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December 21, 2006

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

**Re: Comments Concerning a Unique Device Identification System (Docket No. 2006N-0292) 71 Fed. Reg. 46233 (August 11, 2006)**

Dear Docket Officer:

On behalf of The Healthcare Distribution Management Association (HDMA), the undersigned, I am submitting these comments in response to the U.S. Food and Drug Administration's (FDA) request for comments regarding a unique device identification (UDI) system.

HDMA represents the nation's primary, full-service healthcare distributors. Our members are large national companies and regional, family-owned businesses. Each and every day, HDMA member companies safely and efficiently deliver nine million healthcare products to more than 144,000 pharmacies, hospitals, nursing homes, physician offices, and clinics across the United States. HDMA members serve as the central link in a sophisticated national supply chain. As such, we have a responsibility to work closely with our supply chain partners to safeguard patient health. We take this mission very seriously, and we support manufacturers, pharmacies, and the government in ongoing efforts to ensure the U.S. healthcare supply system remains secure, efficient, and appropriately regulated.

As FDA considers such a system, we would like the agency to take into account our thoughts on the specific items listed below.

***Compatibility with Drug Requirements and Initiatives***

First, we want to bring to FDA's attention the fact that for the convenience and efficient availability of the health care practitioners and other customers, many medical devices are purchased and stored by the same distributors and in the same warehouses as are drug products. It is extremely important for FDA to recognize the complexity of the nation's healthcare product distribution system. For example, **there are some nine million drugs, devices, health and beauty aids, and other related products that are distributed daily** by the nation's healthcare product distributors. A single warehouse inventories **more than 24,000 products, serves more**

2006N-0292

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**than 900 primary accounts, distributes nearly 75,000 products *per day*; and consolidates delivery of products on a next day or daily basis.**

Given the need for extreme accuracy, speed and security of the delivery of these products, HDMA believes that every effort should be made to ensure that any implemented UDI system is compatible with FDA's requirements for human drug products and biological products. The implementation of a UDI system that is not compatible with the existing and pending drug requirements, such as the National Drug Code numbering conventions, or more importantly UPC barcode scanning ideologies, is likely to result in unnecessary investments in the purchase of additional hardware, software, and may result in the need to revise complex wholesale distribution operational systems to accommodate differing identification systems. Without such compatibility, the possibility exists that any UDI system will have the opposite effect from what is intended. That is, it may result in a system that increases the complexity of the wholesale distribution of healthcare products rather than simplifying it.

For example, purchasing additional, or different, product code reading devices and maintain a parallel tracking system for medical device products will erase many of the efficiencies that were intended to be made available to healthcare distributors and others through the implementation of a UDI system.

Additionally, the Center for Drug Evaluation and Research (CDER) has conducted research and encouraged members of the pharmaceutical supply chain to undertake pilot Radio Frequency Identification (RFID) studies for drugs. Should the UDI initiative look to RFID, we urge the Center for Devices and Radiological Health (CDRH) to collaborate closely with CDER to assure that the program standards are compatible and consistent.

### ***Technology and Codes***

HDMA urges FDA to define criteria that any UDI should meet, instead of adopting or endorsing any particular technology. It makes better sense to first develop the criteria and then use these requirements to allow industry to choose the best technological solution for a UDI system. This simple step will help to assure that the selected technology meets the needs of the Agency, while still ensuring maximum flexibility to adopt emerging technologies as they are developed. This is crucial to ensuring the deployment of an effective UDI system that is not limited or hampered by the limitations of the selected technology.

Similarly, we urge the FDA to rely on existing coding requirements and/or define the criteria that such coding requirements should meet rather than attempting to set specific coding standards. Once again, different requirements may result in creating more complexities rather than efficiencies.

Although HDMA takes no position regarding what technology should ultimately be adopted to carry UDI coding, we are aware that EPCglobal has been leading a multi-industry effort to develop standards for Electronic Product Code (EPC) and RFID. If, as we suspect, the EPC/RFID initiative will lead to product identification technology requirements, it merits close FDA scrutiny for its applicability to a UDI system.

***Conclusion***

In sum, CDRH does not operate in a vacuum with regard to UDI. There are numerous other initiatives already underway and some requirements already in place. HDMA therefore urges the Center to collaborate closely with stakeholders as it moves forward in evaluating and potentially implementing UDI.

HDMA appreciates this opportunity to share its views with FDA and to provide our perspectives on this important issue. Should you have any questions about this letter, please feel free to contact me at 703-885-0240 or at [aducca@hdmanet.org](mailto:aducca@hdmanet.org).

Sincerely,



Anita T. Ducca  
Senior Director, Regulatory Affairs and Healthcare Policy