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Roxane Laboratories

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Roxane Laboratories, Inc.

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

August 15, 2005

**Ref: Final Rule on Bar Code Label Requirements for Human Drug Products and Biological Products** (Federal Register, February 26, 2004), and **Draft Guidance on Bar Code Label Requirements - Questions and Answers** (Federal Register, June 7, 2005)

Roxane Laboratories Inc. wishes to be on record concerning the introduction of bar codes and other forms of identification in order to prevent dispensing errors. We agree the rule is beneficial and we support it. However, we have a concern with the possible implementation and interpretation of the rule, which became effective on April 26, 2004.

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The rule indicates that "...for drugs that are approved on or before the effective date of this rule, we would expect compliance within 2 years after that date....A 2-year implementation period will also enable firms to exhaust existing (*labeling*) stock. If a drug has expiration date that exceeds 2 years and that drug was not subject to the bar code requirement at the time it was marketed (*approved?*), we will allow the drug to remain on the market without a bar code."

We assume the above statement not to mean that a product approved and marketed years ago with a shelf life of more than 2 years will be allowed to remain on the market without a bar code, but that any lots of that product packaged after April 26, 2006, should have a bar code.

In a similar vein, the response to Question 7 of the draft guidance reads, "The 2-year implementation date is intended to provide the industry sufficient time to make the labeling changes necessary to comply with the rule by April 26, 2006." Roxane Laboratories has a concern that this guidance can be interpreted to mean that all products shipped after April 26, 2006, must comply with the regulation. This interpretation

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may require Roxane laboratories Inc. to relabel and or repackage products which may have been manufactured and packaged months earlier and which haven't been sold due to changes in the highly competitive generic market. We believe that interpreting the regulation in this manner (such as during a routine inspection), would be an unnecessary burden not intended by the FDA in developing the original rule (which originally had a 3-year implementation time frame). Therefore, Roxane Laboratories Inc. respectfully requests an official statement of the terms of compliance, stating that all products packaged on or after April 26, 2006, must contain bar codes unless the manufacturer has obtained an exemption as allowed by the rule.

Should you have any questions, please do not hesitate to contact me. I can be contacted by telephone at (614) 241-4137 or by telefax at (614) 276-0321.

Respectfully,

*Martin J Williamson*

Martin J. Williamson, Ph.D.  
Associate Director, Drug Regulatory Affairs  
Approved Products