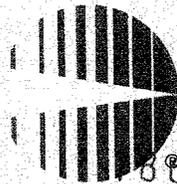


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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
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To Whom It May Concern:

The American Optometric Association (AOA) would like to commend the Food and Drug Administration (FDA) on the Guidance for Industry – Labeling for Human Prescription Drug and Biological Products – Implementing the New Content and Format Requirements issued in the January 24, 2006 *Federal Register*.

We are pleased that the Agency encourages a minimum type size of 10 points for FDA-approved patient labeling.

Doctors of Optometry are the primary health care professionals for the eye. It is estimated that one in every 20 people in the United States suffers from a significant impairment of vision that cannot be further improved by corrective lenses. In addition, many individuals have uncorrected or under-corrected vision problems that limit their visual ability. These individuals could significantly benefit from improved readability and legibility of drug product labels.

We also agree with the Agency's requirements for a minimum 10-point type for Medication Guides that are distributed to patients. There are also factors that are beyond the control of the product labeling process. These would include lighting used when reading the Medication Guides, the distance the Guides are held from the eyes, and whether the reader is using the appropriate vision correction, if needed. The complexities of these variables make it very difficult to establish minimum criteria that will satisfy all needs. However, we agree that the minimum type size of 10 points is adequate to address most situations.

Again, we are pleased with the FDA's recommendations. Thank you for the opportunity to comment on this important area.

Sincerely,

Richard L. Wallingford, Jr., OD

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