



July 20, 2005

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

RE: Docket No. 2005D-0169

Draft Guidance on Useful Written Consumer Medication Information
Docket: 2005D-0169
70 Fed. Reg. 30467 (May 26, 2005)

Dear Ms. Tabak:

AARP is pleased to submit comments on the Draft Guidance regarding Consumer Medication Information (CMI). AARP served as a member of the Steering Committee that developed the *Action Plan for the Provision of Useful Prescription Medicine Information* and helped to draft the *Action Plan's* format guidelines for CMI included in Appendix G of the *Action Plan* and sample CMI leaflets.

The Steering Committee that developed the Action Plan focused only on community retail pharmacies. Nearly a decade ago, mail-order pharmacies did not have a significant share of the market. Recent data, however, shows that mail-order pharmacies account for 14.5 percent of the total market share for U.S. prescriptions – and this market continues to grow.¹ Therefore, AARP urges the Food and Drug Administration (FDA) to include CMI distributed by mail-order pharmacies in future evaluations.

User Friendly CMI

As the reliance on medication therapies increases, it is critical that consumers have access to clear and accurate consumer medication information (CMI). Unfortunately, current research suggests that although the availability of CMI is high – on average, an eighty-nine percent distribution rate – the average "usefulness" of CMI is only about 50 percent.

AARP continues to believe that the best way to ensure that CMI is useful for consumers is through mandatory content and format standards issued and enforced by the FDA. Until that occurs, we support some of the actions by the FDA – such as the issuance of a guidance document – that should result in higher-quality CMI.

It is likely that many of those submitting comments will express concern that compliance with the guidance will result in CMI that is several pages long and both costly for pharmacists and confusing to consumers. Critics will no doubt argue that guidance-compliant CMI will result in "information overload" for consumers.

¹ "U.S. Purchase Activity by Channel," March 2005; 2004; 2003; IMS Health, IMS National Sales Perspectives, <http://www.imshealth.com>

We recommend that FDA address this concern in a number of ways. First, we urge the Agency to suggest some formatting approaches (such as using bullets and bold-face type) for sections of the CMI, such as contraindications, that contain significant amounts of information. Simple formatting devices will make it easier for consumers to identify important information. Towards this end, it would also be helpful if FDA followed the approach taken in the *Action Plan* and include sample CMI that illustrates this approach as part of the final guidance. Second, we encourage FDA to reexamine and prioritize all of the information to be included in CMI. AARP believes that it is most important to include all of the contraindications in the CMI.

In addition, we have specific comments on the draft guidance.

Page 4, line 145: The reference that CMI will be considered *useful* when it is based on “the most recent FDA-approved professional labeling or package insert” may prove to be a very onerous burden on providers of written CMI, especially as FDA transitions to implementation of electronic professional information (PI) with instantaneous updating. The final CMI Guidance should include a reasonable time window for CMI providers to update their clinical information.

Page 9, line 296-299: The first sentence under Criterion 5 is confusing because it discusses “Warnings and Precautions” along with “Possible Adverse Reactions.” To eliminate this confusion, we recommend that FDA delete the first sentence (lines 296-297). In addition, FDA should clarify how it decided that the minimum number of common adverse reactions required to be listed in CMI should be “5-9.” Moreover, FDA should revise the text of the section to reference not only the minimum number of common adverse reactions, but also the number of serious ones.

In closing, we are pleased to see that the Draft Guidance included possible dietary supplements/drug interactions in the precautions and warning section. With a substantial number of consumers taking dietary supplements on a regular basis, they need to know this information, which is not generally included on supplement labels.

We look forward to working with you to ensure the development of truly useful Consumer Medication Information. If you have any questions, please contact Anna Schwamlein of our Federal Affairs staff at (202) 434-3770.

Sincerely,

A handwritten signature in black ink, appearing to read "David Certner", with a long horizontal flourish extending to the right.

David Certner
Director
Federal Affairs