



*Advancing Quality Healthcare
Through Over-the-Counter Medicines
and Nutritional Supplements*

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

July 9, 2003

Ms. Mary Gross
Office of Drug Safety (HFD-400)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Docket No. 2003N-0201; Evaluating Drug Names for similarities; Methods and Approaches (meeting formerly called Minimizing Medication Errors—Methods for Evaluating Proprietary Names for Their Confusion Potential); Public Meeting; Request for Comments; 68 Fed. Reg. 32529 (May 30, 2003)

Dear Ms Gross:

These comments are submitted in response to the above-referenced public meeting of June 26 on evaluating drug names for similarities, which was co-sponsored by the FDA, PhRMA and the Institute for Safe Medication Practices.

The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing manufacturers and distributors of over-the-counter drugs. CHPA members account for over 90 percent by retail sales of OTC drugs in the United States. CHPA has a long history of working toward improving the OTC drug label. In 1991, CHPA pioneered guidelines on label readability that identified technical factors that could improve the OTC label for consumers. FDA has recognized CHPA's work with the agency to improve the OTC label, and the association also urged FDA to adopt regulations on the subject.¹ CHPA is a frequent partner with FDA and other consumer allies in educational efforts to expand consumer knowledge about using the OTC label to ensure the safe and effective use of OTC medicines. Accordingly, CHPA has an important interest in this matter.

I. Introduction

The agenda for the public meeting posed one question that addressed OTC drugs: "Should there be different trade-name evaluation procedures for different classes of drugs

¹ See 62 Fed. Reg. 9031 (February 27, 1997).

(prescription vs. over-the-counter)?” Comments were offered by one FDA participant and by a few of the public speakers. Without supporting data or explanation, it was suggested that there is no difference between prescription and OTC drugs from the standpoint of usage patterns and potential for harm, and therefore that the trade name evaluation process for both should be identical. The practice of brand name line extensions was also challenged as confusing, but no data were offered to support this assertion.

II. Prescription drugs and OTC drugs are different.

There are significant differences between the labeling, purchase, use, and potential for harm of prescription drugs and OTC drugs, which has direct relevance to their trade names.

Prescription drugs and OTC drugs have different safety profiles. A prescription drug is one which because of its toxicity or other potential for harmful effect, or the method of its use or collateral measures necessary to its use, is not safe for use except under the supervision of a physician or other licensed practitioner; or one which for reasons of protection of the public health is limited to use under supervision of a licensed practitioner pursuant to an approved NDA.²

An OTC drug is one which must be safe and effective for consumer use without the supervision of a physician or other licensed prescriber, according to a label that contains adequate directions for use and adequate warnings.³ Thus, an OTC a drug must have a wide margin of safety.

Prescription drugs are available only upon the written or verbal order of a physician or other licensed prescriber. Prescription drugs generally are packaged by pharmacists at the point of sale in uniform containers that bear little written information. Such prescription drug dispensing practices have changed hardly at all in over a century. At the public meeting this was reflected in presentations by panelists on issues such as how to avoid look-alike errors attributable to difficult-to-decipher handwriting, how to avoid sound-alike errors in verbal orders using voice recognition systems, and errors that result from undifferentiated point of sale packaging by the pharmacist.

The OTC drug label contains all the information the consumer needs for safe and effective use. OTC drugs are prepackaged by the manufacturer. OTC labels contain comprehensive information that is pervasively regulated by FDA. OTC labels contain

² 21 USC § 353 (b).

³ 21 USC § 352 (f).

multiple redundancies. Thus, the consumer receives all the information necessary for safe and effective use of the product on the OTC label:

- The Principal Display Panel (PDP) of an OTC must bear a statement of identity as a principal feature. The statement of identity must prominently and conspicuously declare the established name of the drug or in the case of a mixture without an established name, the principal intended action of the drug in terms meaningful to the layman.⁴
- The OTC label must declare active ingredients, inactive ingredients, indications for use, directions for use, warnings and contraindications, and other required information.

Each of these label elements must be presented in a standardized format established by the FDA in its Drug Facts Format and Content rule:⁵

- “Active ingredient[s],” so designated, must be declared first, followed by the established name and the quantity of each active ingredient per dosage unit—repeating information on the PDP for single active ingredient OTCs.
- “Purpose[s],” so designated, must be followed by the general pharmacological category[ies] or principal intended action[s] of the drug—repeating information on the PDP.
- “Use[s],” so designated, must be followed by the indication[s] for the drug—restating information provided in the Purpose section and the PDP.
- “Warning[s],” so designated, must be followed by specific warnings where applicable, each with highlighted subheadings and each in order:

The Reye’s syndrome warning; allergic reaction warnings set forth in any applicable OTC drug monograph or approved NDA; the flammability warning, with appropriate signal words; the water soluble gums warning; the alcohol warning; the sore throat warning; the warning for drugs

⁴ 21 CFR. § 201.61.

⁵ 21 CFR § 201.66.

containing sodium phosphates; warnings to consult a doctor before use in the event of certain preexisting conditions; in-use warnings followed by side effects the consumer may experience when using the product; warnings to stop use and ask a doctor if certain signs or reactions occur; warnings required by an applicable OTC drug monograph, OTC regulation, or approved NDA; the pregnancy/breast feeding warning; the third trimester aspirin warning; the third trimester warning for certain other NDA'd NSAIDs; and the warning to keep out of reach of children.

- “Directions,” so designated, must be followed by the directions for use in an applicable OTC monograph or approved NDA.
 - “Other information,” so designated, must be followed by additional information that is required or is optional under an applicable OTC monograph, other OTC regulation, or is included in the labeling of an approved NDA.
 - “Inactive ingredients,” so designated, must list the established name of each inactive ingredient in alphabetical order (or if the OTC drug product is also a cosmetic, then in descending order of predominance by weight, employing names designated in cosmetic ingredient regulations in 21 CFR Part 701).
 - “Questions?” or “Questions or comments?” so designated, must be followed by the telephone number of a source to answer questions about the product.
- These elements must be displayed in a “Drug Facts” box with the heading “Drug Facts.” The rule specifies minimum type sizes and use of sans serif type. It prescribes the use of barlines and hairlines of specific thickness; headings and subheadings; use of upper and lower case letters; the shapes and sizes of “bullets”; left and right justification; and it restricts the use of hyphens.

FDA has also established a list of 100 interchangeable terms and connecting terms that may be used in the labeling of OTC drug products, provided that their use does not alter the meaning of the labeling established in an applicable OTC monograph or by regulation.⁶

⁶ 21 CFR §§ 201.66 (f) and 330.1 (i) and (j).

An OTC drug product that is not in compliance with these requirements is subject to regulatory action as a misbranded drug.⁷

FDA said that it designed the Drug Facts rule to ensure that all material facts about the safe and effective use of OTC drug products are adequately presented to the consumer with such conspicuousness and prominence that they are likely to be read by the ordinary individual under customary conditions of use.⁸ The agency explained that the standardized format, in conjunction with content requirements, should help the consumer to readily and meaningfully compare OTC drug products, and minimize potential for consumer confusion when comparing products within the same pharmacological class.⁹

Consumers read OTC drug labels. According to a recent study conducted by Roper Starch Worldwide for CHPA, consumers acknowledge the need to exercise care when selecting and using OTC drugs. Ninety-five percent of respondents report reading OTC label directions before taking an OTC drug for the first time. Ninety-one percent look for information on side effects and interactions, and 89% study labels to choose appropriate OTC drugs for their symptoms or condition.¹⁰

Against this background, an OTC trade name is unlikely to result in confusion or error. And given the wide margin of safety for OTCs, there is a low potential for harm in the unlikely event of a mistaken selection.

II. OTC trade names are beneficial to consumers.

OTC trade names, including line extensions, are beneficial to consumers. Line extensions assist consumer purchasing decisions by identifying the source of different products as a known and trusted company. Brand names allow consumers to locate a family of products in which they have faith and experience, and to select from among them the one most appropriate to a current need. The brand name identifies for the consumer a family of related products that are similar in relevant, though obviously not all, respects.

⁷ 21 CFR § 201.66 (g); 62 Fed. Reg. at 9042-9043 (February 27, 1997).

⁸ 62 Fed. Reg. at 9043 (February 27, 1997).

⁹ Id.

¹⁰ “Self-Care in the New Millennium,” Roper Starch Worldwide (March 2001); study conducted for CHPA. Full study available at the association’s website, www.chpa-info.org. This study confirmed the findings of a study conducted in 1992 by the Heller Research Group for the CHPA.

Undue restrictions on OTC trade name line extensions would create a Tower of Babel effect, contributing to consumer confusion by balkanizing and splintering product lines into unpatterned and chaotically named products. Without the helpful shorthand of line extensions, consumers would need to acquire and master separate information about each distinct product, unassisted by the organizing principles that line extensions provide through their use of trademarks. Line extensions facilitate the selection of products that will perform identified tasks, and provide reliable information to enable a consumer to select products effectively.

Complete information about the active and inactive ingredients, indications, purposes, directions, warnings, and other information is available at the point of sale to fine tune the selection process, and accompanies the product once the consumer takes it home and uses it.

Trade name line extensions also facilitate the introduction of useful new OTC products for consumers. Trusted brand names are the principal repository of consumer good will that enables a company to distinguish its products from those offered by others. Undue restrictions on line extensions would raise the cost of introducing products, thereby reducing consumer choice because the expense of establishing new brand names unfamiliar to the public could reduce the introduction of useful new products altogether.

Trade names are costly to create. The start-up costs of producing a memorable brand are high. It is exactly for this reason that line extensions are valuable for both companies and consumers. Line extensions afford a company economies of scale by distributing accumulated consumer good will over a number of related products. Unwarranted limits on OTC line extensions would be disproportionately burdensome to smaller companies in particular, who may lack the resources to launch entirely new brands. Because of the realities of the marketplace, many new products may not be able to be introduced except as line extensions.

Trade names or line extensions may not be prohibited based on the unsupported assertion that they are false or misleading. A line extension must be predicated on firm and reliable evidence that a line extension is, or is likely to be, misleading.¹¹ CHPA is unaware of any evidence that actual consumer confusion as a result of trade names or line extensions is an authentic problem.

¹¹ 108 Cong. Rec. 21,066 (1962). “[T]he 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.” To prevent arbitrary determinations of “misleadingness,” Congress said “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.” [Emphases added.]

There is little reason to believe that consumers are likely to be misled by OTC trade names or line extensions. As described above, OTC drugs are labeled in strict adherence to detailed regulations that require declaration of their active and inactive ingredients, indications, directions, warnings, and more.

In light of the foregoing, any trade name policy must recognize the clear distinctions between prescription drugs and OTC drugs. Unlike the prescription drug setting where little other than the name may be provided to the patient, in the OTC setting the printed label contains all of the information necessary for the consumer to use the OTC drug safely and effectively.

Thank you for your consideration of our views.

Sincerely,



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



Douglas Ws. Bierer, Ph.D.
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