Health Industry Business Communications Council

June 10, 2003

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

RE: HIBCC Comments on FDA Proposed Rule for Bar Code Label Requirements for Human Drug Products and Blood (Docket no. 02N-0204)

In response to the Food and Drug Administration's (FDA) request for comment on their Proposed Rule on Bar Code Label Requirements for Human Drug Products and Blood, the Health Industry Business Communications Council (HIBCC) has prepared the following review.

HIBCC commends the FDA for their efforts in addressing the need for improving the Nation's healthcare-giving system, and in recognizing the importance of the implementation of automated identification technologies in achieving that goal. As the healthcare industry's primary ANSI-accredited Standards Development Organization (SDO) for auto-ID applications (such as bar coding), HIBCC appreciates the opportunity to provide these comments. Additionally, we would be pleased to offer the resources of the HIBCC constituency and technical committees as the FDA continues its assessment.

HIBCC's comments on the Proposed Rule are provided in the order they are presented in the FDA's document and focus on the following areas:

Section II. Description of Proposed Rule

- B. What Products Would Have to Have a Bar Code?

Section VIII. Request for Comments

- Question 4, Costs and Benefits Associated With Lot Number/Expiration Date
- Question 5, Requirement for Specific Symbology and Data Standard

- Question 6, Scanning Technology and Ability to Read Multiple Data Formats

- Question 7, Implications of the Adoption of Different Formats

Section II. Description of Proposed Rule

B. What Products Would Have to Have a Bar Code?

HIBCC supports the FDA's decision to defer action on medical device bar coding until further commentary can be provided by the industry. As noted in the Proposed Rule, medical devices are unique in that they present different classes of risk and are subject to different development practices.

However, HIBCC strongly urges the FDA to begin looking into this area as the benefits of medical device labeling have already begun to be realized and can be further leveraged to the benefit of both the healthcare community and the patients they serve.

Section VIII. Request for Comments

4. Costs and Benefits Associated With Lot Number/Expiration Date

While understanding the challenges associated with including lot number and expiration date, HIBCC strongly urges the FDA to include this as a requirement in the Proposed Rule. Although it is difficult to assess the incidence of injury and death associated with these data attributes, it is clear that the implications of administering expired product to a patient can be profound. Likewise, there is obvious benefit to the patient, the provider and the manufacturer to engender a system that allows for accurate and efficient recall of a specific lot or batch of product in the event of defect or failure. Many manufacturers have already announced their intent or current practice for including this critical information.

5. Requirement for Specific Symbology and Data Standard

The proposed rule's exclusive specification for the use of a linear symbology is of great concern to HIBCC and the constituency that it represents. As drafted, the proposed rule excludes current technologies already in use in provider environments such as two-dimensional symbologies and radio frequency identification (RFID). Furthermore, it inhibits the implementation of evolving technologies such as optical imagers that facilitate applications such as facial/script recognition.

Given the already significant deployment of non-linear codes, as well as the rate of technological advancement, linear bar codes are not suited to long-term relevance within healthcare applications. As written, the FDA Proposed Rule will force the creation of a system infrastructure that will be technologically obsolete by the time the regulation is implemented.

In consideration of the points raised above, HIBCC respectfully requests that the FDA strike all specifications for "linear bar coding" in deference to the broader applications that encompass automatic identification technologies.

Also of considerable concern is the exclusionary specification for the use of UCC.EAN data standards. By narrowly defining the types of bar codes allowable, specifically those developed and promoted by UCC.EAN, the FDA is creating a monopolistic environment that will inhibit the development and implementation of relevant technologies that may be outside of the UCC's purview.

For example, although UCC.EAN standards are by far the most prevalent in pharmaceutical labeling, their predominance is the result of an historical precedent set approximately 30 years ago, when bar code technology was in its infancy and was limited to relatively unsophisticated numeric-only codes. Although modern technology has long since permitted full alphanumeric coding, which allows for literally-encoded information that is inherently safer, the legacy base of numeric UCC.EAN codes has created a barrier to their implementation. FDA's specific requirement of this outdated format will thus inadvertently inhibit elimination of this shortcoming.

The critical component to making the FDA Proposed Rule work is the adoption of a uniform standard for unique identification. By specifying the NDC the FDA has established this uniform numbering system. Given the capabilities of modern scanning equipment to read multiple data standards and symbologies, there is no benefit to the industry to limit the regulation to one symbology or one standard. Doing so has the potential to impede the progress of technology and the associated benefits to patients and the healthcare system.

6. Scanning Technology and Ability to Read Multiple Data Formats

As already discussed, most modern bar code scanners are auto-discriminating, meaning they have the ability to read multiple symbologies and data standards. This is true of the traditional laser scanners, as well as the emerging optical image scanners.

Due to the substantial and continuing reduction in the cost of most technology-driven hardware, including optical image scanners, hospitals now have many cost-competitive options. As such, providers have the opportunity to base their purchasing decisions not on limiting financial factors, but on the merits of a system that will provide the most comprehensive benefits for their entire institution.

7. Implications of the Adoption of Different Formats

Limiting the regulation to linear bar codes will impose unnecessary restrictions on the types of applications hospitals can implement to improve patient safety and will deny providers the opportunity to realize additional benefits for their investment in automated identification systems.