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July 2, 2003

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

Re: Docket No. 02N-0277

Dear Sirs:

The Uniform Code Council, Inc. (UCC), is pleased to submit comments to the Food and Drug Administration for Title III, Subtitle A, Section 306 (Establishment and Maintenance of Records) of the Public Health Security and Bio-terrorism Preparedness and Response Act of 2002, contained in Docket Number 02N-0277.

The Uniform Code Council is a U.S. based not-for-profit organization, which manages the development, implementation, education and promotion of standards for product and location identification, electronic commerce and for data carriers such as bar codes and radio frequency identification. The UCC, in association with its global partner EAN International, manages the EAN.UCC System, an integrated suite of multi-sector physical identification and electronic communication standards that is used by over one million companies conducting business in 141 countries around the world. This system enables companies to efficiently trade and communicate in a common, “global language of business.” Some of the major industries using EAN.UCC Standards include Food and Beverage, Apparel, Foodservice, Publishing, Chemicals, Healthcare, Automotive, Pharmaceuticals and others (see appendix for complete list).

The EAN.UCC System encompasses a variety of data carriers, which include the familiar U.P.C. bar code, other bar codes, and the emerging Electronic Product Code (EPC), which uses radio frequency tags and readers to transmit information. Corresponding to each of these data carriers is a standardized data structure that companies use to uniquely (and uniformly) identify and communicate information regarding their products (i.e. Hellmann’s Mayonnaise 32oz.), services (i.e. installations services), locations (i.e. Sysco Food service distribution center), assets (i.e. desk top computer), and logistic units (i.e. case or pallet) in a pre-defined format. The format may either be in a physical format –

02N-0277

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such as a bar code, or in an electronic format, transmitted between parties in electronic messages, such as Electronic Data Interchange (EDI). The system is driven by industry-developed and internationally accepted standards, supporting the global supply chain, reaching any company, in any industry, in any part of the world.

The Uniform Code Council commends the concerns and efforts of the FDA's proposed regulations to enhance the safety of the U.S. food supply. The UCC shares in those concerns. The goal of our comments is to provide the FDA with an understanding of the EAN.UCC System's capabilities for supply chain tracking and tracing of product - "one up, one down", enabling implementation of the "Establishment and Maintenance of Records" for all trading partners.

The UCC recommends the use of our standards, which supports the proposed regulation. The EAN.UCC System of globally recognized and implemented standards enables traceability of products, and identification of trading parties/recipients, through all locations of the supply chain. The UCC administered system ensures that a unique company identifier, the *Company Prefix*, is globally registered to a trading party. This Company Prefix is used in the assignment of unique identifiers for products, assets and logistic units. All of these identifiers may be captured and stored, with additional descriptive information, throughout its lifecycle. Thus, in the event of product adulteration or other crisis situations, the unique product and trading party identification enhances the ability for the FDA to locate records within the proposed timeframe.

The EAN.UCC System of recommended standards are the Global Location Number, Global Trade Item Number™, and the Serialized Shipping Container Code.

- The Global Location Number (GLN), a 13-digit number, is used to uniquely identify an "entity", such as a domestic or foreign manufacturer, processing plant, transporter/non-transporter, or distribution center, globally. The GLN incorporates full identification of the source, recipient or transport, including name, address, telephone number, etc. The GLN can provide information of where product originated, was processed or reprocessed, packed, or stored throughout the supply chain.

Currently, many countries of NATO require the use of GLN. UCCnet, a subsidiary of the UCC, also requires use of the Global Location Number. Some members of UCCnet using a GLN include, Wal-Mart, Ahold USA, Kroger, Albertsons, A&P, Publix, Food Lion, Super Valu, Home Depot and Lowe's.

- The Global Trade Item Number™ (GTIN™), is a number used to uniquely identify a domestic or foreign product brand and variety/type, more commonly recognized by the U.P.C. (bar code) on a product. The GTIN provides product information, which ties to the brand owner or manufacturer. Today there are over a million companies that identify their products with the U.P.C. This translates into billions of product marked and sold with a GTIN.
- The Serialized Shipping Container Code (SSCC) is a number utilized in a bar code, placed on a pallet or case, that acts as a “unique” identifier for that particular shipping container (more commonly known as a “license plate”). Information carried by the SSCC may include, a Global Trade Item Number, a Global Location Number, date released and lot number. The SSCC is a facilitator for record keeping as it provides vital tracking information as product moves from sender to recipient. Additionally, the SSCC may be referenced by electronic messages, such as the Advanced Ship Notice (ASN), which provides pre-receipt advice of incoming product.

With the vast quantities of products flowing into and through the U.S. supply chain everyday, perishable products such as animal feed, meat, produce and seafood, are very susceptible to the potential of adulteration that presents a threat of serious adverse health consequences or death to humans and animals. This makes it imperative to have the ability to track product and identify the trading parties, while maintaining records to ensure timely and efficient recalls.

We, the UCC, advise the use of the EAN.UCC System and the existing standards that are in place and recognized as the premiere method of global identification within the food industry. The use of GLN, GTIN and SSCC enable the establishment and maintenance of records for the Secretary of Health and Human Services. Combined, they facilitate data exchange and the tracking of cases, pallets and containers through the supply chain worldwide and support the receipt of physical product and documents.

This system has not only been proven to drive cost out of the supply chain, but reduce the number of communication errors between trading parties. Additionally, the system affords a level of accuracy that meets FDA’s standards and requirements.

Additionally, the EAN.UCC System would also support Docket Number 02N-276, Section 305 (Registration).

It should also be recognized that the EAN.UCC System has been endorsed by the FDA’s proposed rule, Docket Number 2N-204, Bar Code Requirements for Human Drug Products and Blood.



Uniform Code Council, Inc.

Thank you for the opportunity to present these comments. We look forward to continuing our work with the FDA in enhancing the safety of the U.S. food supply and its citizens.

Please do not hesitate to contact me.

Thank you.

A handwritten signature in black ink that reads "Greg Rowe" with a stylized flourish at the end.

Greg Rowe
Director, Food & Beverage
609.620.4566
growe@uc-council.org.

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2. Alcohol Beverage
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4. Audio/Visual
5. Automotive
6. Building Materials (Building Supplies/Home Improvement)
7. Chemicals (Household and Industrial Chemicals)
8. Food and Beverage
9. Foodservice
10. Furniture
11. Government (Defense/Public Sector)
12. Hardline Merchandise/Home Accessories
13. Cosmetics and Fragrances
14. Healthcare – OTC, Pharmaceutical and Medical/Surgical
15. Industrial/Commercial
16. Information Technology/Computers
17. Leisure Industries
18. Music Products
19. Photographic Equipment
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21. Service Industry
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24. Electronic Components
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