



**Eli Lilly and Company**

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

**RE: [Docket No. 00N-0086]  
Amendment of Regulations Regarding Certain Label Statements on  
Prescription Drugs; Republication**

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Dear Sir/Madam:

Our comments will address the Proposed Rule published in the Federal Register on April 10, 2000 and republished on April 21, 2000.

In the proposed rule, there is a footnote that states: "The <Rx> symbol appears in bold in this document because of type-setting limitations, however, it should not be bolded when used on the product's label." The Agency had previously stated that the "Rx only" should be conspicuous on the label (Guidance for Industry, "Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997 - Elimination of Certain Labeling Requirements," July, 1998). In order to comply with the requirement to make the "Rx only" conspicuous, it must be bold to differentiate it from the surrounding text in certain instances. We would appreciate clarification, since the footnote in the proposed rule seems to preclude the use of bolding.

As an aside, we would like to mention that Section IV - Frequently Asked Questions in the July, 1998 Guidance for Industry, "Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997 - Elimination of Certain Labeling Requirements" has been an invaluable aid as we implemented these changes. We hope that the Agency will continue to support answers that were provided in this section of the Guidance.

We appreciate the opportunity to comment on this important proposed rule.

Sincerely,

Thomas L. Copmann, Ph.D.  
Senior Director, U.S. Regulatory Affairs  
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