

## Medical Products Group

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

**RE:** *Unique Device Identification; Request for Comments  
[Docket 2006N-0292]*

Dear Sir or Madam:

Abbott Laboratories submits the following comments regarding FDA's request for comments on "Unique Device Identification" published in the Federal Register on August 11, 2006 at 71 FR 46233.

As a manufacturer of a diverse line of medical devices, we appreciate the complexity of implementing a unique device identification system and urge the agency to proceed cautiously and continue to engage stakeholders as it considers a unique device identification system for medical devices. The issues associated with implementing a unique device identification system for medical devices are as diverse as the types of devices.

Our comments respond to the twenty questions posed by FDA in its Federal Register Notice. Additionally, in regards to developing a unique device identifier system, we recommend the agency consider the following items:

- Unique device identifiers currently exist for many device categories. Any new system should recognize and incorporate existing standards, such as GS1 and HIBCC, as well as existing data assignments, such as FDA's own National Drug Code (NDC) and National Health Related Items Code (NHRIC), GS1, and HIBCC. We note that the Global Trade Item Number (GTIN) of the GS1 incorporates both the NDC and NHRIC<sup>1</sup>. Compatibility of any new system with existing systems is key to preventing disruption to manufacturers who have already implemented unique device identifiers.
- For certain product lines, to change existing device identifier systems will have significant implications, which, in some cases, may include disruption in patient

<sup>1</sup> See [http://www.uc-council.org/ean\\_ucc\\_system/membership/universal\\_product\\_number.html](http://www.uc-council.org/ean_ucc_system/membership/universal_product_number.html) (accessed November 8, 2006)

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care. For example, blood glucose monitoring systems use unique device identifiers based on the NDC that are the key identifier for third-party reimbursement within the United States. These unique device identifiers, which are compatible with existing database infrastructure, are involved in 25 million pharmacy transactions<sup>2</sup> annually and \$2 billion in annual sales<sup>3</sup>. FDA issued NDC manufacturer labeler or identifier codes, which are combined with a manufacturer identified product code and package code, have been used to identify blood glucose monitoring devices for greater than 15 years and are an integral part of the United States health care system involved with the management of diabetes.

- Without a well-documented safety benefit, the implementation of a UDI system has significant financial implications. The addition of a manufacturer and product identifier, alone, to product labeling will require redesigns. For one product line, it is estimated that 4,100 labels could require redesign to accommodate a unique device identifier. Inclusion of dynamic information, such as lot number and expiration date, into the unique device identifier not only increases the financial impact, but also would require changes to the overall manufacturing process because lot number and expiration date change with each manufactured lot. For example, installation of internal online printing systems would be required and labeling printed by third parties would have to be printed internally.
- In contrast to the statement, "current requirements do not ensure that devices can be tracked on a lot number basis<sup>4</sup>" in the ERG Report prepared for FDA, professional use *in vitro* diagnostic devices (IVDs) are governed by unique regulations, 21 CFR 809, specifying the content of labels and labeling. These regulations require IVD reagents and instruments to carry lot numbers. Furthermore, professional use IVDs consisting of large instrument systems are serialized and the manufacturer and product identity are readily recognizable by the clinical laboratory. Reagents are tied to specific instruments and bar coded for identification by the instrument system. For these reasons, professional use IVDs warrant consideration outside of medical devices, in general.

### **Response to Questions in the Federal Register Notice**

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

Unique device identifiers (UDIs) currently exist for many device products. To meet market demand or customer needs device manufacturers have voluntarily implemented UDIs. The attributes or elements of the UDI are specific to the product line and customer need. Blood glucose monitoring devices follow the NDC format of

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<sup>2</sup> IMS Xponent, Prescription transactions for meters and strips, 12 month period ending August 2006

<sup>3</sup> Boston Biomedical Consultants, US Blood Glucose Category Revenue

<sup>4</sup> The ERG Final Report "Unique Identification for Medical Devices" prepared for FDA by the Eastern Research Group, Inc. included an assessment of medical device labeling regulations, which concluded, "current requirements do not ensure that devices can be tracked on a lot number basis." (1-3) (March 22, 2006).



manufacturer, product identifier, and unit of use. Cardiovascular products, depending on the need, include all or some of the following: manufacturer, product identifier, unit of use, expiration date, and lot number. The UDIs are reflective of the product and customer needs, such as supply chain or compatibility with infrastructure for third party reimbursement.

Further, many product labels, such as IVDs, contain, in human readable form, the elements identified in FDA's example of a UDI.

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

FDA should foster an environment that encourages global harmonization and recognition of UDIs. Compatibility of existing coding system, such as GS1, HIBCC, NHRIC, and NDC, should remain a primary focus. As development of infrastructure to support UDIs is a critical element, FDA should engage stakeholders, such as manufacturers, distributors, and health care providers to determine how to develop the infrastructure necessary to support a UDI system.

Generally, unique device identifiers (UDIs) should continue to remain voluntary. When bar coding was instituted for drug products, a specific safety need was cited to "help reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time" (68 FR 12500, March 14, 2003). A specific safety issue has not been cited for implementing UDIs for medical devices.

Unlike drugs, devices are not universal. Devices manufactured by different manufacturers look different. For example, in the case of professional use IVD test systems, assay reagents manufactured by manufacturer A will not physically fit into the instrument system produced by manufacturer B. Further, professional use *in vitro* diagnostic devices (IVDs) are governed by unique regulations, 21 CFR 809, specifying the content of labels and labeling. These regulations require IVD reagents and instruments to carry lot numbers. Professional use IVDs consisting of large instrument systems are serialized and the manufacturer and product identity are readily recognizable by the clinical laboratory. Reagents are tied to specific instruments and bar coded for identification by the instrument system. For these reasons, professional use IVDs warrant consideration outside of medical devices, in general

Additionally, even within device product categories the risks presented by devices vary. For example, the category infusion pump includes both medication infusion pumps and enteral feeding pumps. As the intended use and environment of these pumps differ, so does the level of risk. Enteral feeding pumps do not necessarily present the same level of risk as medication infusion pumps.

As FDA considers its role and the system itself, it should also consider unique device factors, such as those described for IVDs and enteral feeding pumps.



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

As described in section two of the ERG Final Report: Unique Identification for Medical Devices, supply chain efficiencies appear to be an incentive for establishing a uniform standardized system of unique device identifiers.

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

Several barriers, which are described in detail below, exist for establishing UDIs. They are: financial, equipment challenges, inadequate infrastructure, and the impact to existing systems.

#### Financial Impact

The redesigning of labeling and packaging, the purchase of printing equipment, printing and verification of UDIs, and other process changes needed to implement a human readable UDI system will have a tremendous financial impact on device manufacturers. Much device labeling has limited space to print information. To add a UDI in human readable, machine readable, or both formats simply cannot be accommodated with current labeling for many device products. For one product line, it is estimated that 4,100 labeling pieces could require changes to accommodate a UDI. For some devices, such as those provided in surgical trays, a requirement to include a UDI on each device would require changes to the entire distribution model and cost structure, incurring additional financial impact. When technology costs are considered, such as bar coding, RFID, or any other technology, for a machine readable UDI, the financial impact is even greater.

#### Printing Equipment

For many device manufacturers, product labeling is outsourced. Requirements to include UDIs with lot number, for example, could have a tremendous impact on this process, as some businesses assign lot numbers at the time of packaging. Internal printing equipment would be needed, rather than reliance upon suppliers.

#### Lack or adequacy of database infrastructure:

The request for comment envisions interfacing the unique device identifier (UDI) with computer databases with capabilities to access a reference data set linked to the UDI. However, unlike drug products and with the exception of OTC devices marketed in retail outlets, such infrastructure does not exist for medical devices. The request for comment discusses distinguishing sterile and nonsterile implants from one another as a potential use of UDIs, but without the infrastructure to hold this information the UDI, alone, would not accomplish this goal. The request for comment identifies UDIs to identify compatibility issues, such as devices, which can be used safely with magnetic resonance imaging (MRI) systems. Yet without links to patient charts from one facility to the next, such processes could not occur. The lack or adequacy of database infrastructure is a barrier to the establishment of UDIs. Further, the maintenance of such information considering the shorter lifecycle of device products versus drugs and the number of medical devices compared to drugs must be considered.

#### Existing Systems Provide Critical Patient Access



Blood glucose monitoring systems (BGMS), which include blood glucose meters, strips, lancing devices, and lancets, which are routinely dispensed through retail pharmacies, contain unique NDC numbers. The NDC numbers on blood glucose monitoring devices are the key identifier for third-party reimbursement of blood glucose monitoring products throughout the United States. The reimbursement process for blood glucose monitors is identical to prescription drugs. The pharmacy enters the NDC code into their pharmacy system to determine the coverage and co-pay for blood glucose monitors. These systems communicate on-line, real-time to Health Plan databases. The BGMS NDC codes are submitted to multiple data banks (First Data Bank, RedBook, etc.) to make available on their on-line network, which is subscribed to by pharmacies and Health Plans, again just like prescription drugs. Without identical infrastructure to support UDIs for blood glucose monitoring systems, significant disruption in patient access to BGMS would be costly both in terms of human and financial undesired health outcomes, caused by interruptions in self-care, primarily compliance with diabetes self-management responsibilities.

**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.**

Certain cardiovascular products bar coded, using HIBCC LIC Primary Data Structure, at all packaging levels, including manufacturer labeler identification code (LIC), product number, and unit of measure identifier. Where deemed necessary, a UCC/EAN Secondary Data Structure containing the expiration date and lot number has been utilized.

Other cardiovascular products coded in accordance with the GS1 standard and include both primary and secondary barcodes that contain the manufacturer, product identifier, unit of use, use by date and lot number.

Professional use IVD assay reagents bar coded to identify the assay reagents to the instrument system.

Blood glucose monitoring systems, which include blood glucose meters, strips, lancing devices, and lancets, are uniquely identified with an NDC number consisting of an FDA issued NDC manufacturers labeler or identifier code combined with a manufacturer identified product code and package code.

**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?**

Unless a well-documented safety issues exists, which can be resolved by UDI, each device manufacturer should determine, which product lines are candidates for UDIs based on company requirements and customer needs.

**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?**



Currently, UDIs are applied at varying packaging levels. The level of packaging using UDIs should continue to remain a decision made by the device manufacturer.

**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)?**

Current technology is and continues to be used. Solutions adopted for one product line, such as implants, are not necessarily feasible for another product line, such as IVDs. The impact of costs associated with various solutions will vary depending on the device product line.

**Implementing Unique Device Identifiers**

**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?**

Manufacturers should determine data sets based on product and customer needs. Generally, manufacturer identifier or labeler codes assigned by GS1, HIBCC, or FDA's own NDA and NHRIC with manufacturer defined product identifiers are common elements that have been implemented in unique device identification systems.

Because lot number and expiration date change with each manufactured lot the addition of lot number or expiration dating to the UDI requires significant changes to the manufacturing process, including moving printing internally from external vendors, the purchase of special printers, employee training on new processes, and additional quality procedures, resulting in significant cost.

**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?**

Infrastructure to support a UDI system is a significant barrier to the implementation of UDI. FDA should work with stakeholders to form a health care industry consortium that includes manufacturers, distributors, and health care providers to determine how to develop the infrastructure necessary to support a UDI system. Consideration of existing systems, such as those supporting the pharmaceutical and retail industry, might be a starting point to identify elements and attributes of the necessary infrastructure. However, consideration of the medical device industry and opportunities to harmonize globally should drive the type of infrastructure to support a UDI system.

**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?**

The amount of labeling space and whether or not the information already exists in human readable format should be considered. Placing UDIs on devices, themselves,



presents challenges, such as the small size of certain devices or devices subjected to multiple cleaning environments.

Requirements to mark the device itself create technical, financial and quality issues. The technological feasibility of adding an UDI to certain devices is questionable. Adding a UDI directly to a metal or non-metallic stent, for example, would pose technical challenges.

**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?**

Manufacturers should select the technology based on product and customer needs. Both linear and nonlinear bar code formats are currently used in voluntary system. Manufacturers with global markets will likely consider UDI systems that are globally harmonized and compatible. Because many devices currently carry a unique device identifier any new system should recognize globally harmonized data carrier or symbology standards, such as ANSI, GS1, or ISO.

#### **UDI Benefits and Costs**

**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.**

The reports commissioned by FDA do not document clearly defined public health and patient safety benefits resulting from having a standardized unique device identification system.

**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.**

The financial impact to medical devices companies would be significant. Implementation of human readable unique device identifiers (UDIs), alone, would require substantial investment, which includes redesigning labeling and packing to accommodate the UDI, bringing outsourced labeling in-house to print information assigned at the time of packaging, purchasing printing equipment for internal printing, and processing changes to print and verify UDIs, resulting in increased work order time. For some product lines, the entire distribution model and cost structure would require change. When technology costs are considered, such as bar coding, RFID, or any other technology, for a machine readable UDI, the financial impact is even greater. For one product line, it is estimated that 4,100 labeling pieces could require changes to accommodate a UDI.

**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?**

In order to implement the use of UDIs for certain cardiovascular products, it was necessary to redesign all labeling to allow for the necessary space for printing the bar code. Special printers were purchased for printing bar codes with the correct resolution and ability to print on label stock. Employees were required to train on the set-up, usage, and maintenance of the printers. Additional inspections during manufacturing were established to verify the content, readability, and correct placement of the bar code. Implementation of the UDI was a marketing decision. The UDI was implemented to aid customers in the maintenance of their inventories, and has not been linked to patient safety issues. Global harmonization or recognition of a UDI format continues to remain a challenge to businesses that have implemented voluntary unique device identification systems.

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

Do not have data to respond to this question.

As questions 17-20 are directed to hospital or other device user facilities, we have not responded to these questions.

Thank you for the opportunity to provide these comments. Should you have any questions, please contact me at (847) 937-8197 or by e-mail at [april.veoukas@abbott.com](mailto:april.veoukas@abbott.com).

Sincerely,

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