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April 19, 2004

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

Re: Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertising
Docket #2004D-0042

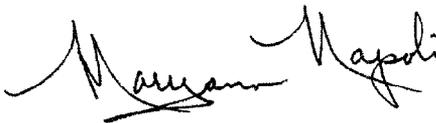
Your proposed guidelines do not address effectiveness, which is arguably the most important missing component of most drug advertising. For these ads to be a source of information for consumers, as the FDA contends, then there must be a standard way of expressing the drug's efficacy as determined in the pre-approval clinical trials. Furthermore, the efficacy should be conveyed in the more consumer friendly absolute risk reduction terms.

The most common and the most serious adverse reactions should appear in the body of the print ads and not in the brief summary. A brief disclaimer should also be required in the body of print ads, making clear how new drugs receive approval from the FDA. The disclaimer could read: "To receive FDA approval, a drug must be proven to be more effective than a placebo. Clinical trials for this drug lasted three months." Where proof of efficacy exists solely for surrogate endpoints, such as a drug proven solely to stop bone loss, then the manufacturers should be required to explain in their ads that improved bone density is not the same as proof of the drug's ability to reduce hip fractures.

Respectfully submitted,



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