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November 21, 2003

Ms. Jennie C. Butler  
Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: Registration of Food Facilities

Dear Ms. Butler:

I recently read the Food and Drug Administration (FDA) interim final rule for Registration of Food Facilities. As a not-for-profit global standards organization, the Uniform Code Council (UCC) can provide valuable support and assistance for this FDA initiative. I have enclosed some information explaining how the EAN.UCC System of Global Standards, specifically the Global Location Number (GLN), can assist the FDA with the registration process. These standards are implemented today with many large/international companies and would complement your current process.

I would also like to point out that the FDA has already endorsed the EAN.UCC System in the FDA's proposed rule, Docket Number 02N-0204, Bar Code Label Requirements for Human Drug Products and Blood. I would welcome an opportunity to visit your offices to provide the FDA with a more detailed overview of the GLN and the EAN. UCC System of global standards. These standards promote globally unique identification and provide enhanced tracking and tracing capabilities essential for consumer safety initiatives. I am confident that these tools can be a valued resource to the FDA to facilitate your registration effort.

Thank you for your consideration. I look forward to hearing from you.

Best Regards,

A handwritten signature in black ink that reads 'Greg Rowe' with a small 'cm' below the name.

Greg Rowe  
Director, Business Development  
Uniform Code Council, Inc.

GR:cbm

Enclosure (2)

02N-0276

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The Uniform Code Council, Inc. (UCC) is pleased to submit comments to the Food and Drug Administration's Registration of Food Facilities Under the Public Health Security and Bio-terrorism Preparedness and Response Act of 2002, contained in Docket Number 02N-0276.

The UCC 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 RFID (radio frequency identification). The UCC and EAN International have a combined membership over 1 million Member companies in over 100 countries. Our standards are referred to as "the Global Language of Business." 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 of data carriers (the familiar U.P.C. bar code and the emerging Electronic Product Code (EPC)) is a global system that allows companies to identify and communicate information regarding their products (i.e. Hellmann's Mayonnaise 32oz.), services (i.e. installations services), locations (i.e. Sysco distribution center), assets (i.e. desk top computer), and logistic units (i.e. case or pallet) in a pre-defined format. The pre-defined format may either be in a physical format – 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 to identify domestic and foreign facilities that manufacturer/process, pack, or hold food for human or animal consumption in the United States, as well as, enhancing the ability to track and trace product through the supply chain.

The UCC recommends use of our standard data structures, which support the proposed regulation. *The EAN.UCC system of standards enables the identification of domestic and foreign facilities through all locations of the supply chain, using these globally recognized and implemented standards.* 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 facilities, products, assets and logistic units. 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 a proposed timeframe.

The EAN.UCC application for consideration is the Global Location Number.

- The Global Location Number (GLN), a 13-digit number 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.

The GLN is an implemented global standard, widely adopted throughout the food/feed industry. Currently, many countries of NATO require the use of GLN.

We, the UCC, advise the use of the EAN.UCC System and the Global Location Number that are in place and recognized as the premiere method of identification within the food industry, globally. The use of the GLN implements a global standard for the “Registration of Facilities” for the Secretary of Health and Human Services. It’s a standard that can co-exist with the current process. (Combined with other EAN.UCC Standards, 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.)

It should also be recognized that the EAN.UCC System has been endorsed by the FDA’s proposed rule, Docket Number 02N-0204, Bar Code Label Requirements for Human Drug Products and Blood.

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 Greg Rowe, Director, Food & Beverage at 609.620.4566 or [growe@uc-council.org](mailto:growe@uc-council.org).

#### Appendix of Industries Served by the Uniform Code Council

1. Agriculture (Agriculture/Farming (non-food), Tobacco)
2. Alcohol Beverage
3. Apparel and Fashion
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
20. Publishing
21. Service Industry
22. Telecommunications
23. Utilities
24. Electronic Components
25. Semiconductor Manufacturing

## Global Location Number (GLN)

## What is GLN?

- GLN is Global Location Number
- A key of the EAN.UCC system, therefore unique and unambiguous
- A 13-digit number that identifies:
  - physical locations
  - functional entities
  - legal entities

## What is a location?

- Physical locations
  - retail store, warehouse, manufacturing plant, particular room in a building, warehouse gate, loading dock, vending machine, cabinet, circuit board rack, etc.
- Functional entities
  - specific department within a legal entity, e.g., accounting department, returns department, etc.
- Legal entities
  - whole companies, subsidiaries or divisions

## GLN Example Manufacturer

EAN.UCC Company Prefix = 0061414

  
Corporate Headquarters  
GLN: 0061414000017

  
Distribution Center  
GLN: 0061414000055

  
Sales Office  
GLN: 0061414000062

  
Farm  
GLN: 0061414000031

  
Packhouse  
GLN: 0061414000045

## GLN Benefits

- Creates a unique location reference number that can be communicated to business partners
- A companies method of identifying locations, within and outside their company
- Ensures location accuracy
- Eliminates the need for proprietary location codes

## GLN Benefits, cont'd

- Can be encoded into UCC/EAN-128 symbols and marked onto.....
  - Trade items (products) in order to identify the parties involved in the transaction
  - Logistic units in order to identify the parties involved in the transaction
  - Physical locations, i.e. place of delivery, point of shipment, point of storage