In Reply.—Although industry and the Food and Drug Administration itself commonly use the words *label* and *off-label* when referring to the package insert, Dr. Moore is correct in stating that Federal Regulations define the label as wording appearing on a carton, bottle, syringe, or ampule.

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Reference

1. FDA proposes rules for dissemination information on off-label uses. HHS News, June 5, 1998
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