Data:</td>
</tr>
<tr>
<td>Event Data:</td>
</tr>
<tr>
<td>Interface</td>
</tr>
<tr>
<td>Master Data:</td>
</tr>
<tr>
<td>GDSN</td>
</tr>
<tr>
<td>EPCIS Master Data</td>
</tr>
<tr>
<td>EPCIS Capture</td>
</tr>
<tr>
<td>EPCIS Query Discovery Services</td>
</tr>
</tbody>
</table>

In addition to these standards, GS1 continues its on-going work at the global level to develop various EPCIS architectures to support global requirements (e.g., centralized; decentralized; etc.), and to develop security, choreographies and checking services for event-based traceability. This work promotes a standards-based approach that helps provide a level of interoperability between what is done in the U.S. and around the world.

By providing the necessary standards to ensure interoperability, the GS1 System provides a comprehensive platform for companies to identify products and other business entities, capture visibility data (i.e., data to support track and trace), and share this data with trading partners to achieve global supply chain visibility. GS1 US encourages the
FDA to pursue this type of collaboration platform structure as it works to establish the track and trace system for the pharmaceutical supply chain pursuant to the DSCSA.

Figure 1: The GS1 System -- an integrated suite of global standards for identifying, capturing & sharing

13b. Please provide any additional information that you think could be helpful for the Agency to consider as it implements these provisions of the DSCSA.

In addition to the new requirements for the tracing of pharmaceuticals pursuant to the DSCSA, the FDA has also been hard at work implementing new requirements for the tracing of food pursuant to the Food Safety Modernization Act (FSMA). GS1 US believes that lessons learned in that effort would be an excellent resource for the Agency to consider with regard to its effort to implement requirements for the tracing of pharmaceuticals pursuant to the DSCSA.

One of the early FSMA requirements for the FDA was to establish pilot projects in coordination with the food industry to explore and evaluate methods for rapid and effective tracking and tracing of foods. The FDA asked the Institute of Food Technologists (IFT) to conduct the pilot projects and prepare a detailed pilot report. The pilot projects were designed to explore and demonstrate methods for rapid and effective tracking and tracing of food, including types of data that are useful for tracing, ways to connect the various points in the supply chain and how
quickly data can be made available to FDA. In March 2013, the FDA released the IFT pilot project report, (entitled Pilots Projects for Improving Product Tracing along the Food Supply System)\(^2\). In addition to providing the findings of the pilot projects, the report contains IFT’s recommendations to FDA for improving the tracking and tracing of food. GS1 US was pleased to participate in the pilot program, and to provide comments to the FDA as it prepared its report to Congress.

A key aspect of the IFT pilots was the testing of various track and trace software solutions available in the marketplace to support FDA traceforward and traceback investigations in the event of a foodborne illness or other food-related emergency. Those solutions were tested using data submitted by pilot participants using their current business processes for managing the related supply chain information. Understanding the importance of time during a food-related emergency, IFT broke down the various tasks needed to perform the investigative analysis and collected time data about how long it took to perform each task. The data collected spotlighted the issues that undermine effective track and trace, and highlighted the key enablers that promote it. Consider the following excerpt from GS1 US’ comment to the FDA (note that IFT used the term “collaboration platform” to refer to the track and trace software solutions):

**Understanding What Slows Investigative Speed**

In describing the mock traceback results on page 22, IFT described the results, and identified a key issue (emphasis added): “Many of the collaboration platforms were able to demonstrate the flow of specific lots of product through the supply chain with minimal effort, and some were able to identify convergence. However, while querying occurred within seconds, the collaboration platform providers reported spending between 3 - 7 days uploading the data into their systems due to the lack of a standard structure or format and the need to re-enter data.” Although this summary information alone was quite telling, IFT collected a treasure trove of time data that further illuminated the issues.

**Time Lost During the Investigation**

Understanding the importance of time during a food-related emergency, IFT broke down the various tasks needed to perform the investigative analysis and collected time data about how long it took to perform each task. On page 100 of the report, IFT described this process:

“Each technology company was asked to give the breakdown of the time they spent trying to understand the data (for tasks such as creating master data, linking the data to the scenarios or to ask IFT clarifying questions), time to feed the data into the system (either manual, semi-automated, or fully-automated data entry as well as error handling), and finally time to query or analyze those data for convergence (time to submit a query into the system as well as receive a meaningful response). The breakdown of time spent working with the data from five out of the nine solution providers is listed in Table 27.”

Table 27. Technology Provider Analysis Data Breakdown

<table>
<thead>
<tr>
<th>Technology Provider</th>
<th>Time to Understand Data</th>
<th>Time to Feed Data</th>
<th>Time to Query/Analyze Data</th>
<th>Percent of Pilot Data Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3 days</td>
<td>4 hours</td>
<td>Within minutes</td>
<td>50%</td>
</tr>
<tr>
<td>2</td>
<td>2 days</td>
<td>8 hours</td>
<td>instantaneous</td>
<td>100%</td>
</tr>
<tr>
<td>3</td>
<td>7 days</td>
<td>3 days</td>
<td>5 minutes</td>
<td>100%</td>
</tr>
<tr>
<td>4</td>
<td>2 days</td>
<td>1 day</td>
<td>10 minutes</td>
<td>33%</td>
</tr>
<tr>
<td>5</td>
<td>24 hours</td>
<td>24 hours</td>
<td>Within seconds</td>
<td>100%</td>
</tr>
</tbody>
</table>

“Time to Query/Analyze Data” (Column 4) relates to the software’s analytical capabilities, and illustrates how technology can enhance and expedite investigations. In contrast, “Time to Understand Data” (Column 2) and “Time to Feed Data” (Column 3) relate to the data itself, and illustrate how data issues can completely undermine investigative speed. In standards and technology circles, these issues are referred to as “data quality issues” and it is critical that the FDA recognize these data quality issues as fundamental barriers to an effective traceforward and traceback system.

Understanding Data Quality Issues

During the pilots, technology providers highlighted the fact that pilot data contained “significant data quality issues.” To be sure, some of the data quality issues were related to business practices (e.g., re-labeling without linking; using batch/lot as an identifier; etc.). These types of problems can be addressed with best practices and education. Some of the data quality issues were related to how data was submitted (e.g., non-searchable PDFs or scanned documents). These types of issues can be minimized with standardized interfaces (e.g., XML; GUI interface; etc.). Some of the data quality issues were due to variations in how products and parties/locations were identified (e.g., red round tomatoes being identified as “5x5 tomatoes” or “tomatoes 5x5” by different trading partners). These types of issues can be resolved by using standardized identifiers (e.g., GTIN and GLN). And some of the data quality issues were due to inconsistent data format and/or uncertainty about what information was being conveyed. These types of issues can be resolved by using data standards.

Standards provide the common language that enables trading partners to communicate with each other, and enables their IT systems to process and manage the data they exchange. When a participant used standards, the data they submitted was usually high quality and able to be processed without further human intervention. When a participant did not use data quality standards, the data they submitted presented numerous challenges that required significant human intervention before it could be processed. IFT was not able to address these issues due to the timing requirements of FSMA, so it looked to the technology providers and software to handle the disparate datasets. Reflecting on that experience on page 31, IFT noted that, “…the utility of an FDA-managed platform for collaboration with public health partners is completely dependent on the submission of accurate, complete event data. Technology should not be expected to compensate for poor recordkeeping.” GS1 US agrees.

GS1 US understands that supply chains and companies have different objectives and ways of implementing track and trace. These differences are attributable to many factors, including product, supply chain role, regulatory and business environments, cost/benefit strategies, and capabilities in terms of enabling technologies. Nonetheless, there are certain fundamental principles that underlie all track and trace systems, and the IFT Report documents hands-on experience with and important insight into many of those principles. GS1 US recommends that the FDA
consider the IFT Report a resource to support its efforts to implement requirements for the tracing of pharmaceuticals pursuant to the DSCSA. We believe this can be a valuable resource as the Agency evaluates “paper-based and electronic practices, processes or systems,” examines how to support investigative needs, and considers what is needed to support DSCSA requirements and its vision of traceability in the pharmaceutical supply chain.