ABBOTT

**Corporate Regulatory & Quality Science**

Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064-6091

FROM THE OFFICE OF RICHARD M. JOHNSON
DIRECTOR, QUALITY CENTER OF EXCELLENCE DRUGS
PH: 847-938-1750 FAX: 847-938-4422

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

RE: [Docket No. 02N-0204]

Dear Sir or Madam:

Abbott Laboratories is pleased to provide these comments on the Proposed Bar-Code Rule. Abbott Laboratories has been very active in this issue, both as a provider of products affected by the rule, and as a member of several industry organizations that have been discussing these issues, including the Pharmaceutical Research and Manufacturers of America (PhRMA), Healthcare Leadership Council (HLC), National Alliance for Health Information Technology (NAHIT), and the Industry Coalition on Patient Safety (ICPS). Our comments are largely supportive and in harmony with the positions advocated by those organizations, but we would like to take this opportunity to offer these direct comments that reflect specific Abbott Laboratories positions.

Abbott is supportive of 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, we offer these following comments.

**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.)?*

   **Abbott Position:**
   Abbott Laboratories is supportive of the position of PhRMA, NAHIT, and HLC that recognize that the packaging of samples may present some unique technical difficulties in applying a bar code label and that samples are not typically used in the hospital's inpatient medication process. Based on these observations, we agree with the FDA that drug samples should not be covered by the rule.

02N-0204

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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.)?*

**Abbott Position:**
Abbott declines to offer input on this section.

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.)?*

**Abbott Position:**
Abbott 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 clinician's order." Additionally, Abbott 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.)?*

**Abbott Position:**
Abbott agrees with the Agency's statement that there is no evidence that supports the benefit to bar coding lot number and expiration date with respect to reducing medication errors. Inclusion of such information will markedly increase the compliance cost for this regulation and may mean that manufacturers cannot meet the three-year phase in period.

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

**Abbott Position:**
Abbott supports the position of PhRMA, NAHIT, and ICPS and 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 EAN.UCC standard. Since linear codes are the only ones currently included in the EAN.UCC standard. this would allow providers that have linear scanning equipment to read the bar codes while allowing longer-term flexibility in the rule if EAN.UCC should include additional symbologies in their standard. The rule's flexibility would provide for future innovation in migrating to different symbologies and scanning technologies and allow capture of additional information.

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.)?*

**Abbott Position:**
As we have learned from direct experience and discussion within the organizations previously mentioned, it is Abbott's understanding that current linear scanners will read all symbologies included in the EAN.UCC standards, although some of these scanners may require software changes/upgrades. By the time the rule is effective, providers with 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 EAN.UCC 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.)?*

**Abbott Position:**
Abbott 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 EAN.UCC rather than a particular technology or format. the FDA can provide for such flexibility in the rule (reference Abbott Response to Questions 5 and 6).

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

**Abbott Position:**
Abbott recommends that the FDA have in place a general mechanism for waivers, which could be applied on a case-by-case basis through a reasonable and expeditious process. In addition, we support the position of PhRMA that there may be some specific categories of products that, due to size or packaging material, may preclude the application of bar codes. In these cases we would suggest that the FDA consider either an exemption and/or relief from the pharmaceutical labeling regulations in 21 CFR Part 201.10 (i) and 21 CFR 610.60.

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.)?*

**Abbott Position:**
Abbott supports an implementation period of 3 years following publication of the Final Rule. This will allow manufacturers sufficient time to incorporate bar codes on all included products as well as time for our healthcare partners to fully embrace the technology.

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

**Abbott Position:**
Abbott declines to offer input on this section.

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.)?*

**Abbott Position:**
Abbott declines to offer input on this section.

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.)?*

**Abbott Position:**
With the suggested changes in these comments Abbott supports moving forward with bar coding of pharmaceuticals as an effective way to minimize medication errors

**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?*

**Abbott Position:**
While specific assumptions in the economic analysis could be challenged, it is Abbott's position that the benefits provide valid justification for the proposed rule. In addition, Abbott 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.

Respectfully,

Richard M. Johnson