



July 21, 2004

Food and Drug Administration
Division of Dockets Management
5630 Fischers Lane
Room 1061
Rockville, MD 20852

Re: FDA-2003N-0324 & RIN 0910-AC35
Toll-Free Number for Adverse Events on Prescription Drug Labeling
69 Fed. Reg. 21778, April 22, 2004

Dear Sir or Madam:

AARP appreciates that opportunity to comment on the proposed rule regarding the addition of a toll-free number for reporting adverse events on prescription drug labeling. We commend FDA for its work on this important instrument and urge its speedy implementation.

The FDA has proposed the following statement to be used for reporting of adverse events: "Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088." Given the importance of this information, AARP urges you to test the proposed labeling language statement with consumers.

The statutory language on which the proposed rule is based uses the term "adverse events," but the proposed rule uses the term "side effects" instead. In the proposed rule, FDA indicated that it chose "side effects" because it "believes" that this term will be understood by a broader consumer audience than would the term "adverse events."

An accurate method for determining the effectiveness of the proposed language is to test it, along with alternative statements, on real consumers. Consumer testing may require additional resources and time, but it is important to ensure that this critical piece of information is presented to consumers in the most effective way possible.

2003N-0342

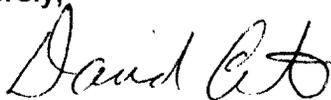
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A large body of science exists on proper approaches to use in designing label statements and protocols to follow in testing possible statements with consumers. FDA has undertaken such testing in the development of other labeling statements for other products¹ and we would urge you to do so in this instance.”

Thank you for considering our comments. If you have any questions, please contact Anna Schwamlein in our Federal Affairs staff at (202) 434-3770.

Sincerely,

A handwritten signature in cursive script that reads "David M. Certner".

David M. Certner
Director
Federal Affairs

¹ See, e.g., FDA, *Iron-Containing Supplements and Drugs: Label Warning Statements and Unit-Dose Packaging Requirements*, 62 Fed. Reg. 2218 (1997)(Consumer research on proposed label statement showed that it was ineffective and, as a result, FDA revised the statement accordingly).