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**Comments to
Docket #2003N-0361
Anti-Counterfeit Drug Initiative
EAN.UCC System Combats Counterfeiting and Promotes Traceability in the
Global Healthcare Supply Chain Today and in the Future**

BACKGROUND:

On July 16, 2003 the FDA announced an initiative to heighten battle against counterfeit drugs. This task group has sixty days to investigate this matter and provide its initial findings to the FDA management, followed by public hearings and a final report scheduled for January 2004.

Enclosed within this paper are three different methods to help combat counterfeiting using the EAN.UCC System keys of GTIN (Global Trade Item Number), SSCC (Serialized Shipper Container Codes), GIAI (Global Individual Asset Identifier) and Application Identifiers.

These EAN.UCC System keys are all overt methods that are in commercial practice today. These methods, used in conjunction with one another, raise a powerful hurdle for counterfeiters. This paper explains the power of the EAN.UCC System to combat counterfeiting with current existing bar codes and data structures. It also discusses how these data structures will be migrated to the Electronic Product Code (EPC), an emerging technology that uses radio frequency identification (RFID) to enable complete visibility throughout the supply chain.

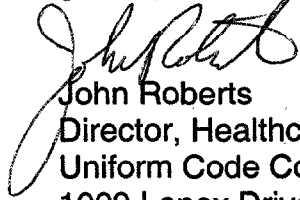
There is no need for the FDA to wait for EPC. Counterfeiting can be combated today with the use of the EAN.UCC System bar codes and data structures and then, when applicable, use the complementary technology of RFID. There are three distinct identification methods all related to different commercial units to help combat counterfeiting:

- The first method to combat counterfeiting is the Global Trade Item Number (GTIN). The GTIN is a unique identifier for a trade item and is recognized in over 104 countries. The GTIN, combined with a serial number and / or lot number, can identify packages from individual unit of use through intermediate and up to cases with precision (coupled with databases). This information (GTIN, serial and lot number) can be bar coded now with available commercial equipment and can be mapped to EPC.
- The second method to combat counterfeiting is the SSCC (Serialized Shipping Container Code). The SSCC acts as an individual license plate for logistics units. The SSCC is widely used in the retail supply chain today. As with individual packages, pallets can be serialized and tracked across the supply chain globally.
- The third method to combat counterfeiting is the Global Individual Asset Identifier (GIAI). The GIAI identifies individual assets to provide tracking and tracing capabilities, facilitate maintenance, and provide equipment management and control. The GIAI has been adopted by the United States Department of Defense to identify their assets.

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These tools to combat counterfeiting are available today in a standardized, globally endorsed system. The FDA should require their use immediately.



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