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Executive Vice President
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March 13, 2002

Mr. Philip L. Chao
Senior Policy Analyst
Department of Health and Human Services
Food and Drug Administration
Room 15-61 (HF-23)
Office of Policy, Planning and Legislation
5600 Fishers Lane
Rockville, MD 20857

1 4 3 6 '03 MAR 13 12:10

Dear Mr. Chao:

This letter is in response to the FDA's proposed rulemaking regarding bar code labeling requirements for human drug products and the invitation to submit comments on this proposal.

I want to take this opportunity to highlight the unique qualifications of the Uniform Code Council (UCC) to address the critical healthcare issue of medication errors. Since its founding nearly thirty years ago, the UCC has been a recognized world leader bar coding, global commerce, and technology-neutral standards that enable accurate product identification and improved supply chain management. Today, the healthcare industry and 22 other sectors rely on UCC solutions to bring greater accuracy, speed, and efficiency to their business practices.

The UCC is best known for the development of the ubiquitous Universal Product Code (U.P.C.), which has been recognized as one of the most important innovations in the history of commerce. Since its introduction in 1974, the U.P.C. has become the basis of the global EAN.UCC System, which enables companies of any industry, size, or geographic location to uniquely identify products, assets, locations, and logistics units throughout the supply chain. I would like to briefly mention the core strengths of our system that can enable your agency and the healthcare industry reduce medication errors:

An Open, Universally-Accepted System

Co-managed by the UCC and our global partner EAN International, the EAN.UCC System is used by nearly one million member companies in 23 major industries doing business in over 140 countries around the world. Our system is already used extensively in the healthcare industry, including pharmaceutical manufacturers, healthcare providers, and retail pharmacies. The use of the EAN.UCC System will not add any additional costs to healthcare users and will not result in any implementation disruptions.

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A Neutral, Not-for-Profit Standards Organization

As a not-for-profit organization, the UCC is both technology-neutral and industry-neutral. All of our standards and technical solutions are placed in the public domain, and are available for use by any interested company. The UCC's neutral, not-for-profit status ensures that our efforts are not compromised by profit or proprietary interests.

Reduced Space Symbology®/Composite Symbology

For years, small healthcare products such as ampoules, syringes, blister backs, and vials lacked the necessary label space to be bar-coded with a U.P.C. In response to the growing global need for a solution for small-item identification, the UCC worked with users from healthcare and other industries to develop a small linear and two-dimensional symbol family to bridge this gap.

The UCC developed Reduced Space Symbology (RSS) and Composite Component, and placed the patent in the public domain in November 1999. In addition to healthcare, RSS has been globally adopted and implemented by the grocery industry for marking produce and variable measure (meat, poultry, deli, seafood) products.

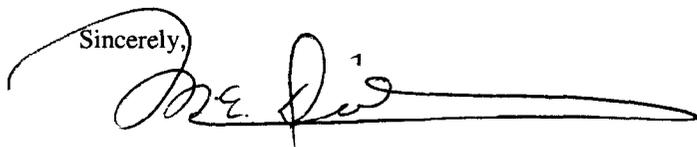
The use of RSS/Composite on small unit dose items will have a positive and significant impact on global healthcare. It will enable accurate and complete identification of healthcare products, to the lowest unit of issue. By improving product identification, inventories will be better managed, with enhanced product safety and traceability. This will reduce loss from out dating, while isolating recalled items in inventory and back to the patient. With all items bar coded backed with appropriate software, medication errors should be reduced.

The UCC has completed three successful case studies examining RSS/Composite from the printer to the provider, which I have enclosed for your review. From these pilot test programs, a healthcare RSS/Composite Component Application Guideline was developed and published (it is available on the UCC website at www.uc-council.org). The General EAN.UCC Specifications will be updated with this information in 2002. All 95 EAN Member Organizations, the UCC, and the Electronic Commerce Council of Canada honor these specifications, which will ensure a timely and seamless global adoption of RSS throughout the healthcare industry.

The enclosed case studies tell only part of the story. We are confident these solutions will enable greater accuracy throughout the global healthcare industry and produce a higher level of safe, quality healthcare for patients.

We would welcome an opportunity to meet with you to discuss our system's capabilities in greater detail. John Roberts, our Industry Director for Healthcare, will contact you to arrange a mutually convenient time.

Sincerely,

A handwritten signature in black ink, appearing to read "John Roberts", with a long horizontal flourish extending to the right. A small number "1" is written above the signature.

cc: John Roberts, Director, Channel Management Healthcare, UCC