



November 9, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Ref. Food and Drug Administration: Unique Device Identification; Request for
Comments (Docket No. 2006N-0292)

To Whom it May Concern:

On behalf of the members of the Coalition for Healthcare eStandards (CHeS), we appreciate the opportunity to respond to the Food and Drug Administration's (FDA) request for comments on unique device identification (UDI) system. CHeS is a collaborative of organizations dedicated to promoting the adoption and use of open data standards in the health care industry. Through the work of task forces, CHeS makes recommendations to accelerate industry-wide adoption of comprehensive data standards and encourages other industry representatives to participate in e-commerce standards work groups. The group purchasing organization (GPO) membership in CHeS manage more than \$80 billion in purchases annually for the nation's health care providers. Core, affiliate and other members of CHeS include the following:

Core Members:

Consorta
MedAssets
Novation
Premier
U.S. Department of Defense/Defense Supply Center

Affiliate and Other Members:

Actoras
Agfa
Association for Healthcare Resource & Materials Management (AHRMM)
Alcon
BD (Becton, Dickinson and Company)
Fulltilt Solutions
IMS
Lawson Software
Medbuy
UHC

CHeS Comments

CHeS appreciates this opportunity to provide comment in order to support the FDA in its consideration of Unique Device Identification (UDI) for medical services to improve patient safety. The following responses to the questions asked are being answered by the Product Data Utility (PDU) Organizing Committee of CHeS. The PDU Committee formed to study the feasibility of creating a product data utility to help synchronize medical /surgical product information across the healthcare supply chain. Among its recommendations is the need to establish a central industry resource for standardized product data from manufacturers that would enable participants to synchronize and maintain accurate product data in real time.

CHeS firmly believes a PDU is an essential, key component of a functioning UDI system.

Health care faces greater challenges to e-business development than other industries. It has made limited use of electronic data interchange (EDI) and bar coding technology that is widely adopted in other industries. Electronic standards have not been widely adopted. Participation in e-commerce exchanges is growing at a slow pace. Transactions along the health care supply chain are hampered by product data disparities between multitudes of file formats and attribute definitions. Product identification disparities have delayed progress in e-business development and e-standards implementation. Data disparities also contribute to an inordinate number of transaction errors at all points across the health care supply chain. Twenty-four percent of supply administration time is spent on data cleaning and corrections. In addition, keeping medical supply information consistent and accurate across trading partners remains a considerable challenge.

Based on the similarity of problems faced by health care and other industries and the success of other PDU initiatives it is reasonable to conclude that a central medical product data utility would help alleviate product data disparities and pave the way for effective e-business development and implementation. A PDU would provide a central industry resource for standardized product data from manufacturers and distributors and

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enable all participants to synchronize and maintain accurate item files in near real time from the manufacture through the supply chain to the end user. The data would be provided and certified by the manufacturers consistent with a data usage agreement that would be established by the PDU.

CHeS conducted a feasibility study, which identified the potential value of product data synchronization through the PDU for each stakeholder constituency in the healthcare supply chain. The following are examples of significant values afforded to stakeholders through the PDU. Note: Data Aggregators are organizations such as exchanges, e-commerce platforms, and any other industry related aggregator that performs e-commerce related services for customers. These organizations could provide PDU services and move data to the PDU.

Value to All Participants: The PDU will benefit all participants by eliminating errors in product identification and reducing product data maintenance costs for everyone. The PDU will also solve the current problem of disconnects between trading partners in the supply chain. Data Aggregators are not connected to the same suppliers and end-users are not connected to all manufacturers and distributors.

A. Manufacturer's Value: The PDU provides a single point of distribution of product information to all participants in the medical supply chain. It eliminates multiple customized product data feeds. It provides a single point for accurate UPN data to be distributed throughout the supply chain so the value of UPN markings can be derived. This will make it easier to integrate product information after manufacturer mergers and acquisitions. The electrical industry conducted a benefits assessment after their industry PDU was implemented. Annual savings to manufacturers were documented to be \$97,000 for every \$10 million of sales— 0.97% of sales.

B. Distributor Value: The PDU provides a single source for accurate product data from hundreds of manufacturers. It provides timely product data on both new products and discontinued products. The PDU will enable the following: Fewer invoice errors with suppliers and customers, Reduction in reconciliation of rebates/charge back mismatches with manufacturers, automatic replenishment by suppliers, closer integration with customer's systems, and tighter integration with data aggregators. The electrical industry conducted a benefits assessment after their industry PDU was implemented. Savings to distributors were documented to be \$73,000 for every \$10 million of sales—0.73% of sales.

C. Hospital/IDN Value: Accurate and consistent item information throughout the healthcare network. Enables easier and faster sourcing of products from prime vendor distributors, data aggregators, and products sold direct from manufacturers. Enables matching of product data master files to GPO and local contract files to assure hospitals

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are being charged the lowest contracted prices for purchases. Automation of new item loads with accurate product information and maintenance of existing items. Standardized identification of product information throughout the supply chain. A synchronized master file of UPN will enable the use of bar coding throughout the healthcare supply chain to increase patient charge accuracy and reduce medical errors.

D. Data Aggregator Value: Enables customers to source and order products easier, faster, and more accurately. Becomes a single source for accurate and robust product data from manufacturers. The PDU provides an open and neutral environment. Enables standardized data for all members of the supply chain. Eliminates multiple standards for product data and provides a single point for standards dissemination.

E. GPO Value: Increased recognition of sales of GPO contracted items. Single source for accurate product data from hundreds of manufacturers. Reduced and simplified data feeds from potential manufacturer contractors. Reduces data cleansing efforts. Better product identification for sales tracking to capture administrative fees and rebates for the GPO members. Enables the GPO to quickly identify and aggregate information on the new items that members are buying that need to be added to GPO contracts.

F. Material Management System Provider Value: Enables numerous values-add features to the MMIS that will increase sales of those MMIS that can utilize the PDU. Becomes a single data standard for Product Data for MMIS records and for accurate medical product data from hundreds of manufacturers to create accurate catalog master records. A MMIS that is integrated with the PDU will appeal to customers. This will enhance the ability to mine data within a hospital and across the hospital in a multiple hospital integrated delivery network.

CHeS Response to FDA Questions

Please note, the Technical Advisory Committee of the PDU Organizing Committee has a high-level description of the key data elements (categories) of information that should be managed with the PDU. Suppliers, identifiers, user organization identifiers, product and packaging identifiers, other key data synchronization elements, that it would like to share with the FDA. The draft document will be finalized within the next couple of weeks. The FDA is more than welcome to refer to this document as needed in your review process. See attached file *Copy of TAG Draft Summary 9-12-06 vs.3.xls*.

FDA Question 1

How should a unique device identification system be developed? What attributes or elements of a device should be used to create the UDI?

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It is recommended that rather than start from the beginning, the FDA should optimize the standards work already completed and the process developed for creating those standards wherever possible. Identification systems for products are already prevalent in the grocery, food service, automotive and electrical industries. Since the health care supply chain includes products from each of these industries it makes sense to build upon what is already in place.

The attributes or elements needed to create a UDI will vary based upon the classification of the device. Therefore, it is important that the UDI system include a classification system that places the device into a class that will in turn determine the appropriate attributes. In developing a single, mandatory system, the FDA should rely on an existing classification system. CHeS recommends the United Nations Standards Products and Services Code (UNSPSC®) that classifies all products. This classification system is an open standard. It is global which is important given the medical supplies manufactured and sold around the world.

The UDI, at a minimum, should include manufacturer, product name, make, model, lot number, unique description, expiration date and unit of measure. The use of a Product Data Utility (PDU) will allow users to extract additional information on the product that might not be included on the label that is attached to the product. This would allow for a richer database and the ability to add additional data elements as needed and agreed upon by the industry.

FDA Question 2

What should be the role, if any, of the FDA in the development and implementation of a system for the use of UDIs for medical devices? Should a system be voluntary or mandatory?

What exists today is a voluntary system where each manufacturer, distributor and provider has their own system. It is a system where duplicate classification systems are operating in parallel. It is hard to conceive that a voluntary system for a unique identification system would be advantageous since it would result in multiple systems that would add to the complexity. These dual systems increase the risk for patients and create operational and safety problems in hospitals. Therefore, CHeS recommends the FDA should mandate that the manufactures of medical devices adopt an existing global standard for creating and representing a UDI.

FDA Question 3

What are the incentives for establishing a uniform, standardized system of unique device identifiers?

The primary incentives are improving patient safety and reducing costs. These include reduction of medical errors, improving inventory control, processing recalls, identifying patients incompatible with devices or allergic reactions, reducing product counterfeiting and cost reductions for all supply chain participants. Another incentive is more efficient sourcing and distribution of products because of the ability to identify products across the supply chain through standardization of descriptions, packaging and labeling.

FDA Question 4

What are the barriers for establishing unique device identifiers? What suggestions would you have for overcoming these barriers?

Barriers include the current lack of a common taxonomy or classification system; the absence of a common industry wide utility that allows for synchronization for the supply chain; product labeling with information that is both human and machine-readable; need for global adoption and current efforts of other countries to implement standards; speed and cost of implementation for providers.

In addition, the barriers within the hospital field would be minimized by making the UDI mandatory and broad in scope. If the UDI were not mandatory, hospitals would be using systems where some items had standard identifiers and others did not.

FDA Question 5

Have you implemented some form of UDI in your product line? Please describe the extent of implementation, type of technology used and the data currently provided.

N/A

FDA Question 6

Should unique device identifiers be considered for all devices? If yes, why? If not, what devices should be considered for labeling with a UDI and why?

The UDI system should include basic information on all medical supplies and devices. CHeS believes that all items can be identified and should be identified by the original manufacturer. The UDI should be included to improve recall processes, increase patient safety and allow the health care supply chain to adopt consistent processes for handling and managing both the products and corresponding information. The information that is included for the products should vary based upon the class of device. For example, the information needed for a band-aid would be different from an implant device.

FDA Question 7

At what level of packaging (that is, unit of use) should UDIs be considered? Should UDIs be considered for different levels of packaging? If yes, should the level of packaging be based on the type of device? Why or why not?

UDI's should be implemented at the package level that is issued to the patient. This would insure the identification of the device as it is provided to the patient (right product and right patient) and minimize the errors associated with the provider organization re-labeling the device for issue to the patient. The information included at the issue to the patient should be sufficient to identify the device and allow it to be linked to the provider database which would be synchronized to the product data repository which would contain a more extensive database on the device. This process would allow different classes of devices to have more information but at the same time limit the required fields on the device itself.

FDA Question 8

What solutions have you developed or could be developed for addressing the technological, equipment, and other problems that might arise in developing and implementing a UDI system (e.g., solutions for packaging issues)?

CHeS has selected standards for identification of supply chain participants, product identification, and product classification and is in the process of participating with the Department of Defense (DoD) on a pilot for a Product Data Utility (PDU). Each of these elements is needed in order to implement an effective UDI and associated information system. This system is modeled after similar systems that are operational in the grocery, food service, automotive and electrical industries. CHeS believes it is important that the health care industry which uses many products from these and other industries adopt similar standards and processes for medical device UDI. The standards used by these industries are the GS1 standards that include GLN (location), GTIN (product), UNSPSC (classification) and GDSN (synchronization) which the health care industry is also considering to be used for a health care PDU.

Through its Committees, CHeS supports users with educational programs, a monthly eNewsletter, a website full of information and webinars. In 2007, CHeS also will be launching an IT working group led by the leading software companies to help providers with implementation of these standards in their current MMIS systems. Also, an IDN working group is being formed to follow closely the DoD pilot for a health care PDU to learn about how the hospital of the future would complete purchasing transactions using a PDU.

FDA Question 9

What is the minimum data set that should be associated with a unique device identifier? Would this minimum data set differ for different devices? If so, how? How would the data in the minimum data set improve patient safety? What other data would improve patient safety?

The minimum data set for all devices should include: Universal Product Number (UPN), manufacturer, make, model number, serial number, expiration date, and the unit of measure.

Medical devices that pose a higher risk to patients, such as implantable items, infusion pumps, surgical instruments and cardiac or respiratory monitors, should include more detailed information, such as a serial number identifying the exact device, whether the product is sterile, or the UDIs for necessary related equipment (such as leads that are compatible with a given implantable cardioverter defibrillator).

The UDI also should connect to a product data utility (PDU) - a system and organization that interconnects trading partners across the supply chain to synchronize core product data to standard specifications. CHeS recommends that PDU data sets include:

- Basic catalog and purchasing transaction data
- Basic usage cautions and restrictions data
- Patient use and billing data
- Product classification data
- Logistics data
- Expanded product attributes

The PDU would distribute standardized product data from manufacturers and distributors to data aggregators and end-users. It would enable participants to synchronize and maintain accurate product and packaging information in near real time. Specifically, the PDU functions would include:

- Loading and validation of standardized data from manufacturers and distributors
- Comparison of product information from manufacturer and distributor files to identify and correct disparities and omissions;
- Access to a central repository or verified, standardized and certified product information for authorized users; and
- Ongoing updating and maintenance of the data.

The data stored in the PDU could include safety information about the product as well as information for recall.

FDA Question 10

How should the UDI and its associated minimum data set be obtained and maintained? How and by whom should the UDI with its associated minimum data set be made publicly available?

Existing standards organizations, such as GS1 US, already develop and maintain classification systems. By choosing an existing standard that is already supported, the FDA could require that manufacturers work with the standards organization to obtain a UDI for each product. It is important that only open, global standards be considered.

FDA Question 11

Should the UDI be both human readable and encoded in an automatic technology? Should the UDI be on the device itself (e.g., laser-etched) for certain devices?

CHeS supports the UDI being both human readable and encoded in automatic technology. The human readable information on the device should be limited to what is minimally required to properly identify the product before applying to a patient. Likewise, the information encoded on the device would only need to be that needed to identify the product for safely distributing it to the patient. The encoded information would allow the automated system to access a richer database on the device that would contain much more information to assist in recalls and other patient specific safety checks.

Ideally, the UDI would be on the product itself, although in some circumstances, such as tiny devices, it may be on the packaging. Technical standards required for the UDI must support auto-ID technologies, including barcodes and RFID. This technical standard must be uniform across the health care field.

FDA Question 12

Should a UDI be based on the use of a specific technology (e.g., linear bar code) or be nonspecific? Please explain your response. If a bar code is recommended, is a specific type of symbology preferred, and if so, what type and why? Should the bar code be "compatible" with those used for the drug bar code rule? If yes, why? If not, why not?

CHeS supports having tracking requirements which include individual serial number, location of serial and lot number, serial number encoded on product, bar code type, lot number and lot number encoded on product. This would allow the caregiver to utilize similar technologies at the patient distribution location. CHeS is not opposed to using multiple symbologies since most current technologies can read and capture most all of these. Rather, it is only necessary to embrace the UDI based on global standards, and leave the selection of symbology and technology to the user community.

FDA Question 13

From your perspective, what public health and patient safety benefits could be gained from having a standardized unique device identifier system? How would such a system contribute to meeting device recall and adverse event reporting requirements, and to reducing medical error? Please submit detailed data to support benefits you identify.

A standardized UDI system will make the connection between medical devices and the information needed about those devices. This connection has many benefits to public health and patient safety as well, including reducing medical errors, facilitating recalls, and improving medical device reporting. Automatic product identification on all product levels ensures a safe and secure supply chain by providing greater visibility, accuracy and velocity for the benefit of all parties involved.

The UDI could facilitate the process of managing device recalls, which, according to ECRI are issued more than 600 times per year. Currently, the numbers used to identify a product can change between the numbers assigned by the manufacturer, the number used by a distributor (who may add a prefix or suffix) and the number maintained in a hospital's inventory management system. Therefore, recalls generally require manual searches of inventory and cannot be done by searching inventory management systems. Identification of patients who have received recalled devices requires manual review of medical records. With UDI, these processes could be conducted via electronic searches, resulting in more timely, complete and accurate management of the recall.

With a UDI, hospitals could more quickly and accurately notify and, if necessary, treat patients who have received a recalled device. All recalls would be facilitated by having a UDI system, as long as all devices have UDI.

FDA Question 14

From your perspective, what are the setup costs measured in time and other resources associated with the development, implementation, and use of a UDI system? Please submit detailed data to support these cost estimates.

CHeS has not looked at costs and without more specifics, it would not be appropriate for us to do so. However, CHeS does know from talking to hospitals and IDNs that much of the technology for a UDI system already exists and is well established. There are many tools readily available in the marketplace today for implementing a UDI system- and the marketplace is quite competitive. Moreover, much of the infrastructure for a UDI is already in place for many users. Many manufacturers already utilize bar codes and data pools, and are proficient users. In addition, many hospitals have already implemented standards-based identification for pharmaceuticals, and therefore have tools, equipment and expertise as well. CHeS identifies the real costs will be associated with integrating

the UDI information into hospital business systems building up their existing infrastructure to support it. However, the potential safety and efficiency benefits outweigh those costs. In considering costs, the implementation of a UDI should be considered separate from the implementation of the latest auto-id technology. Setup costs for implementing the UDI include changing existing hospital materials management and related information systems, redesigning work processes and training staff in how to use the new systems. Assuming the UDI is readable by the human eye; all hospitals could make these changes and realize quality and efficiency gains. These gains are of a sufficient scope that hospitals would begin to use the UDI quickly.

FDA Question 15

If you have already implemented a form of unique identification on your medical device labeling, what investments in equipment, training, and other human and physical resources were necessary to implement the use of UDIs? What factors influenced your decision to implement such a system? What changes in patient safety or economic benefits and costs have you observed since the institution of UDIs?

N/A

FDA Question 16

From your perspective, what is the expected rate of technology acceptance in implementing or using a UDI system?

The results of a 2005 AHA survey of hospitals show that hospitals are already adopting bar coding for a number of uses, including lab specimens, supply chain management, patient ID and pharmaceutical tracking and administration. In addition, 8 percent of the hospitals surveyed had fully or partially implemented RFID. These data are from spring of 2005. CHeS expects further adoption has occurred in the past year. For hospitals already using auto-ID, the UDI could be incorporated into existing efforts. For those yet to adopt auto-ID technologies, having a universal, standardized UDI would increase the value of implementing auto-ID.

FDA Question 17

From your perspective, what are the obstacles to implementing or using a UDI system in your location?

N/A

FDA Question 18

For hospitals and other device user facilities considering technology investments, what would be the relative priority of developing UDI capabilities compared to other possible advancements, such as Electronic Health Records, bedside bar coding for pharmaceuticals dispensing, data sharing capabilities across hospitals and other device user facilities, and other possible advances?

N/A

FDA Question 19

What infrastructure or technological advancements are needed for hospitals and other device user facilities to be able to capture and use UDI for basic inventory control and recall completion purposes? How costly are these advancements?

N/A

FDA Question 20

Referring specifically to completing medical device recalls in your hospital or other device user facility, for what share of the most serious (Class I) or next most serious (Class II) recalls would having access to and an ability to capture UDI information help you to respond?

N/A

In closing, CHeS thanks the FDA for this opportunity to comment on the development and implementation of the UDI. If you have questions on our comments, please contact Mark McDougall, CHeS Executive Director, at 734-677-3300 or mark@CHeStandards.org or Peggy Brody, Director of Communications, at 734-677-3300 or Peggy@CHeStandards.org



CHeS Product Data Utility (PDU)
Organizing Committee
Product Information Component Standard – PICS4& TAG Consolidated
Draft Document
September, 2006

Submitted to:
The Division of
Dockets Management (HFA-305)
Food and Drug Administration:
Unique Device Identification; Request for Comments
(Docket No. 2006N-0292)
November 9, 2006
Not For Distribution

Product Information Component Standard - PICS4 & TAG Consolidated - DRAFT

	CHeS PDU Organizing Committee				Sep-06
Information Category					
	Field Names	(1) GDSN	(2) Req	Format	Example Product Level 1 (Each)
Core Data for Transactions					
	Product Information Private (Y/N)	M		ID1	
	GDSN Product Classification Code	M		N8	
	Country of Origin	M		N3	
	Manufacturer Common Name (Brand Owner)	M	R	AN1/35	BD
	Manufacturer Item #	M	R	AN1/48	306544
	Information Provider ID (GLN)	M		AN13	
	Product Description - 1000	M	R	AN1/255	3 ml fill in 10 ml diameter BD PosiFlush™ normal saline 480/ca)
	Each Unit of Use (UOU)	M	R	ID2	EA
	Each Contents Count	M	R	N1/8	1
	Manufacturer Global Location #	M	R	AN13	1234567123459
	Unit UPC	M	R	N12	123456123459
	Unit UPC UOM	M	R	ID2	UP
	(3) Registered PDU Product ID (GTIN)	M	R	N14	00123456123459 (EACH)
	(4) Child Registered PDU Product ID (GTIN)	D		N14	Not applicable to the EA package
	Total Quantity of Child Products	D		N6	
	Product is a Consumer Unit (Y/N)	M		ID1	
	Product is a Despatch Unit (Y/N)	M			
	Product is an Invoice Unit (Y/N)	M		ID1	
	Product is an orderable Unit (Y/N)	M		ID1	
	Product is a variable Unit (Y/N)	M		ID1	
Product Status & Activation					
	Replaced Item #	D	O	AN1/48	306292
	Item Active Y/N	M	R	ID1	Y
	Product Effective Date	M	R	D8	19990501
	Product Info Cancel Date	D		D8	
	Product Info Publish Date	M		D8	

	First Order Date	M	R	D8	19950601
	First Ship Date	O	R	D8	19990615
	Product Expiration Date	D	O*	D8	20041231
Logistics Data					
	Pack Height	M	R*	R1/8	.900
	Pack Width	M	R*	R1/8	.040
	Pack Length	M	R*	R1/8	.030
	Dimension UOM	M	R*	ID2	IN
	Pack Weight	M	R*	R1/9	.0347
	Weight UOM	M	R*	ID2	PG
Extended and Alternate Descriptors					
	Product Description - 70	M	O	AN1/70	3 ml fill in 10 ml diameter BD PosiFlush™ normal saline
	Product Description - 30		O	AN1/30	PosiFlush Prefilled Syringe
	Product Brand Name	O	O	AN1/48	PosiFlush™
	Sub Brand Name	O		AN1/48	
	Manufacturer Product Category	O			
	National Stock Number (NSN)		O	ID13	9999-00-999-9999
	National Drug Code (NDC)		O*	ID11	12345123412
	Unit Bar Code Labeled		R	ID1	Y
	Each Alternate UPN (HIBCC)		O	ID11/20	JLHH123Z987654321
	Product URL		O	AN2000	http://catalog.bd.com/bdCat/viewProduct.do?customer?
Product Classification					-
	UNSPSC	O	O	ID8	42142610
	UNSPSC Version Number		O*	ID5	8.1
Alerts & Restrictions					
	Dangerous Goods Indicator (Y/N)	M		ID1	
	Class of Dangerous Goods	M		AN4	
	Dangerous Goods Hazardous Code	D		AN10	
	Dangerous Goods Packing Group	D		AN3	
	Dangerous Goods Shipping Name	D		AN200	
	Dangerous Goods Technical Name	D		AN200	
	Special Handling Required (Y/N)	Y	R*	ID1	N
	Special Handling Description	C	O*	AN2000	
	Hazardous Material (Y/N)	M	R*	ID1	
	Hazardous Material Description	DC	O*	AN2000	
	Flash Point Temperature	DC	O	ID9/13	
	Radioactive	DC	O	ID2	

	Product Ingredient Irradiated(Y/N)	M		ID1	
	Raw Material Irradiated (Y/N)	M		ID1	
	Product Genetically Modified(Y/N)	M		ID1	
	URL HAZMAT Instructions	DC	O	AN1/35	
	Disposal Instructions (Y/N)	DC	R*	ID1	
	Disposal Instruction Description	DC	O*	AN2000	
	MSDS Sheet (Y/N)	O	R*	ID1	
	URL MSDS		O	AN2000	
	Shelf Life (Days)		O	ID5	
	Enclosure Restrictions	OC	O	AN2000	
	Keep Dry	OC	O	AN1/35	
	Refrigerate	OC	O	ID9/13	
	Freeze	OC	O	ID2	
	Do Not Freeze	OC	O	AN1/35	
	Sterile (Y/N)	?	R*	ID9/13	
	Sterilize Prior to Use	?	O	AN1/2000	
	Product Warning		O	AN1/35	
	Diet Allergen(Y/N)	M			
	Caustic	DC	O		
	Contains Latex (Y/N)	?	R*	ID1	
	Contains Thimerosal (Y/N)	?	R*	ID9/13	
	Contains Mercury (Y/N)	?	R*	ID1	
	Contains PVC/DEHP(Y/N)	?	R*	ID1	
	Reusable (Y/N)	?	R*	ID1	
	Packaging Returnable (Y/N)	O			
	Packaging Environment Use Cycle (Y/N)	O		ID1	
	Packaging Recyclable Scheme	OC		AN70	
	Product Use Cycle	?	O	AN1/35	
	Product Recall (Y/N)	?	O*	ID1	
	Product Recall Description	?	O*	AN2000	
	Product Recal URL	?	O	AN1/35	
	Expiration Date Required (Y/N)	O	R*	AN1/35	
	Package Expiration Date Type	OC			
	Expiry Bar Code or RFID Tag (Y/N)	?	R*	ID1	
	DEA Doctor-on-site Number Required (Y/N)		R*	AN7	
Tracking Requirements					
	Individual Serial # Tracking Required (Y/N)		R*	ID1	N

	Location of Serial and Lot Number				
	Serial # Encoded on Product (Y/N)	O	R*	AN1/35	
	Bar Code Type	DC			
	Lot Number Required (Y/N)		R*	ID2	Y
	Lot # Encoded on Product (Y/N)		R*	ID1	Y
	Patient Tracking Record Required (Y/N)		R*	ID1	
Patient Use and Billing Data					
	MEDICARE HCPCS Number		O	ID9	
	APC Reimbursement Code		O	ID9	
	APC Version Number		O		
Additional Optional Descriptive Attributes					
	Dosage Form	O	O		
	Potency	C	O		
	Composition	C	O		
	Age	?	O		
	Gender	?	O		
	Ergonomic Location	?	O		
	Properties	C	O		
	Color	C	O		
	Size - Small, Medium, Large, 5,6, AA, AAA, C	C	O		
	Flavor	C	O		
	Fragrance	C	O		
Optional Pricing & Ordering Data	Option 2 - Pricing		O		
	List Price		O	AN1/8	
	Price UOM		O	ID2	
	Priced UOM Quantity		O	N1/8	
	List Pricing Effective Date	O	O	D8	
	List Pricing Expiration Date	O	O	D8	
	Published Distributor Cost	?	O	N1/8	
	Published Distributor Cost UOM	?	O	7	
	Published Distributor Cost UOM Qty	?	O	AN2000	
	Minimum Order Quantity	O	O	M,D,B	
	First Allowable Order Date	O	O	Y/N	

	First Ship Date	O	O	D8	
	Multiple Order Quantity	O	O	N1/8	
	Purchase Sources: Manufacturer, Distributor, Both		O	M,D,B	
	Shippable by Manufacturer		O		
	Legend Notes:				
	(1) GDSN:	GDSN = M: This is a required field on the GDSN - field length and format conforms; D = This is a required field on the GDSN - field length and format conforms; D = This is a required field on the GDSN - field length and format conforms; DC = This is an attribute code required if applicable, OC = This is an optional descriptive optional attribute codes available in the GDSN, ? = Research not complete			
	(2) Req:	<i>R=TAG Recommended Core Requirement; for all Products;</i>			
		<i>R*= Recommended Desired Core Requirement for all products however some organizations may not</i>			
		<i>O*=Optional Field that is required as a Recommended Desired Core Requirement if it applies to the</i>			
		<i>O= Optional Field - discretion of Manufacturer</i>			
	(3) Registered PDU Product ID	<i>Represents a unique ID assigned by the PDU OR by the GDSN (a GTIN) that may be used in the supply chain. Represents only one purchaseable unit of measure. A manufacturer could use the same catalog number for multiple UOMs. Each, but there would be a unique PDU Registered Product number for each UOM</i>			
	(4) Child Registered PDU Product ID	<i>Represents the related unique ID for the next lower unit of measure. (assigned by the PDU OR by the manufacturer) Example the Child of a product that is a Box may be a Case</i>			
	(5) Pack Levels	<i>4 Levels of packaging have been defined. Each packaged unit stands as its own registered product and could have package different dimensions, could have different product activation date, etc.</i>			