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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
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**Re: Final Monograph for Sunscreen Drug Products for
Over-the-Counter Human Use; Docket No. 78N-0038; and
Final Rule for Over-the-Counter Human Drugs; Labeling
Requirements; Docket Nos. 98N-0337, 96N-0420, 95N-0259,
and 90P-0201.**

Dear Sir/Madam:

This submission is filed on behalf of The Cosmetic, Toiletry, and Fragrance Association ("CTFA") for purposes of updating the above-cited dockets on OTC Sunscreen Drug Products and OTC Labeling Requirements for Human Drugs (the "Sunscreen and OTC Labeling Rules"). Specifically, CTFA is submitting information regarding two recent court decisions striking down restrictions imposed by the Food and Drug Administration ("FDA") as inconsistent with the First Amendment's guarantee of freedom of speech. These decisions are particularly pertinent to CTFA's continuing efforts to address unconstitutional FDA limitations on speech and imposition of labeling requirements on sunscreens under the Sunscreen and OTC Labeling Rules. CTFA believes that the specific labeling issues identified below are unconstitutional and that FDA should modify application of the Sunscreen and OTC Labeling Rules accordingly.

In response to FDA's notice reopening the administrative record for OTC Sunscreen Products, 65 Fed. Reg. 36319 (June 8, 2000), CTFA filed comments on September 6, 2000. Among other things, CTFA objected to FDA's restrictions on truthful labeling in the final rule for sunscreens. CTFA characterized the bans imposed by FDA as extending well beyond constitutionally permissible restrictions on commercial free speech. Specifically, we urged the agency to reassess its prohibition on labeling of SPF products over 30, its restrictions on skin aging claims, and its limitations of the indications for use for sunscreen drug products.

98N-0337

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CTFA has also previously objected to FDA's Final Rule "Over-the-Counter Human Drugs; Labeling Requirements." 64 Fed. Reg. 13254 (March 17, 1999). That rule mandates sweeping and detailed changes in the format for required information for all OTC drug products, including cosmetic-drugs. FDA did not, however, provide any factual basis for including the entire category of cosmetic-drug products in the proposed rule. See FDA's Proposed Rule on OTC Labeling, 62 Fed. Reg. 9024 (February 27, 1997). CTFA correctly asserted that cosmetic-drugs do not present the safety or label comprehension concerns that form the basis for FDA's sweeping proposal. Nonetheless, FDA issued the final rule and included all cosmetic-drug products within its scope. CTFA continues to maintain that under the record developed by FDA there is simply no rational basis for the wholesale imposition of the OTC Labeling Rule on cosmetic-drug products. Accordingly, the requirements do not serve any substantial state interest. Absent evidence that the requirements promote health and safety or serve some other substantial government interest, they are impermissible.

Regarding the labeling issues raised under the Sunscreen and OTC Labeling Rules, CTFA does not believe that FDA has met its burden to demonstrate that the claims at issue are misleading or that the restrictions on speech directly advance any substantial governmental purpose. In addition, CTFA believes that any interest the agency has asserted in restricting the speech at issue is served equally well -- if not better -- by regulations that do not restrict speech to the same extent as FDA's regulations. For example, the courts have repeatedly made clear that more speech is to be preferred to less speech; where it has not been demonstrated that a disclaimer or other additional speech will prove inadequate to address the government's concern, the government is not permitted to restrict the speech at issue. Recent case law, discussed below, confirms these conclusions.

First Amendment Protections Apply to FDA Restrictions on Commercial Speech.

By way of background, information about a product offered for sale is "commercial speech" -- speech uttered for the purpose of inviting a commercial transaction. See Virginia Pharmacy Board v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 762 (1976). Although commercial speech was at one time unprotected under the First Amendment, see Valentine v. Chrestensen, 316 U.S. 52 (1942), the Supreme Court in Virginia Pharmacy Board declared that such speech was entitled to constitutional protection; after all, the Court stated, a consumer's "interest in the free flow of commercial information * * * may be as keen, if not

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keener by far, than his interest in the day's most urgent political debate." 425 U.S. at 763. The Supreme Court further refined its test for commercial speech in Central Hudson Gas & Electric Corp. v. Public Service Commission, 447 U.S. 557 (1980). As the Court explained, if commercial speech neither misleads nor relates to unlawful activity, the state's ability to regulate that speech is limited: the state must show that it has a "substantial interest" that is served by restricting the speech, and that its regulation is in proportion to the asserted interest. The regulation must directly advance the interest involved, and "excessive restrictions" on speech will not survive scrutiny. *Id.* at 564. In particular, the Court observed, a state may not "completely suppress information when narrower restrictions on expression would serve its interest as well." *Id.* at 565. The Central Hudson Court then summed up its four-part test:

For commercial speech to come within [the First Amendment], [1] it at least must concern lawful activity and not be misleading. Next, [2] we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether [3] the regulation directly advances the governmental interest asserted, and [4] whether it is not more extensive than is necessary to serve that interest. [*Id.* at 566.]

Recent cases involving FDA restrictions on speech have made clear that application of the four-part Central Hudson test to such restrictions can readily result in invalidation of FDA policies and regulations.^{1/}

Recent First Amendment Cases Involving FDA

CTFA shares FDA's interests in ensuring the accuracy of commercial information in the marketplace and in promoting public health. As described above, however, even where such interests exist, the agency must demonstrate that the restrictions directly advance the government's interests and are the least restrictive means available to do so. Both the D.C. Circuit and District courts have recently expressed intolerance of FDA efforts to impose unreasonable restrictions on commercial speech. In Pearson v. Shalala, 164 F.3d 650 (D.C.Cir. 1999), the D.C.

^{1/} See e.g., Washington Legal Foundation v. Henney, 56 F.Supp.2d 81 (D.D.C. 1999), 13 F.Supp.2d 51 (D.D.C. 1998), 202 F.3d 331 (D.C.Cir. 2000); see also cases discussed *infra* at 3-5.

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Circuit rejected FDA's attempt to prohibit health claims on dietary supplements unless the agency had concluded that such claims had "significant support" in medical literature. The court of appeals first dismissed the agency's argument that health claims with less than significant support were inherently misleading, concluding that the argument amounted to the near-"frivolous" assertion that health claims on dietary supplements so entranced the common consumer as to render him powerless to resist. See id. at 655. Acknowledging the FDA's interests in "ensuring the accuracy of commercial information in the marketplace" and in promoting public health, the court of appeals concluded that FDA's interest in public health was not at all advanced by the regulations when the agency had made no suggestion that the labeling claims at issue threatened public health, but that its alternative interest -- preventing consumer fraud -- was advanced by the agency's prohibition. Id. at 656. The agency's regulation, however, failed because it did not constitute the least restrictive means to advance the interest at issue; in choosing to suppress speech rather than require more disclosure in the form of disclaimers. The court of appeals held that the agency had disregarded "far less restrictive" means of addressing its interest in preventing consumer fraud, and ordered the case remanded to FDA for reconsideration. Id. at 657.

Subsequently, in Pearson v. Shalala, 2001 WL 111161 (D.D.C. Feb. 2, 2001), the United States District Court for the District of Columbia considered a challenge to FDA's handling of one of the four health-related claims -- the so-called "folic acid health claim" -- which had been at issue in the earlier Pearson case before the D.C. Circuit. FDA had concluded on reconsideration that the weight of the evidence was against the claim, that the claim was therefore inherently misleading, and that it could not be made non-misleading with a disclaimer or other qualifying language. The District Court, however, found, "as a matter of law, that Plaintiffs' folic acid claim is not 'inherently misleading,' and the FDA therefore erred in not drafting disclaimers to accompany the claim." Id. at *7. In essence, the court held that the FDA had erred in finding that the existence of conflicting or inconclusive evidence concerning the health claims at issue made those claims inherently misleading. See, e.g., id. at *11 ("the FDA may not ban the folic acid claim simply because the scientific evidence is inconclusive"). Instead, the existence of inconclusive or conflicting evidence "suggests the need for a well-drafted disclaimer, which the FDA has steadfastly thus far refused to even consider." Id. 2/

2/ The District Court made quite clear its conclusion that FDA's position essentially constituted a refusal to comply with the earlier court ruling by the D.C.

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The recent decision by the District Court in Pearson is significant in several respects in connection with the Sunscreen and OTC Labeling Rules. First, it makes clear that for FDA to support a finding that certain statements are inherently misleading, it is not enough simply to find that the evidence is inconclusive or conflicting; FDA must in fact demonstrate that the evidence is against the statement. Second, it confirms that the courts are becoming more willing to scrutinize FDA's conclusions about the weight of scientific evidence; the Pearson court examined the evidence for itself and found that it did not support FDA's conclusion about the folic acid claim. Third, the court reaffirmed the increasing consensus that, where speech is not inherently misleading, FDA is required by the Constitution to consider the use of disclaimers, *i.e.*, additional speech, rather than simply restricting speech. ^{3/}

In another recent decision, Western States Medical Center v. Shalala, 2000 WL 33153172 (9th Cir. Feb. 6, 2001), the Ninth Circuit considered a First Amendment challenge to restrictions on promotion and advertising in connection with the recently enacted pharmacy compounding provisions of the Food and Drug Modernization Act of 1997. Federal Food, Drug, and Cosmetic Act sec. 503A; 21 U.S.C. § 353a. Among other things, the law sets forth parameters under which pharmacists and physicians may compound drugs for use by patients and exempts such products from certain of FDA's good manufacturing practices, labeling and new drug approval requirements. *Id.* at §503A(a) and (c); 21 U.S.C. § 353a(a) and (c). Also included is a ban on the promotion and advertisement of particular compounded drugs. The government made no claim that the prohibited speech was

Circuit. Thus, it observed, "it is clear that the FDA simply failed to comply with the constitutional guidelines outlined in Pearson," that "the agency appears to have at best, misunderstood, and at worst, deliberately ignored, highly relevant portions of the Court of Appeals opinion," and that "the FDA has simply failed to adequately consider the teachings of Pearson: that the agency must shoulder a heavy burden if it seeks to totally ban a particular health claim." 2001 WL 111161 at *5, *11.

^{3/} Indeed, by letter dated May 24, 2000, from CTFA to Charles T. Ganley, M.D., Director, Division of OTC Drug Products, CDER, CTFA responded to FDA concerns regarding high SPF products. At that time, CTFA proposed the following disclaimer for all sunscreen products with an SPF over 30: "[bullet] higher SPF products give more sun protection, but are not intended to extend the time spent in the sun."

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unlawful or misleading, and the court accordingly analyzed the restrictions under the remaining three prongs of the test articulated in Central Hudson.

The Ninth Circuit first determined that the government had not met its burden to demonstrate through convincing evidence rather than mere speculation or conjecture that one of its three asserted interests was substantial. 2000 WL 33153172, at *3. It proceeded to inquire whether the other two asserted goals were directly advanced by the regulatory scheme imposed under the statute. It found that the government had failed to demonstrate that the restrictions were necessary to prevent an increase in demand for compounded drugs that would be injurious to the public health: “[T]he government’s argument falls short of what is required to show that the speech restrictions will protect the public. The government has not offered evidence or even arguments to explain sufficiently why such restrictions will reduce the type of consumption of compounded drugs that is harmful.” Id.

In addition, the court found that the restrictions were more extensive than necessary to achieve the asserted governmental interest. Again, the court turned to disclaimers as a possible solution: “Disclaimers would satisfy the government’s substantial interest in preventing consumers from being misled into taking unsafe drugs.” Id. at *5.

The Ninth Circuit’s decision is yet another demonstration of the courts’ increased willingness to put a substantial burden on FDA when it seeks to restrict speech. The court demanded that the FDA support its claims with evidence, refused to accept speculation and conjecture just because it originated with the FDA and concerned public health and safety, and demanded that the FDA consider the less restrictive alternative of disclaimers. Similar constitutional analysis is applicable to the Sunscreen and OTC Labeling Rules.

Conclusion

Both of the cases described above reinforce the arguments made by CTFA in its September 6, 2000 comments on FDA’s sunscreen regulations, which prohibit speech that is truthful and not misleading. They also support the stance taken by CTFA with respect to the OTC Labeling Rule. Although FDA may claim that certain speech presents the potential for consumer confusion, it is exceedingly clear that the mere potential for confusion is insufficient to remove the speech at issue from the protection of the First Amendment. Where speech is not false or inherently misleading, it cannot be restricted unless the government demonstrates

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that the restriction directly advances a substantial governmental interest and is no more restrictive than necessary to serve that interest. FDA has not carried its burden with respect to the Sunscreen and OTC Labeling Rules.

Even if the courts recognize that the interests asserted by FDA are substantial government interests, they will be hard pressed to conclude that the FDA has demonstrated with compelling evidence that the Sunscreen and OTC Labeling Rule restrictions address real harms in a material way. Whether consumers are told that a product has an SPF rating at a specific level above 30, or that a product containing a sunscreen helps prevent skin aging, or that a cosmetic containing a sunscreen helps prevent freckling or uneven coloration--none of which the FDA has found to be false--it is difficult to see how the transmission of such information results in real harm or how the restrictions proposed by FDA alleviate any such harm in a material way. To the contrary, consumers will clearly benefit from the conveyance of such information. In addition, it appears unlikely that FDA could demonstrate--without even considering the efficacy of disclaimers--that the restrictions it has imposed are not more extensive than necessary to serve its interests.

CTFA urges the agency to reconsider the Sunscreen Rule in light of the cases discussed above and the First Amendment interests of companies in preserving their ability to include truthful labeling on such products. Further, to the extent that the OTC Labeling Rule restricts commercial speech of cosmetic-drug products, it must be reevaluated as well. FDA cannot ignore the mounting judicial intolerance of blanket restrictions by the agency on commercial speech.

Respectfully submitted,



John G. Roberts, Jr.

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