C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

October 22, 1999

E. EDWARD KAVANAUGH
PRESIDENT

BY HAND DELIVERY

Dockets Management Branch
Food and Drug Administration (HFA-305)
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20857

CITIZEN PETITION

On behalf of the members of The Cosmetic, Toiletry, and Fragrance Association ("CTFA"), the undersigned submits this petition under Sections 502, 503, 505, 602 and 701 of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") and 21 C.F.R. § 10.30 to request that the Commissioner of Food and Drugs stay for two years the implementation dates established under the agency's final rule standardizing the format requirements for the labeling of over-the-counter ("OTC") drug products. 64 Fed. Reg. 13254 (March 17, 1999) (hereinafter referred to as the "final OTC drug labeling rule"). This request does not extend to the ultimate six year effective date in the final OTC drug labeling rule.

Introduction

As the 105 year old national trade association representing the personal care products industry, 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 members with cosmetic-drug products are subject to the Food and Drug Administration's ("FDA's") final OTC drug labeling rule and have a critical interest in ensuring two things: a clear resolution of outstanding issues and a reasonable implementation period thereafter.

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Within the OTC drug market, cosmetic-drugs sold in the United States represent a unique sub-category. The FD&C Act, 21 U.S.C. § 321 et. seq., permits lawful marketing of such products under two distinct statutory standards. Cosmetic-drugs are subject to the standards for cosmetics (21 U.S.C. §§ 601-602) and must also comply with those for drugs (21 U.S.C. §§ 501-505). Nowhere in the FD&C Act is either of these standards granted precedence over the other. Thus, absent an affirmative factual basis for concluding that the dual labeling of such products is misleading to consumers, the FDA has an obligation to implement labeling policies that fairly balance the ability of manufacturers to convey important information about all of the relevant functions of their cosmetic-drug products. FDA's refusal to acknowledge the value of the cosmetic attributes and claims of such products, as demonstrated by the agency's failure to differentiate between cosmetic-drug products and traditional OTC drugs for purposes of the final OTC labeling rule, disregards the fact that cosmetic-drugs fall squarely within two legitimate, lawful categories of FDA regulated products. Fair implementation of the final OTC drug labeling rule requires recognition and accommodation of the cosmetic attributes of OTC drugs.

Prior to a review of the many issues that must be clarified in the final OTC drug labeling rule, it is important that FDA clearly understands the deep concerns of the cosmetic-drug industry.

The Regulation as Written is Fatally Flawed

The existing regulation published on March 17, 1999 is legally and substantively flawed as it applies to cosmetic-drugs. There is simply no evidence to justify the application of such severely restrictive labeling requirements to this category of products. In addition, requirements of the rule fail to account for the practical conditions under which manufacturers must sell their products. Without justification, the regulation will prevent manufacturers from selling products in traditional trade dress (consisting of colors, sizes and shapes of packaging that will no longer be feasible under the rule), and will prevent the sale of products in forms and package sizes that are practical and convenient for consumers to use. FDA has the burden to justify such an extraordinary restriction on legal commercial activity and they have simply not done so.

As FDA is increasingly aware, government regulations that restrict a company's right to communicate to consumers commercial messages must fully

comport with the Supreme Court's four-prong test to assure that such restrictions do not violate a company's First Amendment commercial speech rights. Central Hudson Gas & Electric Corp. v. Public Service Commission, 447 U.S. 557 (1980). FDA clearly bears the burden of proving that its regulation directly and materially advances its stated interests. Just last term in Greater New Orleans Broadcasting Association, Inc. (GNOBA) v. United States, 119 S.Ct 1923,1935 (1999), the Supreme Court stated that . . ."'[M]ere speculation and conjecture' will not suffice" to carry the agency's burden. GNOBA 119 S.Ct at 1932. Rather, there must be an "immediate connection" between the prohibition on speech and the asserted end; if, in this situation, the regulation provides only "ineffective or remote support for the government's purpose," it fails Central Hudson's third prong. Central Hudson, 447 U.S. at 564.

Modification of the Regulation to Make it Feasible Will Take Additional Time

While our industry is seriously troubled by this unnecessary imposition of new labeling requirements on cosmetic-drugs, CTFA remains willing to work with the agency as long as a good faith effort is underway to make compliance with this regulation feasible. However, it is painfully obvious from the first six months of efforts to address the many outstanding issues with the agency that substantially more time is necessary to resolve these issues.

Initially, industry asked for a minimum of three years to implement the regulation. FDA granted only two years for certain products, and published a regulation that was much more restrictive and comprehensive than justified or expected. Seven months have passed since publication of the rule, and absolutely none of the issues raised by CTFA or the Consumer Healthcare Products Association ("CHPA") have been resolved. However, it is important to emphasize that no single issue or subset of issues presented is a solution in itself.

Unless FDA is willing to exempt certain cosmetic-drug categories and provide a categorical small package exemption as originally proposed by CTFA, it will take a complex series of modifications of the regulation to make it feasible for all OTC drug products. This will take substantially more time than the agency has provided to decide and give manufacturers enough time to implement.

Procedural History

1. FDA's Proposal

On February 27, 1997, FDA published a sweeping proposal to change fundamentally the way all OTC drugs, including cosmetic-drugs are labeled. 62 Fed. Reg. 9024 (February 27, 1997)(hereinafter referred to as "the OTC drug labeling proposal"). By FDA's own calculation, 100,000 OTC drugs will have to be relabeled over the next six years. Among the primary features of the OTC drug labeling proposal was a standardized format for all OTC drug products with regard to the vast majority of FDA-required information that must be on a product's label or labeling. The primary basis cited by FDA for establishing a standardized format was "the need to significantly improve consumer readability and comprehension of product labels to ensure the safe and effective use of such products." 64 Fed. Reg. 13254.

2. CTFA's Comments

In comments submitted to the agency, CTFA carefully responded to FDA's proposal by analyzing separately each stated rationale articulated by FDA and the data supporting it in relation to cosmetic-drugs for which FDA does not impose any dosage limitations. 1/ Not surprisingly, CTFA's step-by-step analysis demonstrated no public health reason to impose the new format requirements on these cosmetic-drug products. Additionally, CTFA noted the impact of the proposed new labeling requirements on international harmonization given that many cosmetic-drug categories are regulated solely as cosmetics in the European Union. As summarized briefly below, CTFA's comments reveal the absolute dearth of support for application of the new format requirements to cosmetic-drug products.

FDA cites concern that the manner in which consumers use OTC drug products has changed significantly, but cites no such changing patterns for use by consumers of cosmetic-drug products. The increased availability of more potent OTC drug therapies, bears no significant relationship to use by consumers of cosmetic-drug products. There is simply nothing in the vast record compiled by

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1/ See CTFA Comments dated October 7, 1997 to FDA Docket Nos. 96N-0420, 92N-454A, 90P-0201 and 95N0-0259

FDA for its final OTC drug labeling rule that suggests that moisturizers with sunscreens, antidandruff shampoos, skin care products that contain skin protectant ingredients, antimicrobial washes, or antiperspirant/deodorants deserve the same scrutiny or raise the same challenges for the safe and effective use by consumers as the examples of OTC drug products cited by FDA for more serious disease conditions. Unlike many of the examples of OTC drug products examined by FDA during its rulemaking process, cosmetic-drugs do not include products that have been switched from prescription to OTC drug status. They do not raise any serious potential for new uses in the future, nor are FDA's safety fears regarding self-diagnosis and self-medication relevant to the types of daily use products encompassed by the cosmetic-drug category.

FDA concerns regarding the public health ramifications associated with changing patterns of OTC drug use do not exist with regard to cosmetic-drug products. Cosmetic-drug products have an exceptional history of safe use, especially given the long and widespread exposure to these products by the general population. Issues of wrong dose size or frequency of use simply do not exist for products such as sunscreens or other cosmetic-drugs. Nor is there in either the proposed or final rule any data to support the fact that the present manner in which these products are labeled results in consumer confusion or in unsafe or ineffective use of these products. These are simple products used safely and effectively by consumers for decades, and repeatedly purchased by consumers for both their drug function and their cosmetic attributes.

Consistent with the above findings, CTFA made two major requests in its comments. First, it requested that all cosmetic-drug categories for which there are no FDA-mandated dosage limitations be exempted from the proposed labeling changes and be allowed to continue current means of providing FDA-required labeling information. In joint comments filed with CHPA on July 13, 1998 to FDA Docket Nos. 96N-0420, 92N-454A, 90P-0201 and 95N0-0259, CTFA narrowed this request for categorical exemption to five specific cosmetic-drug product categories: sunscreens, antiperspirant/deodorants, skin protectants, antidandruff shampoos, and antimicrobial soaps and washes. Second, given the substantial number of small package SKUs for cosmetic-drugs, CTFA proposed a specific, objective standard to exempt small packages from these requirements.

3. FDA's Final Rule

With no new data to provide factual support for application of its rule to cosmetic-drugs, FDA's final OTC drug labeling rule summarily rejects CTFA's requests to exempt such products from the rule and dismisses its recommendations relating to small packages. 64 Fed. Reg. at 13268-70. Indeed, despite CTFA's July 9, 1998 conference call with FDA and the written comments filed with the agency on July 13, 1998, the final OTC drug labeling rule fails to reflect or address CTFA's decision to narrow its request for a categorical exemption. Rather, FDA's citations to discrete risks from several cosmetic-drug categories include risks from acne products and fluoride preparations, products that have been eliminated from CTFA's request for exemption. FDA further cites the risk that dandruff shampoos must have warning labels if they contain coal tar. Presumably, FDA understands that almost no OTC dandruff shampoos use such ingredients today. Lastly, FDA concludes that the law "requires readable and understandable labeling, irrespective of a specific showing of harm" as the generalized reason for including these categories. 2/ Establishing a "one-size fits all" format for all OTC drug products, FDA has granted OTC drug manufacturers two years to comply with the final OTC labeling rule depending on the present regulatory status of the product and/or the product category, and set an outside deadline of six years from the effective date by which all labels must conform to the new requirements.

To date, FDA has never adequately addressed CTFA's contention that the agency's underlying concerns regarding OTC labeling simply do not exist for the narrow category of cosmetic-drug products for which exemption is requested. Since the publication of the final OTC drug labeling rule on March 17, 1999, CTFA has maintained a steady dialogue with FDA to seek clarification and/or reconsideration

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2/ Certainly, the law requires that drug labeling be neither false nor misleading (§ 502(a)) and that important information be conspicuous on the label so that consumers are capable of reading and understanding the information (§ 503). CTFA and its members fully agree with these mandates and believe that the cosmetic-drug products in the five categories cited presently meet these standards as they have for decades.

of the issues identified in this petition. 3/ While CTFA recognizes that both the cosmetic-drug industry and FDA are earnestly working towards resolution of these complex issues, continued dialogue is necessary, given the scope of this final rule and the vastness and diversity of products it covers. A reasonable period of time is necessary to ensure that these good faith discussions continue at their present pace and to provide sufficient time for manufacturers to implement necessary labeling changes.

A. ACTION REQUESTED

CTFA requests that FDA extend the implementation dates of the final OTC drug labeling rule for two years beyond those currently provided for each OTC drug product category, including those with small volume sales. (See implementation chart, 64 Fed. Reg. at 13274.). Such an extension of time will ensure that all of the relevant format issues currently under review by FDA will be resolved prior to industry-wide initiation of very complex and expensive label revisions. CTFA is not requesting, however, that any two-year extension apply to the ultimate six year implementation deadline in the final OTC drug labeling rule.

B. STATEMENT OF GROUNDS

The cosmetic functions associated with various OTC drug products are important to consumers and raise unique labeling issues that deserve careful consideration in the context of devising a fair implementation plan for FDA's final OTC drug labeling rule. The agency decided to include all cosmetic-drugs within the scope of its final OTC drug labeling rule despite the strenuous objections by CTFA that the five categories of products for which exemption was requested, remain largely outside the areas of public health concern that prompted the new format rules for OTC drugs. Given that the final rule did not provide any new data or further substantiate the rationale for imposing the new rule on cosmetic-drugs, it is vital that the negative impact of certain of the new format requirements be minimized to the greatest extent possible for such products. In order to achieve this FDA needs to consider and resolve in a

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3/ With regard to resolution of particular matters, a feedback letter may be legally sufficient whereas the Administrative Procedure Act (5 U.S.C. § 553) may require notice and comment rulemaking to resolve other matters.

comprehensive manner CTFA's request for an appropriate small package exemption, as well as other outstanding issues, before requiring cosmetic-drug manufacturers to proceed with plans to revise their product labels.

The following discussion briefly reviews the major outstanding issues that have not yet been fully resolved and establishes the basis upon which CTFA believes a request for additional time to ensure fair implementation of the rule with respect to such products is warranted. Granting a two year stay as requested will provide sufficient time to resolve all of the labeling issues in a manner that ensures fair implementation of the final OTC labeling rule for cosmetic-drug products without causing any harm whatsoever to the public health. Providing less than a two-year implementation period will impose a substantial economic burden on cosmetic-drug manufacturers who will be forced into the position of instituting incremental relabeling of their products as issues are resolved. Since not only labeling but packaging changes as well may be necessary, the economic burdens associated with a piecemeal approach could be very significant. Additionally, given the almost total lack of factual justification for applying this rule to the five identified categories, fairness dictates that CTFA be allowed to continue its dialogue with FDA on outstanding issues prior to requiring massive labeling changes. CTFA is committed to working promptly with FDA to achieve a reasonable application of the final OTC drug labeling rule to cosmetic-drug products. Prior to completion of this process, CTFA believes that a two-year stay of the effective date is fully justified and the only acceptable course of action.

1. Further Consideration of a Categorical Exemption for Small Packages is Warranted

a. Small Packages Generally

CTFA continues to request that the agency establish an objective small package exemption standard. Should FDA decline to exempt fully small packages, then it must clearly define the small package exemption process for all OTC drug products. Presently, the final rule establishes a standard that triggers certain limited modifications to the new label format. (See 21 C.F.R. § 201.66(d)(10).) CTFA believes that any package that meets the objective definition of a small package should be fully exempt from the new label format. This is crucial for cosmetic-drug products which come in a wide array of shapes

and sizes and in very small containers. Indeed, the scope of the problem for CTFA members under the existing final rule is enormous. For instance, as we stated at the April 23, 1999 FDA feed-back meeting,

- 30-60% of product SKUs cannot comply with the final rule;
- for larger CTFA member companies, 400-800 OTC SKUs per company (limited to cosmetic-drug product categories) will be unable to comply;
- One CTFA member has 800 cosmetic-drug SKUs, 600 (75%) of which cannot comply with the final rule;
- One CTFA member has 61% of its cosmetic-drug SKUs which cannot comply <u>even after</u> the addition of secondary packaging;

b. <u>Objective Small Package Standard</u>

Among CTFA's earliest responses to FDA's OTC drug labeling proposal was to initiate dialogue on the need for a fair small package exemption (not merely a limited modification). In lieu of an exemption, however, FDA's final OTC drug labeling rule provides for limited modifications for packages with limited available labeling space to meet the general format requirements. 21 C.F.R. § 201.66(d)(10). This does not provide a clear, easy to follow small package exemption. Rather one must first try to comply with all the requirements of the rule, before considering its special provisions which allow modifications to the content and format of a particular label when the information does not fit on small or unusually shaped packages. A package is considered "small" for purposes of determining whether it is eligible to use the modified format if more than 60 percent of the total surface area available to bear labeling would be needed to present the FDA required information.

CTFA continues to believe that a broader set of objective standards for determining whether a particular package qualifies as "small" and ensuring that such "small" packages be fully exempt from the new label format would provide consistent, agency-wide treatment of similarly situated products in a

fair and lawful manner. Thus, CTFA continues to support a small package definition that includes several objective measures of "small", including a conclusion that a package is "small" if:

1. the total surface area available to bear labeling is less than 12 square inches (including the principal display panel); or

2. more than 60% of the total surface area available for labeling on the back and side panels, if any, (excluding principal display panel) must be used to satisfy the content requirements as described in section 201.66(c); or

3. it is a trial size, packette, convenience size or single-use unit.

Obviously, small packages that meet these standards must be labeled, as they are now, with all required information. Given the compliance statistics cited above, it should be plainly apparent that there remains a serious problem that must be resolved prior to implementation.

c. The Exemption/Deferral Provision

Aside from the modifications for small packages permitted under the final OTC drug labeling rule, procedures for requesting exemption or deferral from compliance with particular provisions of the format requirements are also provided. 21 C.F.R. § 201.66(e). The process devised by FDA for requesting exemptions and deferrals is deficient both in the wholly ambiguous nature of the standard that must be met to qualify for an exemption or deferral and as to the procedures for making such a request. CTFA has raised these issues with FDA since publication of the final rule.

The Exemption/Deferral Standards

The current standard for granting an exemption or deferral from compliance with one or more of the format labeling provisions requires a manufacturer to demonstrate that a particular requirement is "inapplicable, impracticable, or contrary to public health or safety." Without further guidance

from FDA as to how these standards may be met, their subjective nature renders them virtually meaningless. Once again, given the compliance statistics cited above, it is clear that many products face major implementation problems that must be fully and publicly addressed prior to initiation of labeling and packaging revisions. CTFA believes that FDA should broaden the objective definition of small packages as discussed above and further provide that any such package be fully exempt from the new label format rule. The current exemption standards are so subjective as to provide no guidance. This arbitrary and capricious standard has thus forced FDA to develop a label-by-label exemption system coupled with a public record process, which as discussed below, raises serious legal issues regarding the disclosure of confidential commercial information.

The Exemption/Deferral Process

The final OTC drug labeling rule sets forth detailed procedures for requesting exemptions from the labeling format requirements. 21 C.F.R. § 201.66(e). Requests must be submitted individually for each OTC drug product for which an exemption is desired and must be accompanied by representations of the proposed labeling intended to be used with the product. All of these materials must be submitted to FDA as part of its public docket process. These requirements raise a number of unresolved issues most of which arise from the fact that FDA rejected CTFA's proposal for objective standards for a full small package exemption.

By establishing a label-by-label exemption/modification process, FDA has created an unwieldy administrative procedure. Among the issues of greatest concern to industry is the confidentiality of certain data that must be submitted as part of an exemption request. Some of the information may be highly confidential commercial information which is not disclosable pursuant to the Freedom of Information Act (5 U.S.C. § 552) and FDA's substantive and binding regulations that implement that statute (21 C.F.R. § 20.61). The kinds of information that may be in these requests (such as confidential marketing strategies and trade dress) are not the usual kind of confidential commercial information that the agency normally considers. Thus, it is critical that FDA and industry must agree on how such categories of information shall be handled. In addition, the process as described in the final rule and in an August

9, 1999 letter to the CTFA and CHPA states that exemption requests must be a matter of public record and that while FDA will decide confidentiality questions ". . .some aspects of the information may become public when the agency's letter is placed in the docket". To release confidential commercial information would violate both the law and FDA regulations.

Thus, the exemption processes raises serious legal questions that must be clarified before companies should be put in a position of having to submit what may be highly confidential commercial information. Furthermore, there are other questions such as an appropriate appeals process and the time limits for initial decisions and appeals that must be addressed. CTFA will continue to work with FDA to fully understand the Freedom of Information Act ramifications of submitting data to a public docket that may be considered confidential by the submitter.

2. Issues of Trade Dress Need to be Resolved

On August 24, 1999, CTFA made a presentation to FDA regarding the enormous negative impact FDA's final OTC drug labeling rule would have on the trade dress of cosmetic-drug products. The final OTC drug labeling rule generally requires use of dark type on a light-colored background in presenting information required by the rule in the new "Drug Facts" format. This requirement amounts to an arbitrary and illegal ban on certain packaging which uses light type on dark background as part of a company's traditional trade dress. This deprives marketers of a valuable property right and consumers of a valuable way to recognize and correctly select products in the marketplace, something this rule was supposed to assist.

CTFA member companies as well as a legal expert on intellectual property, including trade dress, presented testimony and examples establishing the enormous importance of trade dress to the industry as well as the enormous negative impact of this rule. (Copies of the expert legal testimony are attached.) While FDA has acknowledged that this is an issue that warrants further consideration, a final decision may require further dialogue and evaluation by FDA, further justifying an extension of the effective date of the final OTC drug labeling rule while this matter is being resolved.

3. FDA Needs to Harmonize the New Labeling Requirements with Already Existing Cosmetic Requirements.

By focusing solely on providing "Drug Facts" information associated with a particular product, the final OTC labeling rule completely ignores the important impact of cosmetic labeling and the consumer's desire for cosmetic-related information. As discussed above, absent an affirmative fact-based conclusion that certain cosmetic labeling would render the product label false or misleading or otherwise misbranded, FDA must consider how to harmonize lawful cosmetic labeling. Several examples of FDA's failure to fully harmonize the new regulations with current cosmetic labeling requirements demonstrate the lack of full consideration given to cosmetic labeling issues by FDA in the context of the final OTC drug labeling rule. We describe below, in order to illustrate this lack of harmonization, two examples where FDA is not allowing use of long- standing, lawful cosmetic labeling techniques. Most importantly, in the preamble to the final rule, FDA gave no explanation for this affirmative lack of harmonization.

By requiring cosmetics that are also OTC drugs to declare inactive ingredients in accordance with the final OTC drug labeling rule, FDA has unnecessarily deprived cosmetic-drugs with the ability to utilize the alternative ingredient listing provision of 21 C.F.R. § 701.3(i). That alternative listing provision permits certain cosmetic products held and displayed for sale in tightly compartmented trays or racks to provide cosmetic ingredient information via off-label means. In addition, FDA's final OTC drug labeling rule does not accommodate or recognize existing cosmetic labeling regulations for small packages that allow the use of 1/32nd inch type size for inactive ingredients. 21 C.F.R. § 701.3(p).

CTFA raised the first issue with FDA in a meeting on September 17, 1999. These harmonization issues are critically important and all involved parties must have time to work them out and then a fair amount of time given to implement them.

4. Other Labeling Issues of Broad Concern to Industry

Both CTFA and CHPA have also raised several other critical issues that must be clarified for all OTC products including cosmetic-drugs. Indeed, both groups began identifying these as issues of concern immediately upon publication of the final OTC drug labeling rule. These issues include:

- the use, under defined circumstances, of less than 6 point type;
- the use of columns;
- the manner in which single use and convenience size packages shall be treated; and
- the appropriate use of extended text labeling.

Despite good faith dialogue on the part of both FDA and industry, these issues have yet to be resolved. In fairness they must be resolved at least two years in advance of implementation of the final OTC drug labeling rule.

Conclusion

As demonstrated by the above discussion, significant unresolved issues regarding appropriate implementation of FDA's final OTC drug labeling rule persist. None of these issues are being raised for the first time in this request. Rather they represent concerns that industry and the agency have been working on at least since publication of the final rule. CTFA has already had substantial dialogue with FDA on most of these issues, and anticipates that such dialogue will continue as industry moves forward in good faith to achieve compliance with the final OTC drug labeling rule. Given, however, that seven months of the implementation period has already passed and that final resolution of the issues discussed above will continue to reduce the amount of time remaining to finalize labeling revisions and achieve full implementation by many manufacturers, CTFA's request for an additional two years for implementation purposes is reasonable. Such extension will not have any adverse effect on public health, as no immediate health risk has been identified from the current labeling of OTC drug products, nor

does the request impact FDA's ultimate 6 year deadline for achievement of full compliance by all OTC drug products.

C. ENVIRONMENTAL IMPACT

The actions requested herein are subject to categorical exclusion under 21 C.F.R. §§ 25.30 and 25.31.

D. ECONOMIC IMPACT

An economic impact statement will be submitted at the request of the Commissioner.

E. CERTIFICATION

The undersigned certifies that, to the best of their knowledge and belief, this petition includes all information and views on which the petition relies, and includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully yours,

E. Edward Kavanaugh

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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.