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July 23, 2001

Dockets Management Branch (HFD-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Draft Guidance for Industry
Using FDA-Approved Patient Labeling
in Consumer-Directed Print Advertisements
Docket No. 01D-0162

These comments are submitted on behalf of the members of the Newspaper Association of American (NAA) and the Magazine Publishers of America (MPA), the principal trade associations representing daily newspapers and the consumer magazine industry, respectively. The NAA represents more than 2,000 newspapers in the U.S. and Canada. Its members account for nearly 90% of U.S. daily newspaper circulation. MPA represents 240 domestic publishing companies with approximately 1,400 titles, including some of the most widely distributed publications in America, such as Time, Newsweek, and Reader's Digest, and such targeted publications as Arthritis Today and Diabetes.

We applaud FDA's issuance of this draft guidance and urge that it be made final as soon as possible.

Print advertising provides consumers with a valuable source of information about pharmaceutical products. Under the applicable law, it must be truthful and not false or misleading, and must present the "pluses" of the product in fair balance with the "minuses." In addition, as the draft guidance discusses, the display portion of the advertisement must be accompanied by a "brief summary" which provides considerable detail about both risks (side effects, contraindications, and the like) and benefits (indications and effectiveness). The brief summary in a consumer-directed advertisement often uses the same text as that used in an advertisement appearing in a medical journal, so consumers may have to make some effort to understand it. The draft guidance would allow advertisers to replace the brief summary with FDA-approved consumer labeling (either a Medications Guide or other approved patient labeling) containing the necessary risk information. Because such consumer labeling is written in language intended for consumers and because it omits certain information useful to physicians but not ordinarily needed by consumers, it is likely to be much more accessible to consumers, and therefore more useful to them, than the usual brief summary. Thus, a shift to FDA-approved consumer labeling in place of brief summaries is very likely to reward consumers' efforts to learn more about prescription pharmaceuticals, and to increase their knowledge of the benefits and risks of the drug therapies available to them. For these reasons,

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we think this draft guidance represents a very useful step in improving the quality of prescription drug print advertisements, and look forward to working with pharmaceutical advertisers to implement this change as soon as possible.

Sincerely,

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