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September 13, 2002

Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

**RE: Request for Comment on First Amendment Issues; Docket No. 02N-0209**

Dear Sir or Madam:

The Association of National Advertisers (ANA) is a member of the Freedom to Advertise Coalition (FAC). As part of FAC, we have submitted detailed comments on the application of the First Amendment to the FDA's regulations, policies and practices. ANA wholeheartedly supports the First Amendment analysis contained in the FAC comments. We are submitting these supplementary comments to focus on one additional important issue.

ANA commends the FDA for issuing the Guidance in August 1999 to clarify the agency's DTC broadcast advertising regulations for prescription drug products. However, we believe that one area of the FDA's regulations raises serious First Amendment concerns and deserves further consideration: the disclosure requirements for print advertisements.

Under 21 CFR 202.1(e)(1), sponsors of print advertisements are required to present a "brief summary" of information about the product's uses and risks. Sponsors of broadcast advertisements are required to disclose the product's major risks (the "major statement") and to present a brief summary, or alternatively, make "adequate provision ... for dissemination of the approved or permitted package labeling in connection with the broadcast presentation..." The 1999 Guidance describes alternative ways by which a company may meet the "adequate provision" requirement to provide consumers with the package labeling for the advertised product. One "acceptable mechanism" described in the Guidance is a print advertisement that appears concurrently in publications that reach the exposed audience of the broadcast ad.

*Headquarters*  
708 Third Avenue  
New York, NY 10017-4270  
Telephone 212 697 5950  
Facsimile: 212 661 8057

*Washington Office:*  
1120 20<sup>th</sup> Street, NW, Suite 520-S  
Washington, DC 20036  
Telephone 202 296 1883  
Facsimile: 202 296 1430

*Internet:*  
<http://www.ana.net>

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ANA supports the FDA's goal of providing consumers with various alternatives for obtaining the approved package labeling. However, we are concerned that a requirement that all concurrent print ads contain the entire content of the package label could, instead of being helpful, prove counterproductive. Such a requirement also raises serious First Amendment concerns by imposing a regulatory approach that requires disclosures that are not necessary to protect the public health. *United States v. United Foods, Inc.*, 533 U.S. 405, 416 (2001).

In the "Questions and Answers" document issued by the FDA concurrently with the 1999 broadcast Guidance, the agency acknowledged that "product labeling generally is written for healthcare professionals." Therefore, the concurrent print ads contain extremely voluminous, detailed and highly technical information that is certainly not presented in a consumer-friendly format.

As discussed in the FAC comments, advertising and labeling each play a unique role in the consumer marketplace. Advertising is not intended to be an encyclopedia of information about a product. While print advertising may be able to contain more information than a broadcast ad, even print advertising is subject to information overload.

The key constitutional issue is whether the FDA's demand for a plethora of complicated and detailed disclosures be provided to consumers, either in a "brief summary" or a concurrent print ad, is necessary to protect the public health and to prevent the public from being misled. ANA emphatically believes that the answer to this question is "no."

In ANA's view, vast arrays of information are not necessarily better for the consumer and actually may lead consumers to "tune out" or skip over important information that is buried within paragraphs of small print. Effective advertising in the DTC area will provide key and sufficient information to consumers to help them decide whether they should consult their doctors on critical health issues.

Further, a requirement that broadcast sponsors reprint the entire package label in a concurrent print ad imposes additional costs on the marketer, for a print ad that many consumers will find a cumbersome and ineffective information source. There are certainly less extensive and more effective alternatives for providing consumers with important information in a more user-friendly format.



1120 20<sup>th</sup> Street, NW, Suite 520-S  
Washington, DC 20036

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