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June 12, 2003

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

Re: Docket No. 02N-0204
Comments on Proposed Rule:
"Bar Code Label Requirement for Human Drug Products and Blood"

The attached comments to the referenced docket are being submitted by Alcon Laboratories, Inc., 6201 South Freeway, Fort Worth, Texas 76134.

Any questions regarding these comments should be directed to myself at (817) 551-6813, fax (817) 615-3413 or e-mail: rebeccawalker@alconlabs.com.

Thank you for your attention to this matter.

Sincerely,

Rebecca G. Walker
Senior Director, Regulatory Compliance
Alcon Research, Ltd.
representing Alcon Laboratories, Inc.

Attachment

02N-0204 C94

Docket #02N-0204

Comments on FDA's Proposed Rule
'Bar Code Label Requirements for Human Drug Products and Blood'

Submitted by Alcon Laboratories, Inc.

Alcon supports the goal of reducing incidences of medication error in the healthcare environment, and welcomes the opportunity to comment on this proposed regulation.

1. Bar coding is technically complex, with rapidly changing requirements and technologies. Regulatory tools related thereto will need to be sufficiently flexible to adequately keep pace with the technology. While it may be appropriate to mandate the general requirements for a machine-readable code in a regulation, it would be advisable to use a more flexible tool, such as a compliance guidance document, to establish the details of acceptable code parameters. This would allow for the use of current, readily available technologies (e.g., linear bar code) when the regulation becomes effective, but allow for additional technologies (e.g., Auto-ID), as they become readily available, without requiring a change in the regulation itself.

2. It is impossible to provide meaningful comment on the total impact of this proposed regulation until the proposed requirements for changes to the National Drug Code (NDC) scheme are fully understood. Therefore, the agency should publish the proposed NDC changes and allow industry to comment on potential impact on the proposed bar coding system prior to finalizing a coding regulation that requires use of the NDC.

3. The agency should initially focus on those drugs that present significant risk of adverse reactions/drug interactions. Then, after a period of time, evaluate the effect on incidences of medication error to determine if inclusion of additional drugs is warranted.

4. If the agency issues a final regulation requiring bar codes, it should reconsider a phased approach: specifically: rolling out requirements for codes by packaging level: Outer containers = 3 years; Immediate containers = 5 years.

5. The goal of reducing medication errors through the use of bar codes (or any other coding scheme) can be realized only when all downstream supply chain partners have the resources (e.g., scanners) necessary to use the bar codes for the intended purpose. If this proposed regulation is adopted, the government should establish requirements for hospitals to implement corresponding technologies.

6. Alcon supports the agency's position that this proposed regulation should not be applied to prescription drug samples or to medical device products. However, if a similar regulation is promulgated in the future for Medical Device Products, it will be essential that the requirements be compatible with the drug product requirements. This is due to the fact that many manufacturers handle both drug and device products and must be able to accommodate the manufacture and control of both using common systems.

7. The agency should reconsider the appropriateness of applying the proposed regulation to OTC drug products. The fact that these products are sold over the counter indicates that they are regarded as less likely to represent a hazard even when used by a lay person. Instituting a higher level of control or concern in the professional healthcare setting does not make sense. If OTC drug products are included in the scope of a final regulation, there must be guidance beyond that provided in the proposed regulation as to the circumstances under which the drug must be coded in keeping with the regulation. A manufacturer cannot know all of the circumstances under which an OTC drug product may be "ordered" in a hospital setting; therefore, it is unreasonable to hold the manufacturer accountable for knowing which OTC products will be subject to the coding requirement.

8. Alcon supports the agency's position to exclude secondary attributes such as Lot Number and Expiry from the scope of the proposed regulation.

9. The proposed regulation should allow the manufacturer to establish a rationale for the packaging levels of an individual product that are appropriate for bar coding based on the intended use of the product.

   For example: A product is packaged in a foil pouch with 4 unit-dose applications intended to be dispensed and used for one person. The manufacturer should be able to have a bar code only on the foil pouch. However, as currently proposed, the regulation would demand that each of the 4 individual unit-doses be bar coded. In this example, the unit-dose packaging is too small to support even an RSS bar code. Because the contents of the pouch (i.e., the unit-doses) are only being dispensed to one person, the addition of the bar code to the individual unit doses would not be necessary. This example is comparable to a bottle of 60 capsules where the unit-doses are the "capsules" and the foil-pouch is the "bottle".

10. The agency should fully examine the practicality of adding bar codes to existing labels of small volume products. With the addition of even an RSS bar code on many small volume products, there would not be sufficient space for the currently required labeling statements. The agency must indicate which requirement takes precedence when there is not enough room on a small label to accommodate both; and/or provide guidance on how such situations are to be handled by the manufacturer.

11. A final regulation should include a clear statement of what is expected with regard to products that are already labeled (without a bar code meeting the requirements of the regulation) and in the distribution chain at the time of the implementation date. Will there be a provision for such products to remain in the market through their expiration date?

12. The agency should include a description of the process to be followed for reporting bar code printing/scanning errors. What will be the process followed by the agency when it receives reports of alleged errors? Will manufacturers be given an opportunity to address alleged errors before the agency takes enforcement action?

13. Alcon supports the choice of the UCC.EAN system as the basis for compliance. The UCC.EAN system is globally recognized and allows a manufacturer to use one system to satisfy diverse requirements. However, this level of detail about an acceptable coding system should be stated in a guidance document, rather than a regulation.

14. The agency should remove the requirement that the NDC always be the basis for the bar code. This requirement is not in keeping with the UCC.EAN requirements. The bar code is intended to be a "pointer to a record in a database" and is not required to be equal to the product code (NDC in this case). If the NDC code is printed on the label as in current practice, and the intended user has the correct cross-references setup in their system (as is the practice in the grocery and retail industries) then there is no need to force the bar code to be equal to the product code. This is a particular issue for OTC drug products sold through retail channels as the bar code may not be equal to the NDC in order to avoid disrupting the various supply chain participants and retail customers.

15. The agency needs to clarify what is intended or required by the phrase "the bar code to be surrounded by sufficient blank space so that the bar code can be scanned correctly". Is this referring to the UCC.EAN requirement for a "quiet zone"? The proposed regulation should use language that is known and understood by the marketplace; or provide sufficient clarification such that the meaning can be known and understood.

16. The agency should further clarify the requirement that the barcode must "remain intact under normal conditions of use".

17. As a practical matter, any coding system should be "human readable" as well as "machine readable".

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SUBADDRESS	
CONNECTION ID	DMP/DMB
ST. TIME	06/12 13:36
USAGE T	01'36
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RESULT	OK

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