



August 7, 2002

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

**RE: Federal Register Notice June 18, 2002
(Proposed Rules/ FR Vol. 67, No.117, Pages 41360-41361)**

Docket No. 02N-0204

Dear Colleagues:

Baxter Healthcare Corporation ("Baxter") is submitting the following comments to the proposed rule regarding "*Bar Code Label Requirements for Human Drug Products*" released for comment on June 18, 2002.

Baxter is committed to enhancing patient safety and supports the use of automatic identification such as barcodes on pharmaceuticals to reduce the potential for medication errors. Many of Baxter's drug products already use barcode labeling, and the number of bar-coded products in Baxter's portfolio continues to grow. Baxter applauds FDA's effort to implement requirements for bar coding of drug and biologic products in a manner that will encourage improved patient safety while allowing for innovation in auto-identification technology into the future.

Some specific comments on the proposed regulation follow:

Comment 1:

While Baxter supports in principle the enhancement of patient safety through auto-identification of drug products, it became clear from the discussion at the public meeting held on July 26, 2002 that the benefit derived from requiring barcodes on drug/biologic/device products might not be equivalent across the broad range of products available (e.g. home therapy products, diluents, etc.). In the interest of applying least-burdensome principles, it would be desirable to have a mechanism or process to apply for exemption of specific products from any mandatory bar code requirement where it could be demonstrated that the projected benefit would not be derived.

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It has been suggested that for products packaged in exceptionally small sizes, the barcode requirement could be met by eliminating some of the required human-readable text. We believe it would be undesirable to sacrifice human-readable labeling elements to make room for a bar code unless those elements are already present elsewhere on the packaging. From a clinical standpoint, clinicians who are not able to make use of barcode reading systems could be at an increased risk of medication errors if necessary information was reduced in size or absent due to the mandated bar code requirement. This case of small packaging is just one example of where it would be preferable to have an option whereby the product could be exempted from the barcode requirement.

Comment 2:

Based on the complexities presented by medical device products as compared to drugs or biologics, it would be preferable to address the topic of bar-coding medical devices separately. Some of the issues particular to devices include:

1. Vast diversity in size, complexity, and function of devices on the market
2. Issues around combination products
3. Lack of and applicability of lot#/expiration dating on many device products
4. Issues of “multiple use” or reuse, repackaging, refurbishment, re-sterilization
5. Some devices (e.g. empty IV bags and syringes) may be filled with drugs by end-users. The barcode on such a device would not correspond to the drug used in the container.
6. Products supplied in kits may contain multiple drugs and devices
7. Lower risk Class I devices

Comment 3:

It is Baxter’s preference that a mandated bar code/auto-identification requirement stipulate the data structure and content of the auto-identifier, but not the location or symbology choice. While a preferred location for auto-identification could be suggested, it should not be mandated – implementation should allow for varied placement of bar codes on packaging given the different packaging types for various drugs and biologic products. Allowing flexibility in symbology choice will enable manufacturers and healthcare providers to take advantage of advancements in this field well into the future.

Data structure should include a product identification number (drug name and concentration), but should not stipulate use of the NDC as that product identifier. Requiring the NDC number as the specific product identifier will present difficulties for companies that market their products in multiple countries. It would be more desirable to have flexibility around the product identification number in order to address global marketing concerns. In addition, since some NDC numbers are 10 digits and others are

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11 digits, requiring use of the NDC number as the product identifier could result in potential errors where software assumes an 11-digit number.

The UPN (Universal Part Number) system allows the flexibility for manufacturers to develop their own product identification number. The UPN could be coded into the already widely used bar code standards such as either UCC/EAN or HIBC. Use of a Global Trade Identification Number (GTIN) number, which has been proposed by the UCC/EAN to enable global harmonization, could also be considered. The GTIN number can accommodate the NDC number should a manufacturer choose to use it, but it has extra digits to accommodate the maximum number of digits used by other countries for their product identification numbers (or NDC-equivalents). To provide the necessary flexibility in the regulation, which will allow it to remain valid into the future, Baxter would emphasize the need to restrict requirements to “product identification numbers” rather than “NDC” numbers.

Although Baxter recognizes that having multiple bar codes on a single product is less desirable since there is a greater opportunity for mis-scanning, it should be recognized that multiple bar codes on a single product might ultimately be necessary to address product identification for products marketed in multiple countries. Use of a flexible, user-defined auto identification number, such as the GTIN, could alleviate this need for multiple bar codes and the resulting increased opportunity for errors.

Comment 4:

Requirements for bar codes on drugs and biologics should be limited to the unit of use packaging rather than unit dose. Products such as pharmacy bulk-packs could support bar code or other auto-identification labeling, but it would be outside the manufacturer’s control to add bar codes at the unit/dose level where these drugs are subdivided at the pharmacy based on physician-ordered dose.

Comment 5:

While Baxter has already implemented bar coding on much of its packaging, there remains a small subset of products for which the current technology is insufficient to allow barcodes to fit on the current packaging. Although Baxter is working expeditiously to enable application of bar codes to all of its drug and biologic packaging, redesign of packaging or re-tooling of manufacturing locations may mean longer implementation times for a few, more challenging products. For this reason we request that the implementation date occur not less than 3-5 years after the effective date of the regulation, and applied only to product manufactured on or after that date.

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Baxter appreciates the opportunity to comment on this important initiative. If you have any questions regarding our comments please don't hesitate to call Jennifer Paine at (847) 270-5825 or myself.

Sincerely,



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