

C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

March 17, 2000

E. EDWARD KAVANAUGH
P R E S I D E N T

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20857

Re: Technical Amendment
Labeling of OTC Human Drug Products; Final Rule
January 3, 2000
Docket Nos. 98N-0337, 96N-0420, 95N-0259, 90P-0201

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The Cosmetic, Toiletry, and Fragrance Association ("CTFA") submits these comments to specific provisions of the Technical Amendment referenced by notice in the *Federal Register* of January 3, 2000 (65 FR 7). CTFA membership includes approximately 300 active member companies that manufacture or distribute personal care products, including many that provide both cosmetic and drug functions in the same product ("cosmetic-drugs"). CTFA also represents approximately 300 additional associate members who provide goods and services to manufacturers and distributors of personal care products.

CTFA has consistently raised the issue of trade dress and its importance in the context of the final OTC labeling rule. In our comments to the proposed rule we emphasized the importance of distinctive trade dress and expressed concerns that legitimate, commercial interests would be adversely affected by the proposed OTC drug labeling requirements:

"Trade dress – the unique colors, type face, package size and shape – is extremely important because it is an integral part of the overall marketing of the product. Trade dress distinguishes one brand from another and some cosmetic products have trade dress which has been in use for years. A cosmetic product's distinctive trade dress is incorporated into all product labeling and advertisements, product samples, even shelf layout plans and store displays. Cosmetic-drug products must therefore complement the trade dress and packaging of the general cosmetic line, since they are usually sold as a line extension of a cosmetic product." (ref: October 6, 1997 CTFA comments, p. 33).

98N-0337

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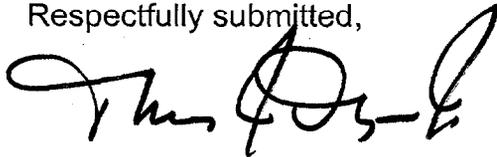
At a public feedback meeting on August 24, 1999 we provided testimony from a legal expert on intellectual property who summarized the legal significance of trade dress and its recognized value to marketers of over-the-counter products. (See Attachment A)

CTFA reiterated its concern about the issue of trade dress in its Citizen Petition filed with the Agency on October 25, 1999.

For these reasons, we support the technical amendment and the Agency's recognition of the importance of trade dress. A standard of legibility and clear presentation can be achieved by means other than requiring labeling to be all black or one dark color, printed on a white or other light, neutral color, contrasting background. As the Agency recognized in the technical amendment, light text on a dark background may also provide good, readable contrast.

In sum, the amended version of the final rule provides appropriate recognition of the value of trade dress for manufacturers who have invested considerable sums of money to promote and protect their distinctive trade dress, as well as for consumers who rely on it to help identify one over-the-counter drug product from another.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Thomas J. Donegan, Jr.", written in a cursive style.

Thomas J. Donegan, Jr.
Vice President - Legal & General Counsel

attachment

cc: Robert DeLap, M.D. (HFD-105)
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Statement of Charles E. Buffon
before the Food and Drug Administration
August 24, 1999
Opposing
Regulations Requiring Black on White
Labeling on Over-the-Counter Products

Background

I am a partner in the Washington office of the law firm of Covington & Burling, practicing in the fields of litigation, intellectual property and trade regulation. I am a 1961 graduate of Dartmouth College and graduated from Harvard Law School in 1964. I am admitted to practice before the Supreme Court of the United States, the Federal Courts of Appeal for the Federal, District of Columbia, Second, Third, Fourth, Sixth and Ninth Circuits and the United States District Courts of Maryland and the District of Columbia. I have also been an Adjunct Professor of Law at American University Law School, and I am a member of the Litigation, Intellectual Property and Antitrust Sections of the American Bar Association.

As part of my intellectual property litigation practice, I have participated in cases involving alleged infringement of patents, trademarks, copyrights and trade dress and have published numerous articles related to intellectual property issues. My most recent reported trade dress case is *Aerogroup International, Inc. v. Shoe Show, Inc.*, 966 F. Supp. 175 (W.D.N.Y. 1997), and my most recent article on the subject (co-authored with Tracy A. Thomas) is "Trade Dress Undress," Intellectual Property (Nov. 1997), discussing the relationship between trade dress, trademark and design patent law. I have also made presentations on intellectual property issues before numerous trade, professional and educational organizations, including the

ATTACHMENT

Cosmetic, Toiletry and Fragrance Association, the National Association of Manufacturers, the Customs Lawyers Association and the International Bar Association.

In this regard, it is important to understand that distinctive trade dress, defined as the overall appearance of a package or container, is a legally protectible and enforceable property right just like a patent, a trademark or a copyright. Distinctive trade dress is a company asset that courts protect against imitation. That is why trial lawyers like myself often get involved in litigation to enforce company trade dress rights. Among other clients, I represent the Coalition to Preserve the Integrity of American Trademarks (COPIAT), as well as individual companies that have trademark and trade dress assets that they consider important to protect and enforce.

These assets also have a substantial monetary value. You often read of a company paying another company many millions of dollars to buy a brand. One example is Procter & Gamble buying Oil of Olay. Another example is Coca-Cola's recent billion dollar offer to buy Dr. Pepper and other soft drink brands. What the purchaser is paying for is much more than just a name. It is also paying for distinctive trade dress that consumers have come to know and recognize. It's like a sports team. Just as the unique burgundy and gold combination associated with the Washington Redskins has a value, so does the trade dress of a well-known over-the-counter consumer product.

Summary of Statement

I am here today, on behalf of the Cosmetic, Toiletry and Fragrance Association and the Consumer Health Care Products Association, to explain why many of their members and others engaged in the marketing of over-the-counter products believe that the regulation recently published by the Food and Drug Administration requiring that all over-the-counter drug products bear certain information in dark printing against a light background is an unwarranted

impingement upon the ability of those companies to create and perpetuate coherent and effective trade dress and is unnecessary to convey important messages to the public. Light on dark printing should also be permitted and would be equally effective and would not spoil the trade dress of companies that choose to distinguish their products by utilizing contrasting light printing against a dark background or sell their products in unique packages characterized by dark color.

Supporting Points

1. Distinctive trade dress and unique packages are crucial vehicles by which marketers of over-the-counter products appeal to consumers, create an image for their products and differentiate their products from those of others.
2. Unlike a prescription drug product, no one is directed to buy a particular over-the-counter product. An over-the-counter product has to make a direct visual appeal to consumers and induce individual consumers to buy this particular product as differentiated from the myriad other products with which it shares store shelves.
3. Consumers have almost an infinite number of choices. A recent case in federal court in the Middle District of Florida reported that "there are over one hundred manufacturers of sun care products [alone]." *Solar Cosmetics Labs v. Sun-Fun Products*, 1996 U.S. Dist. LEXIS 19559 (M.D. Fla. 1996).
4. As also reported by the Court in the *Solar Cosmetics* case, "the color feature [of trade dress] is significant in making the product different from plaintiff's competitors. Also, the colors make the product appealing and easy to buy" For that reason, "use of different colored bottles to package lotions is commonplace." For example, the familiar COPPERTONE container has been updated several times, but for many years it has been distinguished by a uniform dark brown color on which all the printed material is printed in a light color.

5. Color has important associative values as well as being important to achieving distinctiveness. In another recent case, *Majestic Drug Co. v. Olla Beauty Supple, Inc.*, 1997 U.S. Dist. LEXIS 900 (S.D.N.Y. 1997), involving cocoa butter skin lotion, it was reported that producers usually “package their lotions in warm tones, including gold, orange, yellow, brown and red, in order to evoke tropical associations.”

6. Given hundreds of different brands competing for attention, a distinctive combination of colors or unique shape helps a given product stand out and enhances sales success. As reported in the *Solar Cosmetics* case, when it introduced new and distinctive packaging involving bright colors on which “all of the print on the bottle is in white block letters,” plaintiff “experienced an increase in sales.”

7. Companies that market their products in dark colored trade dress often use contrasting white or light colored type in printing their trademark and product information. You have numerous examples before you that illustrate the point. The trademark involved in the *Solar Cosmetics* case also appeared in white on differing dark backgrounds that varied with sunblocking effectiveness. Many manufacturers use a distinctive color design scheme to identify an entire product line, and frequently both a box and the container inside the box bear the same consistent trade dress design.

8. The fact that these companies put their trademarks in light on dark backgrounds is compelling evidence that in their experience consumers notice and apprehend light on dark content. Light on dark material is also common in many other product contexts, including the light on dark print appearing on PEPSI and COCA COLA bottles. I also note that cereal and other food products often bear nutrition and other consumer information appearing in light print on a dark background.

9. It is also obvious in looking at their packaging that many manufacturers have gone to great lengths to create trade dress that presents a coherent impression without patches of material that have no relationship to the overall design. In selling over-the-counter products, integrated and effective trade dress is understood to be an extremely important driver of overall sales success. As I mentioned earlier, it is also a legally protectible company asset.

10. Because trade dress is important to marketers of over-the-counter products, they spend millions of dollars to promote it and, if necessary, additional substantial amounts to defend its distinctiveness against infringement. As reported in the *Solar Products* case, the defendant, a small local manufacturer of suntan lotions, spent over ten million dollars advertising its product in one year. Similarly, in *Parfums Givenchy v. C&C Beauty Sales*, 832 F. Supp. 1378 (C.D. Cal. 1993), a federal court in California found that perfume distributor Parfums Givenchy spent millions of dollars advertising its AMARIGE perfume, whose copyrighted trade dress of a red box with yellow lettering was considered to be "an important part" of the overall product. Also, the opinion in *Bristol-Myers Squibb v. McNeil-PPC*, 786 F. Supp. 182 (E.D.N.Y. 1992), reports advertising for the EXCEDRIN PM brand (which appears in white on a dark background) as exceeding \$81 million.

11. When companies find that their investment in creating and promoting exclusive and effective trade dress is threatened, they sue. In the *Bristol-Myers* case, the manufacturer of EXCEDRIN PM obtained an injunction against the continued use of similar trade dress on TYLENOL PM. *Olay Company v. Cococare* involved a suit by the then-manufacturer of OIL OF OLAY to enjoin the use of similar light on a dark cartouche by a competing manufacturer of skin lotion. In *McNeil-PPC v. Guardian Drug Co.*, 45 U.S.P.Q.2d 1437 (E.D. Mich. 1997), the manufacturer of LACTAID sued to obtain an injunction against use of similar trade

dress on a retailer's competing private label product. The *Solar Cosmetics* case was a suit to enjoin similar trade dress on a suntan lotion product, as was the recent case of *South Beach Suncare v. Sea & Ski Corporation*, 1999 U.S. Dist. LEXIS 7902 (S.D. Fla. 1999), which also involved light on dark packaging. The *Majestic Drug* case involved similar trade dress on competing cocoa butter lotions.

12. Use of light colored material on a dark background has been an important element of a number of these cases. In the *Olay Co.* case, plaintiff sued to protect its distinctive use of its trademark, OIL OF OLAY, printed in white on a dark cartouche against a pink background. In the *Bristol-Myers* case, the maker of EXCEDRIN PM successfully sued to prevent the makers of TYLENOL PM from using what the Court described as its "unique trade dress" consisting of "an outer carton with deep blue background [and] white lettering for the EXCEDRIN PM trademark" The *Solar Cosmetics* case involved use of white print against bright colored orange, magenta, green and blue bottles; the *South Beach Suncare* case involved use of "yellow printing" and "white text" on a "black plastic bottle."

13. The courts in these cases recognized that, given the limited number of packaging choices available, and the many competing products on store shelves, use of light-colored printing against a dark background can be an important means of identifying and distinguishing one's products compared to others. Where that has been done in a unique way, the light on dark feature has been recognized as part of a company's intellectual property protected by the courts against similar usage.

14. In this context, requiring a company that has used a uniform light on dark trade dress design to add a block of black on light material would impinge on the integrity of a company's unique and proprietary trade dress design and impose significant costs. When not

consistent with the overall design, a requirement of labeling content in dark print on a light colored background would diminish and detract from the integrity and effectiveness of the overall trade dress. To the extent all over-the-counter packages are required to bear the same dark on light labeling information, it would diminish distinctiveness between products and make it more difficult and expensive for manufacturers to create unique identities for their products.

15. In sum, a dark on light labeling requirement is viewed by the affected industry as a packaging straightjacket that they do not want to be put in. This is particularly so because their own experience is that light on dark labeling material is at least equally legible and effective and because there is no solid empirical evidence to support a contrary conclusion. With all respect, manufacturers who have spent millions of dollars promoting and protecting their distinctive light on dark trade dress do not believe the FDA is justified in seeking to impose this degree of packaging conformity on marketers of over-the-counter products.

CONCLUSION

Manufacturers of over-the-counter drug products hope that the points made above will lead the Food and Drug Administration to reconsider and modify its recently published labeling requirements to permit light on dark (as well as dark on light) printing to be used to convey all information presented as part of their trade dress. They would also be pleased to have me or others provide any further information on the subject that FDA would find useful.

CROSS FILE SHEET

FILE NO: Q8N-0337/c6

SEE FILE NO: Q6N-0420/C1026
Q5N-0259/C20
Q0P-0201/C73