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October 28, 2002

Dockets Management Branch
(HFA-305)
Food & Drug Administration
Room 1061
5630 Fishers Lane
Rockville, Maryland 20852

Re: [Docket No. 02N-0209], Request for Comment on First Amendment Issues, 67 Fed. Reg. 34942 (May 16, 2002)

These Response Comments are submitted on behalf of the Consumer Healthcare Products Association (CHPA)¹ in response to the May 16th *Federal Register* Notice requesting industry submissions with respect to the agency's regulations, guidance, policies and practices in light of the First Amendment. [Docket No. 02N-0209], 67 Fed. Reg. 34942 (May 16, 2002). CHPA previously filed comments with the agency on September 13, 2002. After review of the submissions of other interested parties, CHPA respectfully files these additional comments to amplify and clarify one issue not raised in its earlier submission.

The comments submitted by the Pharmaceutical Research and Manufacturers of America² (PhRMA) raise concern that FDA's current position with respect to restricting the use of trademarks and trade names that are already approved by the Office of Patents and Trademarks violates the First Amendment. As described in the PhRMA comments, FDA's current stance is that it is empowered to reject certain trade names on the basis that use of those trade names is likely to create confusion without providing evidence of actual confusion. Additionally, the agency has imposed a policy against the use of multiple trademarks or trade names on products containing the same active ingredient. Both raise serious First Amendment issues about the FDA's authority to restrict speech without proof that consumers would be confused or misled.

¹ CHPA is a 121-year-old trade association representing manufacturers and distributors of over-the-counter medicines and dietary supplements. Its membership comprises over 200 companies across the manufacturing, distribution, research, supply and advertising sectors of the self-care industry.

² Comments of the Pharmaceutical Research and Manufacturers of America, Docket No. 02N-0209, submitted September 13, 2002, at pp. 30-33.

CHPA endorses PhRMA's analysis and conclusions concerning the First Amendment protections for trade names. These legal principles apply equally to the selection and use of trade names for over-the-counter (OTC) medicine and dietary supplement products.

As pointed out in CHPA's earlier comments, labeling and advertising of over-the-counter medicines and dietary supplements are clearly protected forms of commercial speech that are entitled to First Amendment protection.³ By communicating information to consumers about the type and quality of a particular product, a trademark, whether used in labeling or advertising, inherently proposes a commercial transaction and is likewise a form of constitutionally protected commercial speech. *See Friedman v. Rogers*, 440 U.S. 1, 11 (1979); *see also Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.* 425 U.S. 748, 762 (1976). Thus, restrictions on advertising and labeling, including limits on how a manufacturer may select and utilize a trademark or trade name, are must survive First Amendment scrutiny articulated by the Court in *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980), and amplified in *Thompson v. Western States Medical Center*, 122 S. Ct. 1497, 1504 (2002).

As suggested in our previous comments, CHPA is hopeful that FDA will re-evaluate its position on a number of First Amendment-related issues. We reiterate our suggestion that FDA should acknowledge its consideration of the views expressed in response to its call for comments through the same vehicle that it requested them – a published statement in the *Federal Register* – that articulates its position on First Amendment rights as they apply to matters under FDA's jurisdiction. CHPA looks forward to a public explanation and discussion from FDA with respect to the issues we and others have raised.

As always, CHPA and its members are eager to work with the agency to find the proper balance between FDA's important public health obligations and the protections afforded under the First Amendment.

Respectfully submitted,



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CHPA/smm/s 10/25/02

³ Comments of the Consumer Healthcare Products Association, Docket No. 02N-0209, submitted September 13, 2002, at pp. 2-3.