

Thomson Healthcare
Five Paragon Drive
Montvale, NJ 07645-1742
Tel (201) 358-7200 Fax (201) 722-2687

THOMSON
HEALTHCARE

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September 18, 2000

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

Re: Docket No. 00D-1306

Gentlemen:

The following comments are submitted by Thomson Healthcare, the publisher of *Physicians' Desk Reference*[®] (*PDR*). As the nation's leading compendium of approved prescribing information, *PDR* figures prominently in any discussion of the distribution and utilization of official prescribing information. It has more extensive experience in the delivery of such information, through a variety of formats and media, than any other independent organization in the United States.

The consistent goal of *Physicians' Desk Reference* is to provide prescribers and other health care practitioners with ready access to all FDA-approved information needed for the safe and effective use of pharmaceutical, biological, and diagnostic products. We therefore fully support any proposal that promises to enhance practitioners' ability to locate drug-safety information that is important to prescribing decisions, and to convey it in a format that is clear, easy to follow, and consistent across different drugs and drug classes.

We believe that the common format provided by the guidance document represents a significant improvement over the format currently in use, and support the proposed changes subject to the following provisos and considerations.

1. Since practitioners are more likely to refer to approved prescribing information when seeking the cause of an unusual complication, it is mandatory that complete listings of every reported adverse event, including those that are infrequent and or minor, be readily available to anyone researching a possible drug reaction.
2. In addition to the practitioners' need for such listings, distribution of anything less than complete prescribing information will not satisfy pharmaceutical manufacturers' obligation under the learned intermediary doctrine.

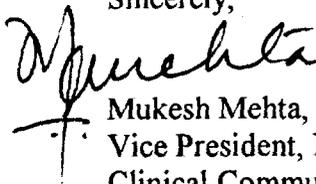
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3. On the other hand, the proposed "Overview" subsection does serve as an excellent vehicle for drawing the practitioner's attention to the information in the drug's adverse reaction profile that is likely to have the greatest impact on prescribing decisions and the observation, monitoring, and guidance of patients. As long as full supporting information is also available for those who must conduct more intensive research, this overview could become a useful and convenient source of quick-reminder information in routine situations.
4. We agree with the proposal in the draft guidance that all labeling carry an explanatory statement regarding the significance of adverse events observed in clinical trials. We also concur with the proposed wording, "Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice." We would suggest that all marketed drugs carry this statement.
5. We agree with the agency's recommendation regarding the need for periodic review and update of the adverse event section of the labeling. In fact, we would recommend ongoing, rather than annual, revision of this section to ensure that it remains accurate.
6. We also believe that the proposed guidelines should be applied to all drugs, both new and old. Although the labeling for newly approved drugs typically provides ample information on all reported adverse effects, the labeling for many long-established products provides only the sketchiest summary of potential adverse events.

Thomson Healthcare and the staff of *Physicians' Desk Reference* will be pleased to cooperate in the implementation of the proposed initiative in any way that may prove helpful. We stand ready to work with all parties involved to bring these improvements to fruition in a timely and orderly manner.

Sincerely,



Mukesh Mehta, RPh
Vice President, New Business Development &
Clinical Communications

MM/lm

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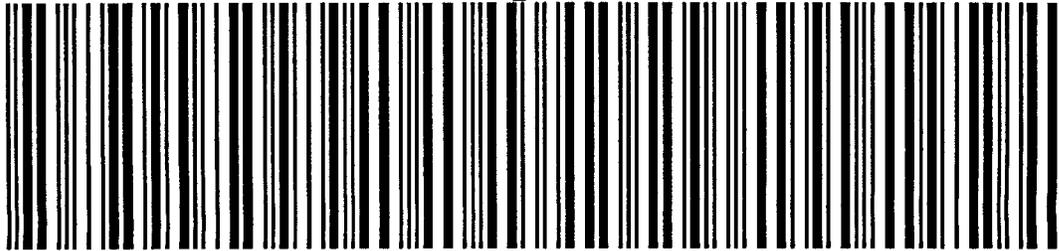
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