



founded 1881

July 7, 2008

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

Re: Docket No. FDA-2008-N-2081; Pilot Program to Evaluate Proposed Name Submissions; Concept Paper; Public Meeting; Request for Comments, 73 Fed. Reg. 27001-02 (May 12, 2008)

Dear Sir or Madam:

These comments are submitted in response to the above-referenced public meeting held June 5 and 6, 2008, on evaluating proposed proprietary names for drug products.

The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing manufacturers and distributors of over-the-counter medicines and dietary supplements in the United States. CHPA members account for over 90 percent of retail sales of OTC medicines in the U.S. CHPA has a long history of working to improve OTC labels, including guidelines on technical factors that impact label readability, a voluntary program to flag label changes, and working with FDA to improve the OTC label for consumers. FDA has recognized CHPA's efforts in this regard.¹ While the primary emphasis of the June 5-6, 2008, meeting centered on discussion of FDA's concept paper and pilot program, and how firms could carry out their own proprietary

¹ See 62 Fed. Reg. 9024, 9031 (February 27, 1997), noting the association's steps to improve labeling as described above. Further, FDA noted that "the Proprietary Association [CHPA's former name] initiated a '*flag the label*' program . . . to alert consumers to significant changes in the ingredients or labeling of an OTC drug product. This '*flag the label*' program informs consumers of changes in indications, dosages, active ingredients, directions, warnings, contraindications, or any other significant new information by using an attention-getting visual device (a flag) on the label. * * * The agency commends the program and encourages its continuation." 53 Fed. Reg. 30522, 30526 and 30530 (August 12, 1988).

name reviews, the meeting also included a panel on “nonprescription review of proposed proprietary names.” Because some panelists raised issues beyond the scope of the concept paper and pilot program, or may not have recognized the extent of label testing common in prescription-to-nonprescription switch NDAs, we submit these comments on:

1. OTC drug labels contain information the consumer needs for safe and effective use

2. Consumers read OTC drug labels

3. OTC trade names are beneficial to consumers

4. Case law and existing FDA policy recognize appropriate use of trade names

1. OTC drug labels contain information the consumer needs for safe and effective use

An OTC drug must be safe and effective for consumer use, without the supervision of a physician or other licensed prescriber, on the basis of a label with adequate directions for use. In contrast, while prescription drugs have extensive labeling, less of this information has to accompany the drug when dispensed to a patient. The OTC drug label is an integral part of the product.

OTC drug labels contain all the information necessary for safe and effective use of the product:

- The Principal Display Panel (PDP – the portion or side of the label first seen by consumers, generally the front of a package) of an OTC drug must bear a statement of identity, which prominently provides the established name of the drug or, for a mixture without an established name, the principal intended actions of the drug (i.e., pain reliever, cough suppressant).

- The OTC “Drug Facts” label (generally the back and some sides of a package) provides a standardized format and content for OTC labels, including the active

ingredients, purposes, indications for use, warnings and contraindications, directions for use, inactive ingredients, and other required information. For example –

Drug Facts	
Active ingredient (in each tablet)	Purpose
Famotidine 10 mg.....	Acid reducer
Uses	
<ul style="list-style-type: none"> ■ relieves heartburn associated with acid indigestion and sour stomach ■ prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages 	
Warnings	
Allergy Alert: Do not use if you are allergic to famotidine or other acid reducers	
Do not use <ul style="list-style-type: none"> ■ if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. ■ with other acid reducers 	
Ask a doctor before use if you have <ul style="list-style-type: none"> ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ heartburn with lightheadedness, sweating, or dizziness ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent chest pain ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain 	
Stop use and ask a doctor if <ul style="list-style-type: none"> ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days 	
If pregnant or breast-feeding, ask a health professional before use.	
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> ■ adults and children 12 years and over: <ul style="list-style-type: none"> ■ to relieve symptoms, swallow 1 tablet with a glass of water. Do not chew. ■ to prevent symptoms, swallow 1 tablet with a glass of water 60 minutes before eating food or drinking beverages that cause heartburn ■ do no use more than 2 tablets in 24 hours ■ children under 12 years: ask a doctor 	
Other information	
<ul style="list-style-type: none"> ■ read the directions and warnings before use ■ keep the carton and package insert. They contain important information. ■ store at 20°-25°C (68°-77°F) ■ protect from moisture and light. 	
Inactive ingredients colloidal silicon dioxide, corn starch, hydroxypropyl cellulose, hypromellose, indigo carmine aluminum lake FD&C blue no. 2, iron oxide red, iron oxide yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol 4000, pregelatinized corn starch, titanium dioxide	
Questions? If you have questions of a medical nature, please contact your pharmacist, doctor, or health care professional.	

The “Drug Facts” rule includes a number of format requirements covering aspects such as minimum type sizes, barlines and hairlines around and within the Drug Facts label, color contrast, bolding, and bulleted lists.

An OTC drug that is not in compliance with these requirements is subject to regulatory action as a misbranded drug.²

In issuing the Drug Facts rule, the agency states that the standardized format, in conjunction with content requirements, will allow consumers to readily distinguish among what could be seemingly similar products and to readily access important drug

² 21 CFR sec. 201.66. While beyond the scope of these comments, there are very limited partial format exemptions.

information, and to allow quick and effective product comparisons, thereby helping consumers to select the most appropriate product.³

Ultimately, it is the Drug Facts label, not the brand name, that should remain the focus in guiding consumer use decisions and actions. The Drug Facts rule recognized this important focus in a discussion on placement of active ingredients and their respective purposes first within the Drug Facts box: “Because the respective purposes will be listed next to each active ingredient, consumers will know why the ingredient is in the product. Regardless of placement on the PDP, such uniform and prominent placement will help to ensure proper product selection, especially for line extensions.”⁴

2. Consumers read OTC drug labels

A number of studies demonstrate that consumers understand the need to select and use OTC medicines responsibly and with due care. For example, in a study conducted by Roper Starch Worldwide for CHPA, 95 percent of respondents reported reading OTC medicine label directions before taking an OTC drug for the first time. Ninety-one percent reported looking for information on side effects and interactions, and 89 percent study labels to choose appropriate OTC medicines for their symptoms or conditions.⁵

Similarly, a more recent study found consumers use the OTC Drug Facts label as an important reference point on their OTC medicines. In this study, over nine in ten consumers report reading the Drug Facts label on medicines they use. When asked about the rationale and situation in which they are most likely to read Drug Facts label information, 34 percent of consumers report they do so before purchase, 24 percent before first-time use, and 21 percent report they do so to refresh their memory if too much time has elapsed between uses.⁶

Since brand name line extensions act to assist consumers in their purchasing decisions by identifying the source of different products as known and trusted, what is most telling is what consumers report reading the Drug Facts label for. In surveying parents, the highest levels of familiarity among the sections of the Drug Facts label occur with the symptoms the product treats and with the directions.⁷

³ 64 Fed. Reg. 13254, 13270 and 13254 (March 17, 1999).

⁴ Id. at 13260.

⁵ “Self-Care in the New Millennium,” Roper Starch Worldwide for CHPA, March 2001.

⁶ “A Survey of American Attitudes and Behaviors Toward OTC Medications,” Global Strategy Group for CHPA, January 2005. In this survey, consumers were asked to respond to which one of 5 statements best describes how they read the drug facts label found on the packaging of nonprescription medicines they use – never, before purchase, before using the first time, before first use and again to refresh my memory if too much time has elapsed, or before each use.

⁷ “Survey of cough and cold medicine use in children under 6,” PEGUS Research for CHPA, September 2007. Using a four-point scale of “not at all familiar,” “somewhat familiar,” “quite

Finally, as new OTC medicines are switched from prescription to nonprescription status through new drug applications, our understanding of the uses and comprehension of label information for OTC medicines continues to grow. For instance, most prescription-to-nonprescription switch applications include label comprehension studies to test how well the label communicates information to consumers and to test the ability of consumers to apply label information in situations in which the drug should or should not be used.⁸ Self-selection studies are also common in prescription-to-nonprescription switches, where the purpose of the study is to determine if a consumer can correctly decide whether or not the product is appropriate for them to use based on label information.⁹ Brand names are typically included in such studies.

3. OTC trade names are beneficial to consumers

OTC trade or brand names, including line extensions, are beneficial to consumers. Brands play a key role in assisting consumer purchasing decisions by identifying the source of different products as known and trusted. Brands are the principal repository of good will that enable a company to distinguish its products from those offered by others.

But brand names are costly to create and develop. The start-up costs of producing a memorable brand name are high, and it is for this reason that brand name line extensions are valuable for both companies and consumers. To detract from the ability to clearly brand products and extend brand names imposes high information costs on consumers, since consumers lose the categorizing assistance of easier, clearer brand communication. For example, when a consumer is in a store aisle looking at potentially hundreds of products, familiarity with known brands acts as a short cut to speed up and narrow the decision-making process. Further, the value and trust consumers place in brands are incentives for firms to drive innovation, which in turn fosters competition in general, brings value to consumers, and helps to keep costs lower for consumers. In short and from an economic perspective, brands, as represented by trademarks, lower consumer search costs by providing a reliable guide to product quality.¹⁰

familiar,” or “very familiar,” in addition to “don’t know/refused,” 93 percent reported they were quite or very familiar with the part of the label that explains directions, and 82 percent reported they were quite or very familiar with the part of the label that explains symptoms, with another 18 percent reporting they were somewhat familiar. A separate study of parents found 77 percent report reading the part of the label that explains symptoms before purchase, 53 percent to refresh their memory on symptoms treated, and 40 percent each time on symptoms treated. “Pediatric Cough & Cold Medicine Benchmark Research,” Nielsen Company for CHPA, May 2008.

⁸ See Andrea Leonard-Segal, “Label Comprehension, Self-Selection & Actual Use Studies: Issues & Challenges,” presentation to Nonprescription Drugs Advisory Committee, September 25, 2006.
⁹ *Id.*

¹⁰ See William Landes and Richard Posner, “Trademark law: an economic perspective,” 30 *Journal of Law and Economics* 265 (1987), as summarized in *Unfair Trade Practices and Consumer Protection: Cases and Comments*, 5th ed., Weston, et al., eds., 1992.

Stated another way, undue restrictions on OTC brand 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 without the organizing principle a brand name family provides.

Implicit in an understanding of the role of brand names, FDA's Drug Facts rule preamble recognized a role for the principal display panel (PDP – ie, the portion or side of the package first seen by the consumers, generally the front with the brand name) apart from communicating label specifics necessary for safe and effective use. For example, where more than 60 percent of the surface area available to bear labeling is needed to present Drug Facts labeling, a company can use the modified Drug Facts format. "This formula is consistent with the idea that 40 percent of available labeling space is generally reserved for the UPC symbol and PDP." 64 Fed. Reg. 13254, 13267 (March 17, 1999).

With the regulatory requirements for the PDP and the Drug Facts label, there is little reason to believe that consumers are likely to be misled by OTC brand names or line extensions. Meanwhile, we recognize that while brand names and brand name line extensions are a vital tool in capturing a consumer's attention to trigger an initial, preliminary shopping choice, the brand name is never a substitute for the Drug Facts label, with all the information needed for safe and effective use, including the active ingredients.

4. Case law and existing FDA policy recognize appropriate use of trade names

Any policy or practice that limits the ability of a sponsor to extend its trade name to another drug product should be based on firm and reliable evidence that such line extensions are, or are likely to be, misleading. When Congress amended the Food, Drug, and Cosmetic Act to enable FDA to disapprove a new drug application containing proposed labeling that was "false or misleading," Congress required that a finding that a proposed label is false or misleading must "have an objective basis."¹¹ This requires "a fair evaluation of all material facts, objective facts of record that are clear and more definite than simply a matter of individual interpretation."¹² This proscription against arbitrary determinations on misleading statements 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."¹³

We are not aware of such evidence that OTC brand name line extensions mislead consumers. OTC manufacturers clearly identify each and every material distinction among

¹¹ 108 Cong. Rec. 21,066 (1962).

¹² *Id.*

¹³ *Id.* (emphasis added.)

drug products they market. As discussed earlier, OTC medicines, including brand name line extensions, must be labeled with ingredients, indications, warnings, directions for use, and other required information – all in accordance with strict, detailed format requirements.

In addressing when a trade name could be misleading, the Supreme Court has been clear 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.’”¹⁴

FDA policy has long followed the direction and concerns laid out by the Supreme Court. In describing the general circumstances in which drugs would be considered misbranded due to trade name deficiencies, 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).¹⁵

5. Conclusion

Brand names and brand name line extensions are one part, and just the initial step, of consumer recognition and selection of OTC medicines. OTC medicine labels must and do contain all of the information needed for safe and effective use by consumers without the intervention of a healthcare professional.

¹⁴ *Jacob Siegel v. FTC*, 327 U.S. 608, 613 (1946) (citing *FTC v. Royal Milling*, 288 U.S. 212, 217). In both *FTC v. Royal Milling* and *FTC v. Algoma Lumber*, 291 U.S. 67 (1934), the Court held the FTC to an extremely high standard before excision of a brand name could be upheld. In *Algoma Lumber*, for instance, the Court supported FTC’s conclusion that cheaper “yellow pine” could not be advertising as the more expensive “California White Pine.” In contrast, the Court held that full excision of a trade name was unallowably extreme in *Royal Milling*, where the defendants should be afforded the less drastic option of clarifying the brand names in question using “milling” with qualifying language, since they did not grind the wheat they sold.

¹⁵ 39 Fed. Reg. 11298 (March 27, 1974). This policy was articulated in a proposed rule which was later withdrawn along with 88 others in an effort by FDA to reduce administrative backlog in light of limited resources. 56 Fed. Reg. 67440 (December 30, 1991). However, the agency made it clear that 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).

As discussed, any change in FDA policy toward OTC medicine brand names must recognize the important but confined role of such names, and should distinguish between prescription and OTC medicines.

Sincerely,

A handwritten signature in blue ink, appearing to read 'D. Spangler', with a long horizontal flourish extending to the right.

David C. Spangler
Senior Vice President,
Policy & International Affairs