



EPCglobal US COMMENT

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
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Anti-Counterfeit Drug Initiative Workshop

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EPCglobal US™ appreciated the opportunity to participate in the FDA Anti-Counterfeit Drug Initiative Workshop on February 8 and 9, 2006. In addition to participating in the Workshop, EPCglobal US is providing this comment to the FDA Counterfeit Drug Task Force in order to support the FDA in its effort to implement the pedigree requirements of the Prescription Drug Marketing Act (PDMA) and the use of an electronic pedigree (e-pedigree).

1 EXECUTIVE SUMMARY

RFID Standards Setting: Global technical standards ensure the universal applicability of EPC-related hardware and software products across the globe for all vertical sectors. EPCglobal is committed to developing horizontal technical standards for EPC-related hardware and software. To accomplish that, EPCglobal brings together trading partners from every vertical sector from every corner of the globe, to develop universal, industry-driven technical standards.

Role of the FDA: EPCglobal US commends the FDA for its support of and participation in the EPCglobal Healthcare & Life Sciences Action Group for standards development. The support of the FDA has been vital to the progress made thus far, and EPCglobal US appreciates their efforts. EPCglobal US also looks forward to the FDA expanding and continuing its participation by endorsing standards, providing guidance on security and privacy issues, publishing standardized protocols for drug efficacy testing with regard to RFID, and providing leadership in examining relevant legislation and working with the states and other federal agencies.

Mass Serialization: The optimal approach to serialization is the implementation of a single numbering convention. Multiple numbering systems are inefficient and invite mischief by persons intent on exploiting any weakness in legitimate systems for profit. Moreover, multiple numbering systems bring about undesirable consequences, like collision (i.e., duplicate numbers for the same item) and incompatibility (i.e., redundant processes being developed and implemented by trading partners). The standards-based approach utilized in the EPCglobal Network provides a comprehensive, uniform approach which is best suited for the needs of pharmaceutical trading partners in the global supply chain.

NDC: The NDC as represented by the Global Trade Item Number® (GTIN) should be incorporated into EPCs in order to avoid collision with other national drug codes in the global marketplace. Privacy concerns regarding the integration of NDCs can be addressed

through a variety of solutions, including masking the NDC and utilizing password locks on EPC tags.

Universal Pedigree: A universal pedigree that is acceptable to all states and the FDA could eliminate barriers and reduce complexity for industry and regulators. EPCglobal helped form and supports the Unified Drug Pedigree Coalition (UDPC) to further the work necessary to develop universal pedigree standards.

Data Management: A distributed approach to data management reinforces local control and ownership of EPC data, and provides a secure and efficient method for connecting trading partners together to share EPC information. The alternative approach to data management, implementing a central database for EPC information, is less desirable as it adds cost to each participant in the supply chain, and creates a singular target for those seeking to disrupt the nation's drug supply chain.

Information Security: EPCglobal's Hardware and Software Action Groups are committed to the rigorous examination of all aspects of EPCglobal Network security and to developing appropriate solutions. The Electronic Product Code does not contain, collect or store any personally identifiable information. As with conventional barcode technology, data which is associated with EPC will be collected, used, maintained, stored and protected by the EPCglobal member companies in compliance with applicable laws.

Privacy: EPCglobal and its Subscribers are committed to understanding and addressing the complex issues that surround consumer privacy and the use of EPC technology. EPCglobal Network participants are committed to gaining and retaining public confidence in the value and benefits of EPC technology, as well as the integrity of its use. In order to achieve that, EPCglobal is committed to the creation and dissemination of information about EPC tags and technology; working with industry and consumer organizations to provide information about EPC and RFID technology; and finding efficient and reliable technology solutions to address privacy concerns and further enable customer choice.

Notice: The *2003 Guidelines on EPC for Consumer Products* provide that consumers will be given clear notice of the presence of EPC on products or their packaging and will be informed of the use of EPC technology. This notice will be given through the use of an EPC logo or identifier on the products or packaging.

Consumer Education: Consumer information about EPC technology and its uses and benefits is essential. EPCglobal is committed to working with industry and consumer organizations to provide consumer education about EPC tags and RFID technology, and to create and disseminate information that is meaningful to the public.

2 WHO IS EPCglobal?

The AutoID Center, headquartered at MIT and working in conjunction with industry leaders and academic institutions around the world, designed a system for bringing the benefits of Radio Frequency Identification (RFID) to the global supply

chain. That system is referred to as the EPCglobal Network™. Once EPC technology was developed in an academic setting, the AutoID Center sought an experienced, standards-making body to commercialize the EPC technology and work with the business world to develop the necessary standards to make the EPCglobal Network a global supply chain solution. They chose two premier standards-based organizations: the Uniform Code Council, Inc.® (*now known as GS1 US*) and EAN International (*now known as GS1*). Together, these two organizations formed the joint venture EPCglobal Inc™. (EPCglobal US is the member organization of EPCglobal Inc that serves Subscribers in the United States.) EPCglobal is an open, subscription-based, not-for-profit standards organization. Neutral and consensus-based, EPCglobal is industry’s trusted partner for driving the global adoption and implementation of the EPCglobal Network across industry sectors. To that end, EPCglobal develops and oversees the standards for the EPCglobal Network.

3 WHO IS GS1?

As a joint venture between GS1 and GS1 US, EPCglobal leverages a nearly thirty-year heritage of successfully partnering with industry. GS1 is a leading global organization dedicated to the design and implementation of global standards and solutions to improve efficiency and visibility in supply and demand chains. GS1 and its subsidiaries and partnerships connect companies with standards-based solutions that are open, consensus-based, and universally endorsed. From bar codes, eCommerce, and data synchronization, to EPC/RFID, and business process automation standards, GS1 US is the trusted source to deliver innovative products, services and solutions for business’ most pressing supply chain challenges.



The Global Language of Business

OVERALL BENEFITS:
Improving efficiency & visibility in supply and demand chains

 <p>Global standards for automatic identification</p> <p>RAPID AND ACCURATE ITEM, ASSET OR LOCATION IDENTIFICATION</p>	 <p>Global standards for electronic business Messaging</p> <p>RAPID, EFFICIENT & ACCURATE BUSINESS DATA EXCHANGE</p>	 <p>Global Standards for data Synchronisation</p> <p>STANDARDISED, RELIABLE DATA FOR EFFECTIVE BUSINESS TRANSACTIONS</p>	 <p>Global Standards for RFID-based Identification</p> <p>MORE ACCURATE, IMMEDIATE AND COST EFFICIENT VISIBILITY OF INFORMATION</p>
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4 WHAT IS THE EPCglobal NETWORK?

The EPCglobal Network is a community of trading partners that engage in the secured capture, sharing and discovery of EPC related data about individual items as they move through the supply chain. This is achieved through the establishment and adoption of EPC technical standards that end users and solution providers use to develop the various hardware and software components. By using standards-based, EPCglobal-certified hardware and software components and interfaces, end users are assured that their EPC implementations and systems are compatible with their trading partners, enabling them to capture, store and share EPC related data up and down the supply chain.

5 CAPTURING & SHARING DATA IN THE EPCglobal NETWORK

The EPCglobal Network utilizes RFID technology to capture data, and Internet technology to share and discover data. To capture EPC data, EPC tags carrying a globally unique EPC identifier are affixed to containers, pallets, cases and/or individual units. Then, EPC readers at strategic points throughout the supply chain read each tag as it passes and communicate the EPC number with the time, date and location of the read. That read event is then registered and stored at the local read site. *(NOTE: If advanced functionality like a temperature sensor is also on the tag, this information will also be passed to the EPC reader.)*

Once the EPC data is captured as described above, Internet technology is utilized to share that EPC data among authorized trading partners in the global supply chain. When a trading partner queries the Network for information about an EPC, the query is directed to the location where information related to that EPC can be found. From there, various security services, including authorization and access control, are performed before access is granted to the requested EPC information.

6 EPCglobal NETWORK COMPONENTS

There are seven standards-based hardware and software components utilized by trading partners to capture, store and share EPC related data in the EPCglobal Network:

Electronic Product Code (EPC)	Globally unique number that identifies a specific item in the supply chain. This number may be used to identify a container, pallet, case or individual unit. The EPC format supports multiple standards-based numbering systems, including the NDC of the pharmaceutical industry.
EPC Tag	Radio frequency tag attached to an item consisting of a microchip that contains the EPC for that item, and an RFID antenna to reflect the EPC back to an EPC reader.
EPC Reader	Radio frequency reader that detects EPC tags and communicates their associated EPC numbers to the EPC Middleware.

EPC Middleware	Software that sorts and manages data coming in from the EPC readers.
Object Naming Service (ONS)	Network resolution services that direct EPC queries to the location where information associated with that EPC can be accessed by authorised users.
EPC Information Services (EPC-IS)	Information services necessary for the storage, communication and dissemination of EPC data in a secure environment.
Discovery Service	IN DEVELOPMENT - Mechanism for securely locating all read events and information for a given EPC, regardless of the data owner.

7 STANDARDS DEVELOPMENT

Global technical standards ensure the universal applicability of EPC-related hardware and software products across the globe for all vertical sectors. In addition, unified global standards combine all sectors and geographic regions in the market for EPC-related hardware and software products, creating a critical mass that encourages competition among vendors and manifests economies of scale that drive down costs. EPCglobal is committed to developing horizontal technical standards for EPC-related hardware and software. To accomplish that, EPCglobal brings together trading partners from every vertical sector from every corner of the globe, to develop universal, industry-driven technical standards.

7 - 1 EPCGLOBAL STANDARDS DEVELOPMENT PROCESS

As manager of the standards development process, EPCglobal encourages members of all vertical sectors, as well as any standards organizations for those sectors, to participate in the standards process by becoming active participants in the EPCglobal Action Groups. The Action Groups assist in developing the foundational building blocks of the EPCglobal Network, and serve as the forum through which trading partners can influence the process. By bringing operational, business and practical considerations to the table and working with researchers, regulators and vendors to ensure that each of those considerations are reflected in the network design, companies are investing in a standards format with the benefits of freedom of choice, interoperability and global applicability.

The EPCglobal Action Groups are making great strides in developing the numerous standards required for all seven Network hardware and software components. Higher performance tags, multiple frequencies, and other areas like biologics, medical devices and cold chain processes are under active consideration in the EPCglobal Action Group community.

7 - 2 HEALTHCARE & LIFE SCIENCES BUSINESS ACTION GROUP

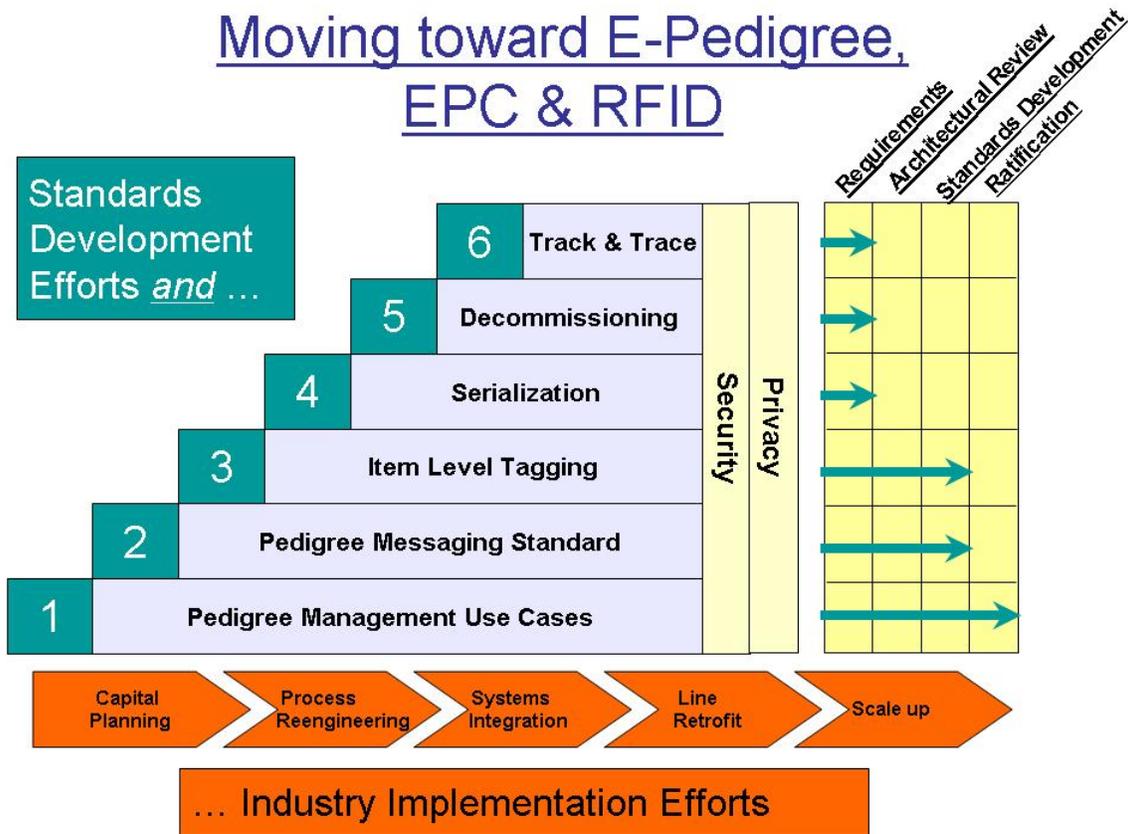
The EPCglobal Healthcare & Life Sciences Business Action Group (HLS) was formed in 2004 to establish business requirements, use cases and standards to support the implementation and use of the EPCglobal Network within the healthcare industry. There are currently over 300 participants in the HLS representing 150 companies, including thirty of the forty largest global manufacturers, the three largest distributors, and three of the four largest retail pharmacies. The HLS was formed in association with leading industry groups, including HDMA, NACDS, PhRMA and others, and benefits from the active participation from all key supply chain roles (i.e., manufacturers, distributors, retailers, and hospitals). The HLS is focused on addressing critical needs, including pedigree management, air interface standards, serialization, decommissioning and network security. In addition, EPCglobal helped form and supports the Unified Drug Pedigree Coalition (UDPC). The UDPC leads the effort to define uniform pedigree requirements, and its membership includes the FDA, Florida Department of Health, California Board of Pharmacy, Nevada Board of Pharmacy, and trade associations.

7 - 3 PROGRESS TOWARD ePEDIGREE

Standards development for the EPCglobal Network is a complex endeavor both in terms of the breadth of the standards to be developed, as well as the process for developing and adopting them. The Standards Development Process brings together a large and diverse community of supply chain trading partners and competitors in an effort to arrive at a consensus for the numerous standards that must be developed for all seven Network hardware and software components.

Significant progress has been made by the HLS in the development of standards for the healthcare industry, which are *in addition* to the standards for the network components.

Moving toward E-Pedigree, EPC & RFID



The other essential component for implementing the PDMA and ePedigree is industry implementation. As with standards development, industry implementation is a complex endeavor which takes time. From capital planning, to process reengineering, to systems integration, to line retrofits, to scaling up to full production – a committed and methodical industry implementation effort is as essential to the implementation of the PDMA and ePedigree as standards development.

7 - 4 ROLE OF FDA

EPCglobal US commends the FDA for its support of and participation in the HLS. The FDA's participation has demonstrated their on-going commitment to the examination of healthcare applications of EPC technology, as well as their commitment to support industry in the development of standards. The support of the FDA has been vital to the progress made thus far, and EPCglobal US appreciates their efforts.

Looking to the future, EPCglobal US looks forward to the FDA expanding and continuing its participation by endorsing standards, providing guidance on security and privacy issues, and publishing standardized protocols for drug efficacy testing with regard to RFID. In addition, the FDA can provide leadership in examining

relevant legislation and working with the states and other federal agencies, like the Drug Enforcement Agency (DEA).

8 SERIALIZATION OF ELECTRONIC PRODUCT CODES

The Electronic Product Code (EPC) is the standardized number in the EPCglobal Network. Standards-based numbering systems are essential for efficient and effective communication of product information in the supply chain. Many industry sectors have long utilized their own standards-based numbering systems for product identification within their sector (e.g., NDC for pharmaceuticals; UID for United States Department of Defense; EAN.UCC for consumer goods; ISBN for books; etc.). In order to facilitate the use of the EPCglobal Network by all sectors, the EPC data structure utilizes a flexible framework that supports multiple numbering schemes. This flexible framework enables each sector to incorporate its existing standards-based numbering system into its EPCs. The ability to incorporate the globally accepted standards of all sectors promotes the convergence of supply chains, a desirable goal for today's complex markets where supply chain lines are blurring and channels of distribution for various sectors are overlapping. This is especially true of the pharmaceutical industry where the supply chain has expanded to include supermarkets and consumer goods retailers in addition to traditional pharmacies.

8 - 1 EPC TAG DATA STANDARD FOR SERIALIZATION

The EPC Tag Data Standard defines the general data format for EPC number. In order to incorporate the globally accepted standards of all sectors, the EPC Tag Data Standard provide a structured, hierarchical numbering scheme in which the EPC is a numerical string comprised of several distinct segments. Three of those segments, the *EPC Manager Number*, *Object Class* and *Serial Number*, are relevant to this discussion:

- **EPC Manager Number:** An EPCglobal Network member who issues EPCs is referred to as an *EPC Manager*. EPCglobal issues a unique identifier, called the *EPC Manager Number*, to each *EPC Manager* to identify that member within the EPCglobal Network, regardless of industry sector or geography. The integration of the *EPC Manager Number* as a segment on the EPC string avoids fragmentation by enabling trading partners from any industry sector to be joined together in the EPCglobal Network.
- **Object Class:** The *Object Class* segment identifies the type of product to which the EPC is attached (e.g., a bottle of medication). As noted above, many industry sectors have long utilized their own standards-based numbering systems for product identification within their sector. The *Object Class* segment utilizes a flexible framework that supports multiple numbering schemes. For the pharmaceutical industry, the standardized identifier is the NDC, and the EPC Tag Data Standard includes a

mechanism for converting an NDC into a GTIN. The NDC as represented by the GTIN is then used to populate the *EPC Manager Number* and *Object Class* segments for pharmaceutical EPCs in order to support global compatibility.

- **Serial Number:** The *Serial Number* segment identifies a specific instance of the object class (e.g. this specific a bottle of medication). In order to enable *EPC Managers* to assign new EPCs without the possibility of collision with EPCs issued by other *EPC Managers*, the EPC Tag Data Standard nests the *Serial Number* segment beneath the *EPC Manager Number* and *Object Class*. This provides a framework to manage serialization that is thin, distributed and pervasive, and that supports the assignment of unique identifiers for the indefinite future. (It should be noted that serial numbers are random, not sequential.)

The structured hierarchy of EPC numbers nests identification information onto distinct segments of the EPC string (i.e., the *EPC Manager Number* segment identifies **who**, the *Object Class* segment identifies **what**, and the *Serial Number* segment identifies **which**). As a result, each segment conveys a different level of information about the item to which the EPC is attached. This is important not only for managing serialization and ensuring the uniqueness of EPCs, but also for connecting EPCs to the information associated with them on the network. Thus, utilizing a structured EPC format is optimal approach for serialization. The alternative approach of using totally randomized tags would be disruptive to the supply chain because in order to get any information associated with that random number, trading partners would need to go to the manufacturer's database, as opposed to just reading the EPC tag. However, the use of randomized numbers could be used temporarily for pilot testing.

NOTE: *Although the preceding discussion provides a high level description of the information represented by three segments on the EPC string, it should be emphasized that that information is not discernable by a visual inspection of an EPC number. The EPC data structure is a complex string of segments that includes the technical specifications necessary to read the various segments of the EPC (e.g., header, bit and filter values). As a result, EPCs can only be read utilizing software that implements the EPC Tag Data Standard to decipher the EPC string.*

8 - 2 SERIALIZATION FOR THE PHARMACEUTICAL INDUSTRY

The optimal approach to serialization is the implementation of a single numbering convention. Multiple numbering systems are inefficient and invite mischief by persons intent on exploiting any weakness in legitimate systems for profit. Moreover, multiple numbering systems bring about undesirable consequences, like collision (i.e., duplicate numbers for the same item) and incompatibility (i.e., redundant processes being developed and implemented by trading partners). Thus, the standards-based approach to EPCs described above provides a comprehensive,

uniform approach best suited for the needs of pharmaceutical trading partners in the global supply chain. Moreover, the NDC as represented by the GTIN should be incorporated as the *EPC Manager Number* and *Object Class* for EPCs in order to avoid collision with other national drug codes in the global marketplace.

Privacy concerns regarding the integration of NDCs can be addressed through a variety of solutions, including masking the NDC and utilizing password locks on EPC tags. For example, the NDC can be masked on the EPC string and the EPC tag itself password protected. By so doing, the tag would be locked during transit between trading partners and easily unlocked by authorized parties with the password for appropriate use in the supply chain for shipping, receiving and put away operations. Deactivation of tags is another option. Deactivation is being evaluated with special consideration of the numerous consumer and industry benefits of post-sale uses of tags and at what point in the supply chain tags should/could be deactivated.

9 UNIVERSAL PEDIGREE

Drug pedigrees are currently regulated at both the federal and state level. Consequently, there is the potential for inconsistencies and/or discrepancies that could inhibit passing a pedigree from one state to another due to variations in state pedigree regulations. A universal pedigree that is acceptable to all states and the FDA could eliminate those barriers and reduce complexity for industry and regulators. EPCglobal helped form and supports the Unified Drug Pedigree Coalition (UDPC) to further the work necessary to develop universal pedigree standards. The UDPC leads the effort to define uniform pedigree requirements, and its membership includes the FDA, Florida Department of Health, California Board of Pharmacy, Nevada Board of Pharmacy, and trade associations.

The UDPC examined the various state and federal pedigree regulations, and provided the EPCglobal Healthcare & Life Sciences Business Action Group (HLS) with a report of the data elements that should be included to achieve a universal pedigree. The HLS incorporated the UDPC universal pedigree data elements into the *Drug Pedigree Draft Messaging Standard*, which was submitted to the UDPC in February, 2006 for review and endorsement.

10 ePEDIGREE

A drug pedigree documents the distribution of a drug from the point of manufacture to the final dispenser. An ePedigree is an electronic drug pedigree. The EPCglobal Network provides a methodology that enables pharmaceutical trading partners to use RFID to capture and communicate supply chain events necessary to support the electronic pedigree requirements. The utilization of RFID and serialization for electronic drug pedigrees provides major advancements to drug supply chain management. RFID enables remote, accurate and efficient data collection for drug pedigrees. RFID eliminates the line of sight requirement to

read product identifiers; therefore, security mechanisms on cases do not need to be disabled so that cases can be opened to confirm what is inside. Moreover, serialization enables the collection of pedigree data particular to a specific unit, pedigree data that is unobtainable without serialization.

In conjunction with the two primary challenges facing the pharmaceutical industry today, the key objectives for the HLS in developing the *Drug Pedigree Draft Messaging Standards* were to:

- **Provide a universal data interchange format to express pedigree requirements of varied state regulations as drug products flow from one state to another, and**
- **Enable trading partners to send and receive pedigrees in a secure and interoperable manner that leverages existing business to business technologies and processes.**

In order to meet those objectives, the HLS defined the specific business and regulatory process and format requirements for drug pedigrees, and then utilized those requirements as the basis for developing the *Drug Pedigree Draft Messaging Standards*.

10 - 1 REQUIRED DATA ELEMENTS

The *Drug Pedigree Draft Messaging Standards* supports all required data elements of the PDMA and the states as recommended by the UDPC. To do that, the standards define the ePedigree format for the pedigree data elements required by the various regulations, including product information, transaction information, distributor and recipient information, and digital signatures, as well as item information to describe the specific non-serialized or serialized products in the transaction.

Product Information	Drug name
	Manufacturer
	Product NDC, dosage form, strength, container size
Item Information	Lot number and expiration date
	Quantity of units by lot
	Product serial number (if serialized)
Transaction Information	Transaction identifier (e.g., PO, Invoice) and date
	Transaction type (e.g., sale, transfer, return)
	Date received
Trading Partner Information	Business name, address, and license of seller
	Alternate ship-from location of seller
	Seller contact information for authentication
	Business name, address, and license of recipient
	Alternate ship-to location of recipient
Signatures/ Certifications	Digital signature of seller
	Digital signature of recipient

In addition, the standard defines the ePedigree envelope for sending multiple pedigrees to trading partners, including identifying information about the envelope, optional information about the relationship of pedigrees to products in cases to facilitate product-to-pedigree matching, and pedigrees for the products in the shipment.

10 - 2 SIGNATURES & AUTHENTICATION

The *Drug Pedigree Draft Messaging Standards* use digital signatures to electronically “sign” or certify the pedigree at each required point along the supply chain. Digital signatures are recognized as extremely secure, thus providing for document integrity, authentication and non-repudiation. In addition, ePedigrees will be authenticated electronically, using electronic verification of the digital signature *and* the signed transaction content for each transaction. This will ensure that signatures are valid and the transaction information has not been altered since signed.

NOTE: Authentication in this context refers only to authentication of the electronic pedigree signatures, not authentication of the actual drug to which the ePedigree pertains. Authentication of drugs requires chemical analysis, which is beyond the scope and capabilities of ePedigree.

10 - 3 VALUE OF THE ePEDIGREE INTERCHANGE STANDARDS

The standards developed by the HLS respond to the needs of the pharmaceutical industry and the associated regulatory agencies today. The standards provide a common format that meets federal PDMA and state needs, addresses regulatory and business requirements, and enables interoperability among trading partners in the drug supply chain.

- **Common format that meets PDMA and state needs**
 - ✓ Supports all required data elements for PDMA and states
 - ✓ Extensible format supports future state requirements

- **Addresses regulatory and business requirements**
 - ✓ Support for non-serialized as well as serialized items
 - ✓ Support for repackaged products
 - ✓ Support for sales, transfer, and return transactions
 - ✓ Support for creating electronic pedigree from paper pedigree
 - ✓ Support for digital signatures and electronic authentication

- **Enables interoperability among trading partners**
 - ✓ Representation of pedigrees in a common portable format
 - ✓ Exchange using existing business data transfer mechanisms

11 DATA MANAGEMENT

The EPCglobal Network utilizes a distributed approach to data ownership that vests authority over EPC information in each *EPC Manager*. To that end, each *EPC Manager* assigns its own EPCs, and has an EPC-IS that stores, secures and controls access to its EPC information. In order to link trading partners together, the ONS serves as a directory of the EPC-IS location for each *EPC Manager*. Thus, when a trading partner queries the network for information related to an EPC, the ONS simply directs the query to the appropriate EPC-IS. The EPC-IS then performs the necessary security services before granting (or refusing) access to its information.

This distributed approach to data management reinforces local control and ownership of EPC data, and provides a secure and efficient method for connecting trading partners together to share EPC information. The alternative approach to data management, implementing a central database for EPC information, is less desirable as it adds cost to each participant in the supply chain, and creates a singular target for those seeking to disrupt the nation's drug supply chain.

NOTE: It is foreseeable that there will be solution providers that offer data management services to enable individual *EPC Managers* to outsource their pedigree management needs instead of maintaining their own EPC-IS. This type of service would not be inconsistent with the EPCglobal Network distributed approach to data management. In such instances, the ONS would simply direct the query to the EPC-IS of the appropriate data management service.

12 SECURITY

The EPCglobal Network is in the early stage of implementation where significant effort is on-going to analyze and develop the specifications and standards for implementing the network. Even at this early stage, significant attention is paid to security for all aspects of the network. Toward that end, EPCglobal's Hardware and Software Action Groups are committed to the rigorous examination of all aspects of EPCglobal Network security and to developing appropriate solutions. Because that work is on-going at this time pursuant to the strict requirements of the EPCglobal Standards Development Process, it would be inappropriate to discuss any specific approach to network security as all aspects of and approaches to network security are being scrutinized. However, an overview of some of the aspects of network security being examined is provided below.

12 - 1 TAGS/READERS

The EPC tags contain RFID antennas that communicate the EPCs to the EPC readers within the network. Concerns have been raised about privacy issues when

EPC tagged items move from the supply chain to the consumer. These concerns, as all security issues, are being carefully examined.

Considerations to note about tag security:

- When EPC tags pass through EPC readers throughout the supply chain, the only information collected is the EPC and the time, date and location of the read. (If advanced functionality like a temperature sensor is also on the tag, this information will also be collected.)
- All information associated with an EPC is found in the network and is only accessible to authorized users behind firewalls, encoding and other security measures. (*Security regarding access to network information is discussed below.*)

12 - 2 ONS

As discussed above, the EPCglobal Network utilizes Internet technology to create the network for sharing information among authorized users. EPC searches mimic regular Internet searches in that users query the ONS with the EPC and the ONS returns the locations where information associated with that EPC can be found. From there, actual access to data in the EPCglobal Network is managed at the local level by the EPC-IS where each trading partner itself designates who has access to its information. (*Security regarding access to network information is discussed below.*)

Considerations to note about ONS security:

- These types of security concerns are not unique to the EPCglobal Network. In fact, they mirror the concerns with any Internet application. The EPCglobal community is working diligently to develop standards and best practices that ensure the security of EPC-related information communicated over the Internet.
- Although the network can be queried by anyone in this manner (i.e. the ONS will return the URL for the product information related to a given EPC), actual access to that information is restricted by the EPC-IS to only those users who have authorization.

12 - 3 NETWORK INFORMATION

As noted above, the ONS, when queried, returns the locations where information associated with that EPC can be found. However, each trading partner in the EPCglobal Network owns and controls the data associated with its EPCs. Therefore, actual access to information in the EPCglobal Network is managed at the local level by the EPC-IS through which each trading partner itself controls who has access to its information.

Considerations to note about the security of network information:

- The EPC-IS will leverage the security services technology necessary for the communication and dissemination of EPC data to only authorized users, including authentication and access control.
- Although the ONS is built upon an Internet-type infrastructure and is therefore public by its very nature, the EPC-IS provides the services necessary for secured communication and dissemination of EPC data, including authentication and access control.
- Each company in the EPCglobal Network owns and controls the data associated with its EPCs. As with all corporate information, companies have a vested interest in the security of their information and systems, and are therefore committed to the on-going development of the EPC-IS information security components.

13 PRIVACY

EPCglobal and its Subscribers are committed to understanding and addressing the complex issues that surround consumer privacy and the use of EPC technology. For EPC to gain broad acceptance, consumers must have confidence in the value and benefits of EPC technology, as well as the integrity of its use. EPCglobal Network participants are committed to gaining and retaining this public confidence. In order to achieve that, EPCglobal is committed to the creation and dissemination of information about EPC tags and technology; working with industry and consumer organizations to provide information about EPC and RFID technology; and finding efficient and reliable technology solutions to address privacy concerns and further enable customer choice.

13 - 1 PRIVACY GUIDELINES FOR CONSUMER PRODUCTS

EPCglobal adopted privacy guidelines for consumer products in 2003. The *2003 Guidelines on EPC for Consumer Products* are based on the Fair Information Practices and provide for:

- **Consumer Notice:** Consumers will be given clear notice of the presence of EPC on products or their packaging and will be informed of the use of EPC technology. This notice will be given through the use of an EPC logo or identifier on the products or packaging.
- **Consumer Choice:** Consumers will be informed of the choices that are available to discard or remove or in the future disable EPC tags from the products they acquire. It is anticipated that for most products, the EPC tags would be part of disposable packaging or would be otherwise discardable. EPCglobal, among other supporters of the technology, is

committed to finding additional efficient, cost effective and reliable alternatives to further enable customer choice.

- **Consumer Education:** Consumers will have the opportunity easily to obtain accurate information about EPC and its applications, as well as information about advances in the technology. Companies using EPC tags at the consumer level will cooperate in appropriate ways to familiarize consumers with the EPC logo and to help consumers understand the technology and its benefits. EPCglobal would also act as a forum for both companies and consumers to learn of and address any uses of EPC technology in a manner inconsistent with the Guidelines.
- **Record Use, Retention and Security:** The Electronic Product Code does not contain, collect or store any personally identifiable information. As with conventional barcode technology, data which is associated with EPC will be collected, used, maintained, stored and protected by the EPCglobal member companies in compliance with applicable laws. Companies will publish, in compliance with all applicable laws, information on their policies regarding the retention, use and protection of any personally identifiable information associated with EPC use.

13 - 2 PRIVACY GUIDELINES FOR THE HEALTHCARE INDUSTRY

EPCglobal organized a Public Policy Steering Committee (PPSC) working group on Healthcare and Life Sciences (HLS) to consider how to best ensure consumer privacy in the implementation of EPC technology within the healthcare industry. This group includes representatives from manufacturers, distributors and retailers of pharmaceuticals and biologics. The PPSC HLS working group is currently in the process of adapting the *2003 Guidelines on EPC for Consumer Products* for the healthcare industry, taking under consideration the challenges of prescription pharmaceutical labeling and packaging guidelines required by the FDA.

13 - 3 CONSUMER EDUCATION

As the use of EPC tags becomes more prevalent in the drug supply chain, it is important to ensure that consumers and the public in general are educated about EPC tags and technology. Consumer information about EPC technology and its uses and benefits is essential. EPCglobal is committed to working with industry and consumer organizations to provide consumer education about EPC tags and RFID technology, and to create and disseminate information that is meaningful to the public. To guide this effort, the PPSC HLS working group will review all relevant studies on patient privacy and has engaged a research firm to conduct patient focus groups and general population surveys. We think it is important for the FDA to be actively involved in these discussions.

14 CONCLUSION

EPCglobal US supports the FDA in its effort to implement the pedigree requirements of the Prescription Drug Marketing Act (PDMA) and the use of serialization and RFID for electronic drug pedigrees. The utilization of RFID and serialization for electronic drug pedigrees provides major advancements to drug supply chain management. RFID enables remote, accurate and efficient data collection for drug pedigrees. RFID eliminates the line of sight requirement to read product identifiers, and serialization enables the collection of pedigree data particular to a specific unit, pedigree data that is unobtainable without serialization. The EPCglobal Hardware and Software Action Groups are committed to the rigorous examination of all aspects of EPCglobal Network security and to developing appropriate solutions. In addition, EPCglobal and its Subscribers are committed to understanding and addressing the complex issues that surround consumer privacy and the use of EPC technology, and to gaining and retaining public confidence in the value and benefits of EPC technology, as well as the integrity of its use.

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For additional information, please contact:

Jack Grasso
EPCglobal, Inc
Princeton Pike Corporate Center
1009 Lenox Drive, Suite 202
Lawrenceville, NJ 08648
(609) 620-4555