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CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

July 9, 2003

Daniel E. Troy, Esq.
Chief Counsel
Food and Drug Administration
5600 Fishers Lane (GCF-1)
Rockville, MD 20857

Re: Docket No. 2003N-0201; Evaluating Drug Names for similarities

Dear Mr. Troy:

FDA recently co-sponsored a public meeting with PhRMA and the Institute for Safe Medication Practices on evaluating drug names for similarities. The June 26 meeting focused on prescription drugs, but one question addressed OTC drugs ("Should there be different trade-name evaluation procedures for different classes of drugs (prescription vs. over-the-counter)?"), and some speakers challenged the practice of OTC brand name line extensions.

At the meeting, the FDA announced plans to develop a draft guidance on drug naming practices. Comments to the Office of Drug Safety were invited. A copy of CHPA's[1] comments is enclosed for your information. CHPA describes the significant differences between the labeling, purchase, use, and potential for harm of prescription drugs and OTC drugs. The association also explains how OTC trade names, including brand name line extensions are beneficial to consumers.

Because of the significant legal issues bearing upon trade names, and consistent with the agency's Manual of Policies and Procedures document for Developing and Issuing Guidance for Industry,[2] we believe that any draft guidance should be reviewed by the Office of Chief Counsel. We are therefore providing our perspective on the case law and FDA policy applicable to the regulation of trade name line extensions.

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[1] CHPA, founded in 1881, is the national trade association representing manufacturers and distributors of OTC drugs and nutritional supplements. CHPA members account for over 90 percent of retail sales of OTC drugs in the United States.

[2] MAPP 4000.2 at 7 (4/29/98).

Background

As explained in our attached comments to the Office of Drug Safety, OTC brand name line extensions are useful and not misleading. Trade name line extensions foster accurate and informative associations in the minds of consumers among different products from the same source. The OTC brand name conveys the unambiguous message that the product on which it is used is available from the same company as another previously-marketed product, with which the consumer is familiar. Such information is critical to educated consumer purchasing decisions and to cost-efficient manufacturer marketing activities.

A policy limiting OTC line extensions must be predicated upon firm and reliable evidence that line extensions are, or are likely to be, misleading. When Congress amended the Food, Drug, and Cosmetic Act to enable FDA to disapprove any new drug application containing proposed labeling that was "false or misleading," it was particularly concerned that these terms not "open the door to possible administrative abuse."[3] To prevent this, Congress required that a finding that a proposed label is false or misleading must "have an objective base."[4] That is, "the finding . . . must be based on a fair evaluation of all material facts[, which requires] objective facts of record that are clear and more definite than simply a matter of individual interpretation."[5] Specifically, this proscription against arbitrary determinations of "misleadingness" requires:

> that there must also be, to warrant a disapproval or a revocation, objective facts of record which make the proposed labeling demonstrably false or demonstrably misleading.[6]

Without such evidence, FDA may not prohibit line extensions. There is no reason to believe that consumers are, or are likely to be, misled by OTC brand name line extensions. OTC drug manufacturers clearly identify each and every material distinction among drug products they market. Products are labeled, as they must be according to law, with ingredients, indications, directions for use, warnings, and other required information, all in accordance with strict format requirements, as described in CHPA's comments to the Office of Drug Safety.

Because a significant limitation on a line extension would be the functional equivalent of a trade name excision, and because such excision is appropriate only in the

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3 108 Cong. Rec. 21,066 (1962).

4 *Id.*

5 *Id.*

6 *Id.* (emphasis added.)

most extreme circumstances, a prohibition of line extensions would be inconsistent with both case law and FDA policy. Supreme Court doctrine and FDA policy have long prohibited trade name excision unless consumers are, or are demonstrably likely to be, misled by a trade name and no less drastic measure than excision would alleviate confusion.

Supreme Court case law

The Supreme Court has consistently indicated that "the policy of the law to protect [trade names] as assets of a business indicates that their destruction 'should not be ordered if less drastic means will accomplish the same result.'"[7] Thus, the property value of trade names requires that even misleading names be remedied by any means short of a name's proscription, if this is at all possible.[8]

In *FTC v. Royal Milling Co., et al.*, 288 U.S. 212 (1932), the Court agreed that use of the term "milling" in defendants' trade names was misleading because they did not grind the wheat they sold. Nevertheless, the Court held that full excision was unallowably extreme, and that businesses should be afforded the less drastic option of clarifying the name with qualifying language.

> [W]e think under the circumstances the commission went too far in ordering what amounts to a suppression of the trade names. These names have been long in use . . . They constitute valuable business assets in the nature of good will, the destruction of which probably would be highly injurious and should not be ordered if less drastic means will accomplish the same result. The orders should go no further than is reasonably necessary to correct the evil and preserve the rights of competitors and public; and this can be done, in the respect under consideration, by requiring proper qualifying words to be used in immediate connection with the names.

Id. At 217. The kind of qualifying language the Court affords misleading brand names is precisely the kind of language nonprescription manufacturers already supply on their labeling to ensure that consumers are aware of product differences, as described above.

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7 *Jacob Siegel v. FTC*, 327 U.S. 608, 613 (1946) (citing *FTC v. Royal Milling*, 288 U.S. at 217) (while petitioner's trade name "Alapcuna" misleadingly suggested the presence of vicuna fleece in appellant's fabric, FTC must consider whether qualifying language, rather than excision, would protect public interest in knowing true composition of fabric).

8 *See Friedman v. Rogers,* 440 U.S. 1 n.11 (1978) (citing *FTC v. Royal Milling, supra* and *Jacob Siegel v. FTC, supra.*

OTC brand name line extensions in no way present circumstances so severe as to warrant trade name excision, as is evident from contrasting them with the facts of cases in which such extreme circumstances were found present. Two such cases are representative of the extremity necessary to make excision appropriate.

In *FTC v. Algoma Lumber,* 291 U.S. 67 (1934), the Supreme Court held that the FTC could properly conclude that no method short of trade name excision would protect the public from being misled into purchasing "yellow pine" that was advertised as the superior and more expensive "California White Pine." Similarly, in *Indiana Quartered Oak v. FTC,* 26 F.2d 340 (2d Cir. 1928), *cert denied* 278 U.S. 623, advertising as "Philippine Mahogany" wood that was not mahogany at all made excision the only appropriate remedy.

Thus, courts consider excision appropriate only when the brand name is so misleading that only a bold and blatant contradiction could begin to repair the overt, indisputable, and extravagant misrepresentation of the brand name.

FDA Policy

FDA policy has long and explicitly reflected the same concerns as those articulated by the Supreme Court. FDA, as early as 1974, specifically addressed the question of manufacturer changes in the formulation or indications of already marketed drug products. When describing the general circumstances in which drugs would be considered misbranded due to trade name deficiencies, and in the context of elaborating the bases of a proposed rule, FDA stated:

> It is the policy of the Food and Drug Administration, in accordance with principles laid down in the courts, to require excision of a brand name only where nothing short of excision would eliminate the possibility of deception, and to permit retention of a brand name where either permanent qualification of the name or prominent public disclosure of the change in the product for a significant period of time is sufficient to inform the public of the change in the product or its use, e.g., *Jacob Siegel Co. v. Federal Trade Commission,* 327 U.S. 608 (1946); *Federal Trade Commission v. Algoma Lumber Co.,* 291 U.S. 67 (1934).

39 Fed. Reg. 11298 (March 27, 1974).

This FDA policy was reflected in section (c) of the proposed regulation, which established that a change in the formulation or listed indications of a drug product:

1) does not require excision of the trade name if such change does not significantly alter the product's use or active ingredients;

2) requires prominent public notice if the change significantly alters the product's use or active ingredients;

3) requires qualification of the trade name if such change fundamentally alters the indications for use or active ingredients of the product and the trade name includes or suggests a use or formulation that is no longer applicable;

4) requires excision of the trade name if a) the change fundamentally alters the indications for use or active ingredients of the product, b) the trade name suggests a use or formulation that is no longer applicable, and c) qualification of the name is inappropriate or inadequate to correct and prevent ambiguity, confusion, or misbranding.

39 Fed. Reg. 11299 (March 27, 1974). The proposed rule thus recognized what a sensible policy must—that there are a variety of contexts in which a modification to a brand name might be appropriate, and that an excision is a drastic measure necessary only in severe and limited circumstances.[9]

Line extensions provide distinct benefits to the OTC consumer and manufacturer alike. They are most commonly used not as indicators of specific ingredients at specific dosage levels, but as identifiers of a product line—a family of products all of the quality that the consumer has come to expect from the manufacturer. They facilitate efficiency in the marketplace and ensure that a wide variety of new products are available to consumers based upon the economies from carryover good will.

Thank you for your consideration of our views.

Sincerely,

Eve E Bachrach

Eve E. Bachrach
Senior Vice President, General Counsel
and Secretary

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[9] This proposed rule was technically one of 89 outstanding proposed rules withdrawn by FDA in an effort to reduce administrative backlog, in light of the agency's limited resources and changing priorities. 56 Fed. Reg. 67440 (December 30, 1991). Nevertheless, FDA was careful to make clear that such withdrawal was "not intended to affect whatever utility the preamble statements may currently have as indications of FDA's position on a matter at the time the proposal was published," and that "the preambles may still reflect the current position of FDA on the matter addressed." 56 Fed. Reg. 42668 (August 28, 1991).

Attachment: CHPA comment dated July 9, 2003 to Docket 2003N-0201 (Evaluating Drug Names for similarities; Methods and Approaches; Request for comments; 68 Fed. Reg. 32529 (May 30, 2003))