

Lilly

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

**Re: Docket No. 02N-0204; Bar Code Label Requirement for Human Drug Products and Blood;  
Proposed Rule; 68 Federal Register 12500**

Dear Sir/Madam:

Eli Lilly and Company supports FDA's Bar Code proposed rule as a means to further promote the safe and effective use of medicine. We participated in the Pharmaceutical Research and Manufacturers of America's (PhRMA's) comments to the Docket and agree with those comments, as well.

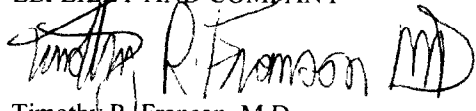
Lilly is demonstrating its commitment in this area by initiating a plan to ensure that most of our institutional-based products in a unit dose presentation are affixed with a bar code including the National Drug Code (NDC) by the end of the 2003. Similarly, all new institutional focused products launched by Lilly in a unit dose presentation will be affixed with a bar code.

Given FDA's pragmatic approach to bar codes as outlined in the proposed rule, we believe that for institutional products, FDA should reassess whether it is feasible to implement the rule in less time than the three year period suggested in the proposed rule. Initially, industry was not certain exactly what data FDA wanted to be imbedded into the bar code, and this raised questions about the potential impact on production lines (lot and expiration date in the bar code could have required on-line printing which would have resulted in new equipment and/or slower production lines). Because the issue has been clarified to be the NDC, it would be reasonable to expect that the industry could implement bar codes on institutional based products within 2 years at the most. Lilly supports this strategy barring any unforeseen changes, including new guidance on NDC, that may affect schedules for implementation.

We would recommend a faster implementation as a means to encourage health care institutions to implement new computer systems and bar code readers. Until hospitals and other institutions have the systems to read and store bar code information, patients will not fully realize the additional protections which bar coded products could provide.

Sincerely,

ELI LILLY AND COMPANY



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Answers That Matter.