



AMERICAN OSTEOPATHIC ASSOCIATION

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June 20, 2001

Documents Management Branch (HFA-305)

Docket No. 00N-1269

Food and Drug Administration

5630 Fishers Lane Room 1061

Rockville, MD 20857

To Whom It May Concern:

As president of the American Osteopathic Association, which represents the nation's 47,000 osteopathic physicians it is a pleasure to submit to you a copy of comments on prescription drug package inserts submitted by one of our distinguished members, Angelyn K. Moultrie-Lizana, D.O.

Our profession is privileged to have such accomplished colleagues who stand ready to contribute their knowledge and expertise to the important work of the Food and Drug Administration. Dr. Moultrie-Lizana serves on the Practicing Physicians Advisory Council.

Please let me know if I can be of further assistance.

Sincerely,

Donald Krpan, D.O.
AOA President

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18 June 2001

To Whom It May Concern:

I am a practicing Family Physician in Southern California and I applaud the FDA's proposal to make changes to the package inserts. I realize that there is a plethora of information that must be put on the insert but it is so very cumbersome to wade through. The idea of an index is marvelous. I've spent a lot of time skimming inserts looking for specific information I need, and an index would substantially shorten the process. I also appreciate the Highlights of Prescribing Information with the bullet format. Placing the most commonly needed information at the beginning of the insert not only saves time, it makes the most sense. I am confident the proposed changes will benefit both physicians and patients alike. This seemingly simple idea is one of the smartest proposals to come along in years. It places the responsibility of education back in the hands of the manufacture where it belongs, thus, reducing the chance for misinterpretations by the medical community. In closing, I would like to thank you for soliciting the physician sector and giving us an active voice in the developmental stage. I eagerly look forward to viewing the "finished products".

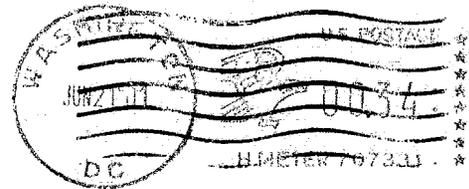
Sincerely

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