Medication Delivery
Regulatory Affairs

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Comments on Docket No. 02N-0204

June 9, 2003

Baxter

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

RE: Federal Register Notice March 14, 2003
(Proposed Rules/ FR Vol. 68, No. 50, Pages 12500 - 12534)

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 March 14, 2003.

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

Some specific comments on the proposed regulation follow:

Comment 1 – Size Limitation Issue:

Baxter supports in principle the enhancement of patient safety through auto-identification of drug, biologics and blood products. However, there exists a subset of Baxter products for which the current technology recommended in the proposal is insufficient to allow barcodes to fit on the current packaging (syringes, vaccines, small vials). The proposed rule indicates that for products packaged in exceptionally small sizes, the barcode requirement could be met by implementing RSS technology. Baxter believes that even RSS would not be sufficient to address some of these smallest sizes.

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Restricting the barcode system to linear technology limits the industry from utilizing newer technologies. Baxter recommends that the agency allow the use of nonlinear barcodes such as data matrix or other auto-identification technology which could potentially resolve these size limitation issues. Since bar coding technology is going to continue to evolve, we believe that the UCC/EAN should drive the approved standards for the healthcare industry and not lock the US market into one symbology that may not accommodate future technological requirements. It is Baxter's position that the agency should accept the UCC/EAN system for the qualification of barcodes/auto-identification technologies. Baxter also recommends that all systems including nonlinear systems qualified under the UCC/EAN organization be allowed under this proposed rule.

Comment 2 - Diluents:

It is Baxter's position that there are cases in which diluent products should not fall under the scope of this proposed rule. Small Volumes Parenterals (SVP) labeled as "small volume diluents for reconstitution use" are packaged with the sole purpose of admixture with an active drug/biologic product. Therefore, any auto-identification should reflect the admixture as a single product to properly address the goals of the barcode regulation. Baxter believes that barcodes or auto-identifiers for SVP diluent products should be voluntary and driven by the market, based on practicality and the cost to both manufacturer and ultimately the customer.

Comment 3 – Timeframe extension:

If the agency chooses not to consider exemptions, we request that the implementation date occur 5 years after the effective date of the rule to allow for further development of new technologies necessary to address the space limitations on smaller products.

Comment 4- Inclusion of all stakeholders

While Baxter believes that barcoding requirements for medical products is an important step forward, we feel it would be remiss to not emphasize that automatic identification of medical products alone will not reduce medical errors. All stakeholders, FDA, providers, manufacturers and others, must be committed to championing systems to create an environment that allows the industry to realize the value of this barcoding initiative.

Baxter appreciates the opportunity to comment on this important initiative. If you have any questions regarding our comments please don't hesitate to call Karen Spranger at (847) 270-5426 or myself.

Sincerely,

Karen Spranger
for Marcia Marconi

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