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Lester M. Crawford, D.V.M., Ph.D.  
Commissioner  
Food and Drug Administration  
U.S. Department of Health and Human Services  
5600 Fishers Lane  
Rockville, Maryland 20857

Dear Dr. Crawford:

On behalf of the Healthcare Information and Management Systems Society (HIMSS) and our 17,000 individual, 275 corporate members, and 43 chapters nationwide, we are pleased to provide comment on the Food and Drug Administration's (FDA) automatic identification (auto-ID) initiatives.

In the attached statement we submit our comments regarding the FDA's Guidance for Industry: Bar Code Label Requirements Questions and Answers, June 2005 (Federal Register Notice, June 7, 2005, Docket Number 2005D-0202). In particular, the attached statement addresses our perspective on FDA actions to accelerate the life saving benefits of bar code enabled medication administration and repeat our desire to see committed FDA action on the National Drug Code (NDC) system. We have specific comments on the Interpretation of Effective Date; Lot and Expiration Date; NDC Coding; Bar Coding Quality; and Unit Dose Packaging. Due to the patient safety implications, Unit Dose Packaging is of particular interest to HIMSS members. HIMSS would like to suggest a joint effort with FDA to survey progress being made by U.S. hospitals and the pharmaceutical industry in developing unit dose packaging protocols.

We look forward to continuing the necessary dialogue with the FDA and other federal agencies as we work to achieve a successful rollout of auto-ID technology for medication safety.

If you have any additional questions please contact Mr. Thomas M. Leary, Director, Federal Affairs, [tleary@himss.org](mailto:tleary@himss.org), or 703.837.9814.

Sincerely,

H. Stephen Lieber, CAE  
President and CEO  
HIMSS

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**HIMSS Response to FDA Draft Guidance for Industry: Bar Code Label  
Requirements Questions and Answers**

**August 2005**

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)

The Healthcare Information and Management Systems Society (HIMSS) is pleased to submit our comments regarding the FDA's Guidance for Industry: Bar Code Label Requirements Questions and Answers, June 2005 (Federal Register Notice, June 7, 2005, Docket Number 2005D-0202). We have specific comments on the Interpretation of Effective Date; Lot and Expiration Date; NDC Coding; Bar Coding Quality; and Unit Dose Packaging. Due to the patient safety implications, Unit Dose Packaging is of particular interest to HIMSS members. HIMSS would like to suggest a joint effort with FDA to survey progress being made by U.S. hospitals and the pharmaceutical industry in developing unit dose packaging protocols.

HIMSS is the healthcare industry's only membership organization exclusively focused on providing leadership for the optimal use of healthcare information technology and management systems for the betterment of healthcare. HIMSS represents more than 17,000 individual, 275 corporate members, and 43 chapters nationwide. HIMSS seeks to shape healthcare public policy and industry practices through its educational, professional development, and advocacy initiatives designed to promote information and management systems' contribution to quality patient care.

As an organization, HIMSS is committed to achieving the benefits pervasive automatic identification (auto-ID) technology brings to healthcare delivery through improvements in patient safety, clinical and administrative processes, and patient quality of life. In January 2003, HIMSS established the HIMSS Auto-ID and Bar Coding Task Force as part of our Patient Safety and Quality of Care Steering Committee. By bringing industry experts together through our volunteer structure, HIMSS hopes to offer a coordinated voice to the national discussion on these important healthcare issues.

HIMSS offers its support and appreciation to the Food and Drug Administration (FDA) leadership to facilitate faster adoption of auto-ID technology in the provider setting. We are well positioned to help bridge any communication gaps on this issue between manufacturers and distributors, the government and the provider community. HIMSS stands ready to assist in any way to assure that FDA initiatives create effective delivery of safe medication in the patient care setting.

***HIMSS recommends:***

HIMSS accepts and supports the answers the FDA has proposed with the exceptions noted and described below

1. Interpretation of Effective Date
2. Lot and Expiration Date
3. FDA National Drug Code (NDC) Improvements
4. Bar Code Quality
5. Unit Dose Packaging

***1. Interpretation of Effective Date***

*Q7: How is the 2-year implementation date intended to work?*

A7: The 2-year implementation date is for drug products that received approval before April 26, 2004. This 2-year period is intended to provide the industry sufficient time to make the labeling changes necessary to comply with the rule by April 26, 2006. Drugs approved on or after April 26, 2004, have 60 days from their approval date to comply with the bar code rule.

***HIMSS Comments:***

Does the April 26, 2006 date relate to items “packaged on or after” or “shipped on or after?” We request clarification--either packaged or shipped, so that manufacturers, supply chain managers, and hospitals are appropriately prepared, and that the mandate is followed consistently.

***2. Lot and Expiration Date***

*Q10: Can a firm use another automatic identification technology, such as a radio frequency identification (RFID) chip or a two-dimensional symbology, instead of a linear bar code?*

A10: No. The final rule requires the use of a linear bar code to encode the NDC number on most prescription drug products and certain OTC drug products. However, we will not object if firms voluntarily encode lot number and expiration date information, and we recognize that some firms might use other technologies to encode that additional information (response to comment 35, 69 FR 9120 at 9134-9135).

In addition, we stated in the preamble to the final rule that we will consider revising the rule to accommodate new technologies and may begin examining other automatic identification technologies by April 2006 (69 FR 9120 at 9138).

***HIMSS Comments:***

HIMSS supports the optional inclusion of lot and expiration date. While less than what was desired, the FDA position that lot and expiration can augment the linear NDC code (for example, lot and expiration could be included in the 2D part of a composite code) is a step in the right direction. However no specific mention is made of any other type of information that might be voluntarily added in that fashion. If a labeler adheres to the GS1 standards and guidelines, there are literally hundreds of types of additional

information that could be included based on Application Identifiers (AI.) Based on the established standards using GS1, AIs would not be a design or implementation burden.

For clarification, patient safety, and cost containment we recommend the following:

1. Amend answer to this question "...However, we will not object if firms voluntarily encode *SUCH ADDITIONAL INFORMATION AS* lot number and expiration date information. ..."
2. If lot, expiration date, or any other information is to be included in a medication linear or 2D bar code, it must be done in compliance with either GS1 or HIBCC standards. Bar coding is a mature technology with well developed standards. When the data carrier is a bar code existing standards should be followed.
3. If lot, expiration date, or any other information is to be included in an RFID tag, it should utilize pertinent standards from an American National Standards Institute (ANSI) accredited standards organization. RFID is an emerging technology and standards have not been broadly developed. Those that have are not capable of handling the diverse needs of healthcare providers. When the data carrier is RFID, flexibility for innovation is needed.

### **3. FDA National Drug Coding System Improvements (NDC)**

*Q11: What should be used in lieu of an asterisk in an NDC?*

A11: Nothing should be put in place of the asterisk in an NDC number in a bar code.

Under 21 CFR 207.35(b)(2), the Agency uses the National Drug Code (NDC) numbering system in assigning an NDC number. The number is a 10-character code that uses only numerals.

The NDC number is divided into three segments. The first segment, the labeler code, identifies the manufacturer or distributor and is four or five characters long. The second segment, the product code, identifies the drug product and is three or four characters long. The third segment, the package code, identifies the trade package size and type and is one or two characters long. The 10-character NDC number can be in the following three configurations of labeler code–product code–package code: 4–4–2, 5–4–1, or 5–3–2.

The asterisk is for FDA's internal use only. For entries into our database, the asterisk is a dummy character used to differentiate between the three different configurations. A zero cannot be used in place of the asterisk because a zero is a real numeric character in an NDC number. An NDC number that contains a non-numeric character (an asterisk) reverts to a 10-numeric character code when used on the labeling of a drug product or included in a bar code. For example, if the NDC number for a firm's product is in a 5–3–2 configuration, the Agency, potentially, assigns a dummy asterisk as follows: 12345–\*542–12. When a bar code is placed on the product, the asterisk is dropped, and the number included in the bar code is 1234554212.

#### ***HIMSS Comments:***

In the Bar Code Final Rule as well as in the Proposed Rule, the FDA committed to a separate rulemaking initiative to address the inadequacies and deficiencies of the

National Drug Code system (II.C.1) and to maintaining a database of all unique NDC numbers identifying dosage, strength, nature, and form of administration (VII.D and VII.E.6.) We are unaware of any movement of these critical issues. While the NDC system has apparently been acceptable for supply chain use, point-of-care systems require a much improved NDC system to prevent medication errors. As our industry moves forward with not only bar code enabled medication administration, but also initiatives such as electronic health records (EHR) and computerized provider order entry (CPOE), the deficiencies and limitations of the current NDC system become all too clear.

From the provider perspective there is a need for development of a standard “clinician-level” dictionary of medications. The NDC code standard addresses pharmacy packages. Even if there were not problems with the NDC code, it does not meet provider needs where different systems will use different vocabularies. There is a government project, the National Library of Medicine RxNorm project, which is making headway in resolving this, but it has not been established as a recognized standard. We encourage the FDA to coordinate with the Centers for Medicare and Medicaid Services as they revise their drug establishment registration and listing regulations to make the NDC number unique and more useful to informational databases. We believe RxNorm and NDC should be mutually supportive and consistent. Together, the NDC packaging information and RxNorm vocabulary should be the drug identification standards for all federal initiatives. We are eager to see publication of proposed rule for the NDC system and the establishment of the NDC database.

HIMSS is also supportive of the recommendations of the National Committee on Vital and Health Statistics related to the promotion of RxNorm, as described in their September 2004 and March 2005 electronic prescribing recommendations.

Finally, in the Bar Code Final Rule, the FDA also committed to a creation of a public database of assigned NDC numbers. As the April 2006 date approaches, the source of truth for NDC assignments is urgently needed.

#### **4. Bar Code Quality**

*Q14: Does FDA intend to issue guidance regarding bar code quality, such as size, symbol quality, symbol grade, and reflectance?*

A14: No. We believe there are sufficient documents and standards issued by third parties to address such bar code quality and standard matters (response to comment 56, 69 FR 9120 at 9144).

#### ***HIMSS Comments:***

Regarding Sec. 201.25.c(1) “Each drug product described in paragraph (b) of this section must have a bar code that contains, at a minimum, the appropriate National Drug Code (NDC) number in a linear bar code that meets European Article Number/Uniform Code Council (EAN.UCC) or Health Industry Business Communications Council (HIBCC) standards.”

The EAN.UCC, now GS1, and HIBCC publish documents such as standards, guidelines, and implementation guides. Taken in their totality they describe all aspects of bar coding for interoperability. In particular, size and quality are clearly and unambiguously defined

directly and by reference to the products of other standards organizations, most notably ISO. HIMSS believes that 201.25.c(1) should be understood as encompassing all balloted documents of GS1 and HIBCC. This would establish a minimum quality level symbol grade, reflectance, and other beneficial characteristics.

## ***5. Unit Dose Packaging***

### ***HIMSS Comments:***

According to the FDA's Final Rule titled Bar Code Label Requirements for Human Drug Products and Biological Products, "bar codes can help reduce or detect potential medication errors by enabling health care professionals to check whether they are giving the right drug via the right dose and right route of administration to the right patient at the right time."

While the safety benefits of "five rights" checking using bar codes on drug packages are potentially great, HIMSS recognizes a significant barrier to hospital adoption of bar code scanning at the point of care technology in that the FDA chose not to require pharmaceutical manufacturers, repackagers and relabelers to package medications sold to U.S. hospitals in unit dose packaging with bar codes.

Pharmacy wholesalers indicate that about 50% of their current unit dose line items destined for hospital use presently carries the linear bar coded NDC numbers called for by the FDA. However, the language in the Bar Code Final Rule in Section 201.25 Bar Code Label Requirements does not compel manufacturers to use unit dose packaging. In fact, the FDA stated in the Bar Code Label Requirements for Human Drug and Biological Product final rule:

We decline to require manufacturers to use unit-dose or unit-of-use packaging. We recognize that concerns may exist over the rule's impact on such packaging, and we even raised the issue ourselves in our public meeting (see 67 FR 41360 at 41361). However, as we noted in the preamble to the March 2003 proposal, our industry contacts suggest that the costs associated with a bar code requirement "would not be great enough to significantly impact the market" and that "the expected reduction in hospital over-packaging could increase market demand for unit-dose products despite the cost difference" (see 68 FR 12500 at 12526). In other words, our industry contacts suggest that unit-of-use or unit-dose packaging decisions depend more on market demand than on bar code costs.

HIMSS notes that most U.S. hospitals have yet to adopt bar code scanning at the bedside. A significant challenge to implementing these systems is the need for onsite repackaging of bulk tablets and capsules as unit doses with individual bar codes. This repackaging can be complicated, costly and worse, it introduces an unnecessary source of potential new packaging errors. Further, while there is significant demand for unit dose products in our nation's hospitals there is a concern that the FDA bar code rule will perversely result in fewer drugs marketed in unit dose packaging so that manufacturers can rightly claim full compliance with the rule while hospitals are left to repackage more drug products than before in order to use bar code scanning systems.

The market will drive the extent to which hospitals will be able to purchase medications in unit dose packages. As in so many healthcare areas the issue of who pays and who benefits will be resolved for better or worse by market dynamics. There is a role for the FDA in this patient safety dilemma. HIMSS offers to work with the FDA to periodically conduct studies of the extent that unit dose packaging is available to hospitals. We look forward to further discussions on this matter.