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Dockets Management Branch (HFA - 305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

**Docket Number 2000N-1269 also
Docket No. 2005D-0011, CDER 200362.**

Re: Guidance for Industry Labeling for Human Prescriptions Drug and Biological Products – Implementing the New Content and Format Requirements

Lilly appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) Draft Guidance Labeling for Human Prescription and Biological Products – Implementing the New Content and Format Requirements. In general, we found this draft guidance to provide helpful information that will assist us in successfully complying with the new content and format requirements of labeling for human prescription drug and biological products.

As a result of our review of the draft guidance and our initial work on migrating labeling to the new format, we are seeking clarification of some specific points:

1. The revision of 314.70 and 601.12 require applicants to obtain prior approval of any labeling changes to Highlights, except for identified minor changes. How does the agency intend to address 314.70(c) "Changes Being Effectuated (CBE)" supplements that cause a change to the highlights section? We are concerned that waiting for prior approval of the highlights section will delay timely implementation of the safety changes to the labeling submitted via the CBE.
2. In section V.A.1. *New NDAs, BLAs, and Efficacy Supplements*, the draft guidance document provides a list of efficacy supplements that trigger the requirement to revise the labeling to the new format. Should the addition of new routes of administration to labeling be included in this list?
3. In the 21 Mar FDA Webinar it was stated that the revised date should be the date that the labeling was approved by FDA. How should a sponsor address the date when a CBE is submitted as the submission is not approved until after the labeling is published?
4. When a prior approval supplement is submitted to migrate a USPI to the new format without any other changes no user fee is required. Will a timeframe for approval be assigned to this submission despite the lack of user fee?

Sincerely,

ELI LILLY AND COMPANY

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Director
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