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June 18, 2001

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

Docket Number 00N-1269

Re: Requirements on Content and Format of Labeling for Human Prescriptions Drugs and Biologics; Requirements for Prescriptions Drug Product Labels; Proposed Rule

As a member company of the Pharmaceutical Research and Manufacturers of America (PhRMA), Lilly participated in the formulation of comments on the proposed rule and stands in agreement with what was submitted to the docket. We do, however, want to present some additional comments and suggestions, which focus on the changes that will have the greatest impact on the goal of reducing the possibility of medication errors and adverse events by simplifying drug product labeling.

An efficient way to locate information in the Comprehensive Prescribing Information (CPI) section certainly is essential for improved usability of the package insert. We strongly assert that the proposed index and reorganization of the CPI provides this utility. We do not think, however, that the time and effort necessary to overcome the many issues associated with the proposed highlights section will have the results for which the agency is striving.

The highlights section presents a dilemma – we cannot fit the necessary information in the proposed space allocated for this purpose, and practitioners do not want to increase the length of the section. If electronic labeling and the ease with which information can be hyperlinked were more clearly envisioned in the early '90s, we wonder whether the same request by physicians for a summary of information would have been as evident. We urge the agency to explore how the more accepted index and reconfigured CPI can be maximized "...to make it easier for healthcare professionals to find, read, and use information important to the safe and effective prescribing of prescription pharmaceuticals (drugs and biologics) for patient treatment" given today's evolving technology.

Given the momentum of the movement toward electronic labeling and the cost burden associated with accommodating the exponential increase in size of the printed package insert that accompanies the trade package to market, we urge the agency to allow the font size of these printed inserts to remain unchanged. When we applied the proposed

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format requirements to the ZYPREXA package insert the size of the insert more than doubled (8 ½ x **24** inches to 8 ½ x **54** inches - each two-sided). Our current equipment will simply not handle inserts of this size. We recommend focusing on increasing the font size of presentations of the package insert that the prescriber is more likely to reference at the point of prescribing. These presentations include electronic versions of labeling, package inserts included with promotional materials and sample packages, and the PDR. If we assume that only electronic labels will exist in the U.S. in the future, then the information eventually will be available in a more readable format at the point of dispensing, as well. We do not think it is value-added at this time to expend resources to increase the size of the font in the labeling that accompanies the trade package to the market, because this printed version of the insert is probably the one seen least often by prescribers and is likely to disappear in the future.

The agency acknowledges that prescribers reference labeling for "older products" much less frequently than for newer products. Although we agree that more effective means of communicating new information about existing products must be established, we wonder whether the proposed content revisions (i.e., removal of discussion of studies not supporting approved indications, suggestion of uses or indications not included in the "Indications and Uses" section, or discussion of in vitro and animal studies on drug action or efficacy that have not been shown to be pertinent to clinical use by adequate and well-controlled studies) will accomplish that goal. Will the costs associated with making these changes in labeling that previously has been reviewed and approved by the agency result in the changes in prescribing behavior desired by the agency? Will removal of these data limit a physician's access to information that currently is utilized in prescribing decisions? We suggest that focusing on improving the effective communication of labeling information will have a much greater impact on prescribers.

We appreciate the opportunity to comment on the details of the proposal. Lilly urges the FDA to work with industry to make key prescribing information more readily available and easy to use.

Sincerely,

ELI LILLY AND COMPANY

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Vice President
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TRF/saa

cc: Janet Woodcock, M.D.

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