



Pamela G. Bailey
President & CEO

April 13, 2005

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

Re: OTC Antiperspirant Drug Products
Reopening of the Administrative Record
Docket No. 1978N-0064
69 Fed. Reg. 61148 (October 15, 2004)

The Cosmetic, Toiletry, and Fragrance Association (CTFA) submits these comments in response to FDA's request for data and information relating to duration claims for the effectiveness of OTC antiperspirant drug products, published in 69 Fed. Reg. 61148 (October 15, 2004).

CTFA is the national trade association representing the personal care product industry. It has an active membership of more than 300 companies that manufacture and distribute the vast majority of finished personal care products marketed in the United States, as well as a large number of OTC drug products that are both drugs and cosmetics. CTFA also represents approximately 300 associate member companies from related industries, including testing laboratories and manufacturers of raw materials, ingredients, packaging, and services used in the production and marketing of finished products. Since its inception, CTFA has strived to foster a fair and responsible marketplace for cosmetic products and has worked to support the industry's commitment to safe and effective personal care products for consumers.

Summary

The final monograph for OTC antiperspirant drug products set forth in 21 C.F.R. Part 350, as promulgated in 68 Fed. Reg. 34273 (June 9, 2003), should be revised to authorize any claim of the duration of effectiveness that is supported by testing conducted in accordance with the testing guidelines established by FDA under Section 350.60. There should be no limit on the length of any duration claim, as long as it is supported by such testing. The results of such testing should be required to be maintained in the company's files for inspection by FDA under Section 704(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and should not be required to be submitted to FDA. The failure to allow duration claims in accordance with these principles would constitute a violation of the right to commercial free speech under the First Amendment to the United States Constitution.

I. Background

In 68 Fed. Reg. 34273 (June 9, 2003), FDA promulgated a final monograph for OTC antiperspirant drug products. In that final monograph, FDA imposed an arbitrary 24-hour limitation on a claim of the duration of effectiveness, using the protocol specified in the monograph, regardless of whether a company could support a longer duration claim on the basis of testing using the same FDA-approved protocol. CTFA and Revlon, Inc. submitted timely petitions for reconsideration and stay of action with respect to this limitation, on the ground that it violated the Administrative Procedure Act and the First Amendment to the United States Constitution. In response, FDA published a notice in 69 Fed. Reg. 61148 (October 15, 2004) staying the limitation until further notice and reopening the Administrative Record to permit further comment and data on this matter.

II. The Failure to Permit Duration Claims of Effectiveness that Comply With the FDA-Approved Testing Protocol, Without Any Limitation on the Length of that Duration, Would Violate the First Amendment to the United States Constitution

Claims in OTC drug labeling are “commercial speech” protected by the First Amendment to the United States Constitution. As explained below, under conventional commercial speech doctrine, FDA may not draw a distinction between 24-hour and longer duration claims that have been documented using the FDA-approved test protocol and that are truthful and nonmisleading. For this reason, FDA must eliminate the temporal restriction on duration claims.

A. Applicable First Amendment Principles

Under conventional commercial speech doctrine, the government may not prohibit or restrict commercial speech unless it satisfies the test in Central Hudson Gas & Electric Corp. v. Public Service Commission.¹ Under this four part test, the government may prohibit commercial speech only if the speech is inherently false or misleading or proposes an unlawful transaction. Otherwise, it may regulate commercial speech only if it has a significant interest in doing so, the regulation in question directly furthers that interest, and there is no less restrictive form of regulation that will further that interest.

The Central Hudson test can be distilled into two principles. First, “only false, deceptive or misleading commercial speech may be banned.”² Second, commercial speech that

¹ 447 U.S. 557 (1980).

² Ibanez v. Florida Department of Business and Professional Regulation, 512 U.S. 136, 142 (1994) (citing Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio, 471 U.S. 626, 638 (1985)).

is not false, deceptive, or misleading may be restricted, but only if the government shows that there is a “reasonable fit” between its objectives and the degree of restriction that it uses to achieve its objectives.³

As to the first principle, FDA has the burden to establish that a claim is false or misleading, before it may ban that claim.⁴ As to the second principle, FDA has the burden “of identifying a substantial interest and justifying the challenged restriction.”⁵ FDA may not satisfy its burden with speculation. It must present proof that its feared harm is real and that the intended statement will indeed harm the public.⁶

Any restriction on speech must be “narrowly tailored.”⁷ The “cost” of the restriction -- that is, the burden it imposes on the speech -- must be “carefully calculated.”⁸ That cost/benefit assessment in turn requires that “the regulation not ‘burden substantially more speech than is necessary to further the government’s legitimate interests.’”⁹

The Supreme Court strongly reaffirmed these First Amendment principles in its recent Western States decision declaring FDA’s restriction on pharmacy advertising to be

³ Board of Trustees of State Univ. of New York v. Fox, 492 U.S. 469, 480 (1989).

⁴ Cf. Ibanez, 512 U.S. at 142.

⁵ Greater New Orleans Broadcasting, 527 U.S. at 174.

⁶ Ibanez, 512 U.S. at 143; Edenfield v. Fane, 507 U.S. 761, 770-771 (1993); Zauderer, 471 U.S. at 648-649.

⁷ Fox, 492 U.S. at 480.

⁸ Id. at 480.

⁹ Id. at 478.

unconstitutional.¹⁰ As the Court stated, “if the First Amendment means anything, it means that regulating speech must be a last -- not first -- resort.”¹¹

The members of CTFA that manufacture antiperspirants seek to make truthful and nonmisleading claims about how long their antiperspirant products are effective. These claims will be supported by data developed using FDA’s own testing protocol. Under Central Hudson and Western States, FDA may not categorically ban such claims. Rather, it must satisfy a heavy burden of justifying any restriction on the claims by showing that it has a significant interest in restricting such claims, that the regulation directly furthers that interest, and that there is no less restrictive means of furthering that interest. FDA has not done so in this case, and it cannot do so. It must therefore eliminate the 24-hour restriction on enhanced duration claims.

B. Unlimited Duration Claims That Are Supported By Testing Conducted In Accordance With the FDA-Approved Protocol Are Not False, Deceptive, or Misleading

CTFA wishes to emphasize that its members support only claims relating to the duration of effectiveness of OTC antiperspirant drug products that are fully supported by appropriate testing, using the protocol established by FDA under Section 350.60 of the Final Monograph. Such claims will be truthful and accurate, and not false, deceptive, or misleading in any way. Accordingly, as the Supreme Court has made clear, those claims of effectiveness -- whether for 24 hours, 48 hours, 72 hours, or some other duration -- are constitutionally protected under the First Amendment and may not be banned by FDA.

¹⁰ Thompson v. Western States Medical Center, 535 U.S. 357 (2002).

¹¹ Id. at 373.

C. The Limitations That FDA Has Considered for Duration Claims Do Not Demonstrate a “Reasonable Fit” Between the Legitimate Government Objectives and the Degree of Restriction That Would Be Imposed

1. As Long As Any Duration Claim is Supported By Test Data Using the FDA-Approved Protocol, No Other Restrictions Can Be Justified Under the First Amendment

FDA appears to be taking the position that, unless at least one test result has been submitted to the agency demonstrating a duration claim using the FDA-approved protocol at every point in time, no duration claim will be permitted for any point other than 24 hours. On its face, this is a flagrant violation of First Amendment principles.

FDA unquestionably has a legitimate role in determining that only duration claims that are fully supported by testing conducted in accordance with the FDA-approved protocol for duration claims may be made. Enforcement of this legitimate objective, however, does not require that products be formulated, and testing be conducted, to support 48-hour, or 72-hour, or other duration claims prior to the conclusion of this rulemaking and submitted to FDA. There is no “reasonable fit” between requiring that this formulation and testing be conducted and submitted to FDA prior to the conclusion of this rulemaking as contrasted with subsequent to the conclusion of this rulemaking. The sole legitimate governmental interest is in assuring that appropriate testing is, in fact, conducted before any duration claim is made.

Nor can any requirement for a prior submission to FDA of individual product duration testing results, before a new claim can be made, be justified under the First Amendment. Such a prior submission requirement represents an unlawful prior restraint that does not bear a “reasonable fit” with the legitimate government interest of assuring that duration claims are properly made. This point is, indeed, implicitly conceded by the terms of the Final Monograph

that pertain to 24-hour duration claims. A manufacturer may formulate a new product, conduct testing under the FDA-approved protocol, and immediately go on the market with a 24-hour duration claim without any requirement of informing FDA or submitting the test results to FDA. If FDA wishes to determine that the testing has in fact been done, and that the results support the claim, it may easily do so by an inspection of the company records in accordance with Section 704(a)(1) of the FD&C Act. This is, of course, the least restrictive form of governmental regulation -- the standard by which the Supreme Court judges the constitutionality of such regulatory requirements under First Amendment jurisprudence.

If FDA concludes -- as it unequivocally has -- that this form of "least restrictive" regulation is appropriate for a 24-hour claim, there is no basis for the agency to argue that a 48-hour or 72-hour or any other length of duration claim should be subject to greater restriction. By imposing greater restriction on other duration claims, FDA directly violates fundamental First Amendment principles.

2. Imposing Additional Restrictions on Duration Claims Longer Than 24 Hours Would Also Be Inconsistent With the FDA Determination That Such Restrictions Are Not Necessary for Regulation of Other OTC Drugs

FDA has on several occasions included in final and tentative final monographs testing requirements without a requirement that the test results be submitted to FDA. In fact, in none of these monographs has FDA required submission of supporting data to the agency. The supporting data required to justify making the claim, or even marketing the product, are retained in the manufacturer's files. Under Section 704(a)(1) of the FD& Act, FDA has the authority to inspect these records in order to verify that the claims are truthful and not misleading. The

following OTC drug monographs and tentative final monographs contain performance testing standards with no requirement for submission of the resulting test data to FDA.

Final Monographs

1. Antacid Drug Products. Section 331.20 requires testing to determine the percent contribution of each active ingredient, calculated according to a formula set forth in the monograph.
2. Anticaries Drug Products. Section 355.70 provides that a fluoride dentifrice product must meet biological test requirements for animal carries reduction and either an enamel solubility reduction test or a fluoride enamel uptake test.
3. Sunscreen Drug Products. Subpart D of Part 352 sets forth testing procedures to determine the SPF value of the product and to determine the water resistance of the product.

Tentative Final Monographs

4. Topical Health-Care Antiseptic Drug Products. Section 333.470 proposes to require testing to demonstrate that the active ingredients provide in vitro activity against specified microorganisms and that the finished products demonstrate both in vitro and in vivo activity against specified microorganisms.¹²
5. Internal Analgesic Drug Products. Section 343.90 proposes to require dissolution testing requirements for final analgesic drug products.¹³
6. Oral Antiseptic Drug Products. Section 356.90 proposes to require final product testing demonstrating in vitro reduction of specified bacteria.¹⁴

We reiterate that in none of the above instances has FDA found it necessary or appropriate to require the submission of data to the agency to justify the use of the claims involved. In each instance, it has been sufficient that the manufacturer of the drug product has in fact conducted

¹² 59 Fed. Reg. 31402, 31444-31452 (June 17, 1994).

¹³ 53 Fed. Reg. 46204, 46260 (November 16, 1988).

¹⁴ 59 Fed. Reg. 6084, 6122-6124 (February 9, 1994).

the required testing in accordance with the FDA-specified protocol and has achieved the required results. FDA is then free to examine those results at any time, if it wishes to do so.

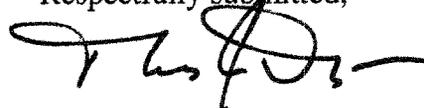
These six examples, in addition to the example of the OTC Antiperspirant Drug Final Monograph provisions relating to a 24-hour claim, demonstrate that there is no regulatory justification for prior submission of data to FDA to support monograph OTC drug claims in general and effectiveness duration claims in particular. A requirement of prior submission of data for antiperspirant effectiveness duration claims greater than 24 hours, where FDA has determined that no such requirement is justified in all of these comparable situations, unequivocally demonstrates that, as the Supreme Court has said, there is no "reasonable fit" between the requirement and the legitimate government objective. Any restriction on commercial speech must be "narrowly tailored" and "carefully calculated" in order not to "burden substantially more speech than is necessary to further the government's legitimate interest." As the Supreme Court admonished FDA in the recent Western States decision, "if the First Amendment means anything, it means that regulating speech must be a last -- not first-- resort." Because FDA itself has demonstrated that there is a less restrictive means of furthering its interest in assuring that antiperspirant duration claims are supported by adequate testing, the limitations that are being considered by FDA in this proceeding on effectiveness duration claims for OTC antiperspirant drugs should be abandoned.

Lastly, products demonstrating enhanced duration greater than 24 hours should not be required to have specific direction statements about how frequently to apply the product. The directions in section 350.50(d), "apply to underarms only" are sufficient.

III. Conclusion

For the reasons set forth above, CTFA requests that FDA revise the Final Monograph on OTC antiperspirant drug products to delete the limitation on effectiveness duration claims so that any duration claim may be made if it is supported by testing conducted in accordance with the FDA-approved protocol under Section 350.60.

Respectfully submitted,



Thomas J. Donegan
Vice President – Legal & General Counsel

cc: Charles J. Ganley, M.D. (HFD-560)
Susan S. Johnson (HFD-20)
Gerald M. Rachanow (HFD-560)
Gerald F. Masoudi (GCF-1)