NJHA
NEW JERSEY HOSPITAL ASSOCIATION

June 19, 2003

Commissioner Mark B. McClellan, M.D., Ph.D.
Documents Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: 02N-0204
Bar Code Label Requirements for Human Drug Products and Blood

Dear Dr. McClellan:

As a member of The National Alliance for Health Information Technology (NAHIT), the New Jersey Hospital Association supports the consensus position developed by their Bar Code Working Group and submitted to the Food and Drug Administration in early June 2003. We believe that the bar coding of human drug and blood products is an essential step in working to ensure the safety of all of our patients and improving the quality of care. A copy of the NAHIT consensus is enclosed.

We look forward to the implementation of these regulations and to working with the pharmaceutical industry, many of which are headquartered in New Jersey, to ensure its success.

Sincerely,

Gary S. Carter, FACHE
President and CEO

Enclosure

xc: Lora L. Fulton, Program Manager
National Alliance for Health Information Technology

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760 Alexander Road ■ PO Box 1 ■ Princeton, New Jersey 08543-0001
Tel 609-275-4000

The National Alliance for Health Information Technology

Comments to FDA's Proposed Rule: Bar Code Label Requirement for Human Drug Products and Blood

The National Alliance for Health Information Technology ("NAHIT") commends the FDA on issuing its proposed rule in the March 14, 2003 Federal Register (Volume 68, Number 50, Docket # 02N-0204) on the Bar Code Label for Human Drug Products and Blood. The rule reflects the FDA's active process of listening to all stakeholders and its thoughtful consideration of the complex issues surrounding this topic. NAHIT is willing to provide the FDA with any assistance required as this rule is formulated and especially as the FDA considers modification to the National Drug Code (NDC) numbering system. This modification will require careful review and input from all stakeholders involved in the use of the NDC numbering system.

NAHIT is generally pleased with the overall rule as proposed, but in response to Section VIII. (Request for Comments) for questions 1 through 12 and economic analysis concerns, as requested by the FDA, NAHIT offers these following comments. As was the case with NAHIT's prior submission (dated August 2, 2002), this position reflects the consensus views of a working group representing eighty-four (84) members from across the spectrum of healthcare.

Questions 1 through 12

1. FDA Question:
   Should the rule require bar codes on prescription drug samples and if so what are the costs/benefits of their inclusion (reference the FDA Proposed Rule, Section II.B.2.a.)?

   NAHIT Consensus:

   NAHIT encourages the pharmaceutical industry to include a bar code label, encoding the NDC, on the label of all prescription drug sample packaging and suggests that the FDA encourage this practice. However, NAHIT also recognizes that the packaging of samples may present some unique technical difficulty in applying a bar code label. Based on these observations, NAHIT agrees with the FDA that drug samples should not be covered by the rule.

2. FDA Question:
   What are the risks and benefits of including vaccines in the rule (reference the FDA Proposed Rule, Section II.B.2.a.)?

   NAHIT Consensus:

   NAHIT agrees with the inclusion of vaccines in the final rule for bar code labeling. NAHIT recommends that the FDA require the inclusion of Lot Number and Expiration Date, as well as the NDC, on vaccines within the three-year implementation timeframe of the proposed rule (reference the FDA Proposed Rule, Section II.G.). Since a permanent vaccination record is required after inoculation, including the Lot Number would facilitate better record keeping and improvement in patient safety. NAHIT respectfully suggests that the FDA should work with the vaccine manufacturers to achieve compliance to this requirement without interrupting the supply of vaccines.

3. FDA Question:
Are the terms used to describe the Over-the-Counter (OTC) drug product covered by the rule sufficient (reference the FDA Proposed Rule, Section II.B.2.b.)?

NAHIT Consensus:

NAHIT suggests in describing an OTC drug product in the FDA Proposed Rule, Section 201.25 (b), the phrase "over-the-counter drug products that are dispensed under an order" be changed to "non-prescription drugs used therapeutically pursuant to a "prescriber's order." Additionally, NAHIT recommends defining the term "commonly used in hospitals" as packaged for hospital use, labeled for hospital use, or marketed, promoted, or sold to hospitals.

4. FDA Question:
Should the Lot Number and Expiration Date be included in the rule and if so what is the data on the costs and benefits that would justify their inclusion (reference FDA Proposed Rule, Section II.C.2.)?

NAHIT Consensus:

NAHIT continues to recommend that the Lot Number and Expiration Date be included in the bar code for all package sizes, including the unit-dose level, within 5 years from the date of the final FDA rule. NAHIT is also sensitive to the difficulty of reaching this goal so again offer the following suggestions:

If the technology to print the Lot Number and Expiration Date is not available in five (5) years, then the regulatory language should state that manufacturers will provide the FDA with an unbiased, objective assessment of the current state of technology and valid reasons why the printing of the Lot Number and Expiration Date in bar codes is not feasible. The FDA should then be willing to provide pharmaceutical manufacturers a reasonable extension for the required inclusion of Lot Number and Expiration Date. This could be achieved by asking the FDA to commit to holding a hearing two (2) years before the five (5) year deadline to affirm the feasibility of adding the Expiration Date and Lot Number to bar codes. If the FDA does not develop a requirement for the inclusion of Lot Number and Expiration Date, the FDA should require any voluntary encoding of the Lot Number and Expiration Date to follow the UCC/EAN guidelines.

This approach would provide patients, practitioners, and institutions the assurance that, if the technology is available, then bar codes on all package sizes will include Lot Number and Expiration Date within five (5) years from the date of the final FDA rule. This approach gives an "out" for pharmaceutical manufacturers should the technology not be advanced enough to include the Lot Number and Expiration Date along with the NDC in bar codes.

NAHIT strongly recommends that the FDA require the Lot Number and Expiration Date on vaccines and plasma derivatives as part of the final rule (reference NAHIT Consensus Response to FDA Question 2).

5. FDA Question:
Should the rule refer to linear bar codes without mentioning any particular standard (reference FDA Proposed Rule, Section II.D.1.)?

NAHIT Consensus:

NAHIT recommends that the FDA drop the reference to linear bar codes and retain the requirement that the bar code used meet the Uniform Code Council's UCC/EAN standard. The rule's flexibility would provide for future innovation in migrating to different symbologies and scanning technologies and allow capture of additional information.

While not included in the current proposed rule, as the FDA considers auto identification requirements for medical devices, it should propose that those requirements meet either HIBCC or UCC/EAN standards.

6. FDA Question:
What is the current state of bar code scanners and their ability to read various symbologies (reference FDA Proposed Rule, Section II.D.1.)?

NAHIT Consensus:

It is NAHIT's understanding that some existing scanners that read linear code may not be compatible with all symbologies included in the UCC/EAN standards, although some of these scanners may require software changes/upgrades. By the time the rule is effective, recently-purchased scanning technology should be able to read the manufacturer's bar code labels. As the technology evolves, the FDA can promote innovation by requiring the bar codes to meet UCC/EAN standards, which may in the future include other auto identifiers and allow providers to migrate to this new technology.

7. FDA Question:
Should the rule adopt a different format for the machine-readable code; what should that format be; how widely is it accepted by the industry; and will hospitals be able to read it with existing equipment or equipment under development (reference FDA Proposed Rule, Section II.D.1.)?

NAHIT Consensus:

NAHIT encourages the FDA to have enough flexibility in the rule to encourage the adoption of improved auto identification technology as it develops. By referencing a class of standards such as UCC/EAN rather than a particular technology or format, the FDA can provide for such flexibility in the rule (reference NAHIT Consensus Response to Questions 5 and 6).

8. FDA Question:
Should there be specific product exemptions from the rule and how should they be defined?

NAHIT Consensus:

NAHIT recommends that the FDA not provide exemption for particular products or class of products; but rather have in place a general mechanism for waivers, which could be applied on a case-by-case basis through a reasonable and expeditious process.

9. FDA Question:
Is the implementation timeframe of three years appropriate or can it be shortened; should there be a different timeframe for new drug products (reference FDA Proposed Rule, Section II.G.)?

NAHIT Consensus:

NAHIT continues to recommend that the FDA final rule requiring a bar code label encoded with the NDC number for all human drug products become mandatory for 1) new drug product applications two (2) months after the effective date of the final rule; and 2) existing drug labels as soon as practical, but, in no instance, later than three (3) years after the effective date of the final rule. Inclusion of the Lot Number and Expiration Date should be phased in over five (5) years as outlined in NAHIT's Consensus Response to Question 4.

10. FDA Question:
Should the ISTB-128 standard be adopted for blood or should an UCC/EAN standard be required (reference FDA Proposed Rule, Section II.H.)?

NAHIT Consensus:

The FDA should require a standard for the bar coding of blood products that is recognized by the field and that could be read by the same scanning technology employed in the medication use process. NAHIT recommends that this standard be the ISBT-128. By adopting the standard with a recognition that Codabar will continue to be necessary until existing inventory is completed and requiring it within three (3) years of the final rule, the FDA will move the field forward with compliance to standards with which there is already voluntary consensus.

11. FDA Question:
How will the rule for blood affect hospitals purchasing decisions for bar code technology given the requirements in the rest of the rule for drug products (reference FDA Proposed Rule, Section II.H.)?

NAHIT Consensus:

By adopting the ISBT-128 standard, the FDA will promote the scanning of blood products with the same bedside scanning technology used for human drug products. Since current UCC/EAN standards and the ISBT-128 standard are linear codes, scanners now used in hospitals can recognize both.

12. FDA Question:
    Are any of the alternatives discussed by the FDA in the economic impact section of the rule, of issuing no rule or requiring additional information in the code, viable (reference FDA Proposed Rule, Section II.O.)?

    NAHIT Consensus:

    NAHIT agrees with the FDA that most of the alternatives discussed in the economic impact section are not viable with the exception of inclusion of the Lot Number and Expiration Date, which NAHIT has already discussed (reference NAHIT Consensus Response to Question 4).

FDA Economic Analysis Concerns

FDA Question:
Are there concerns about the economic assumptions made by the FDA in the proposed rule and how might they be addressed?

NAHIT Consensus:

While specific assumptions in the economic analysis could be challenged, it is NAHIT consensus that generally the assumptions are reasonable and provide a valid justification for the proposed rule. In addition, NAHIT strongly feels that, in the long-term, the positive benefits of this rule will far outweigh its costs for manufacturers, providers, and, more importantly, patients.