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THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

July 8, 2003

Dockets Management Branch (HFA-305)
 Food and Drug Administration
 Room 1061
 5630 Fishers Lane
 Rockville, Maryland 20857

E. EDWARD KAVANAUGH
 PRESIDENT

Re: Petition for Reconsideration and Stay of Action;
 Final Monograph on Antiperspirant Drug Products for
Over-the-Counter Human Use: Docket No. 78N-0064

Dear Sir or Madam:

This Petition is submitted by The Cosmetic, Toiletry, and Fragrance Association (hereafter "CTFA") in accordance with 21 C.F.R. Sections 10.33(b) and 10.35(b). We are asking for reconsideration and a stay of two provisions of the Final Monograph for Antiperspirant Drug Products for Over-the-Counter Human Use 68 Fed. Reg. 34273 (June 9, 2003). Those provisions are: (1) the 24-hour limitation on a duration claim for antiperspirants; and (2) the requirement that the following warning appear on the label of antiperspirant products in aerosolized dosage form: "When using this product [bullet] keep away from face and mouth to avoid breathing it."

A. Decision Involved

The decision making-process on this Monograph has spanned more than 25 years. Significant actions by the Agency have included publication of an Advance Notice of Proposed Rulemaking on October 10, 1978 (43 Fed. Reg. 46694), publication of a Tentative Final Monograph on August 20, 1982 (47 Fed. Reg. 36492), and publication of this Final Monograph on June 9, 2003 (68 Fed. Reg. 34273). We are filing this petition because of the following concerns about FDA action in the Final Monograph.

1. Duration Claims

The Final Monograph fails to allow "enhanced duration claims" for antiperspirants that claim more than 24-hour efficacy, even where such claims are substantiated by tests conducted in accordance with the FDA protocol approved in the Monograph. Not only does the Agency fail to justify this action in light of previous

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comments contending that such claims be allowed, but we also believe failure to allow these claims violates First Amendment Protections for truthful claims.

2. Warnings

The final monograph requires the following two warnings for products in an aerosolized dosage form.

21 C.F.R. Section 350.50(c)(4)(i) requires the following warning:

“When using this product [bullet] keep away from face and mouth to avoid breathing it.”

21 C.F.R. Section 350.50(c)(4)(ii) requires the additional warning “required by 21 C.F.R. Section 369.21 for drugs in dispensers pressurized by gaseous propellants.”

“Warning – Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.¹

Although the first of these two warnings appears directed at normal use and the second is directed at intentional misuse, the common theme – avoiding inhalation – is redundant and FDA has failed to justify the need for the new, lengthy warning in Section 350.50(c)(4)(i).

B. Action Requested

Petitioner requests the Commissioner to reconsider and eliminate the limitation on duration claims to 24-hours in 21 C.F.R. 350.50(b)(3) and (b)(5). In addition, Petitioner requests the Commissioner to reconsider and eliminate the requirement for the warning specified in Section 350.50(c)(4)(i), or in the alternative shorten or consolidate the two inhalation warnings as discussed below. We request that the effect of both provisions be stayed pending a decision on this matter.

¹ Section 369.21 also independently requires the statement “Warning – Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120° F. Keep out of reach of children.”

C. Statement of Grounds

1. Duration Claims

a. Administrative Procedure Act

CTFA believes the Agency has failed to meet the requirements of the Administrative Procedure Act that are intended to ensure full and meaningful public participation and Agency consideration of all the issues and evidence before a decision is made.

FDA's regulations implementing the Act require that a proposed regulation contain the terms or substance of the proposal or a description of the subjects and issues involved, and that a final regulation have a preamble that provides supplementary information about the regulation, summarizes each type of comment submitted in response to the proposal, and presents the Commissioner's conclusions with respect to each. 21 C.F.R. 10.40 (b)(1)(viii), 10.40 (c)(3). The preamble to a final regulation must "contain a thorough and comprehensive explanation of the reasons for the Commissioner's decision on each issue." 21 C.F.R. 40(c)(3)

In considering duration claims for antiperspirants, the Advisory Panel did not distinguish between 24-hour duration claims and claims of longer protection. The Panel stated that a claim for a "specific or prolonged duration of activity...must be substantiated by a modification of the protocol described above for the measurement of effectiveness." 43 Fed. Reg. at 46728 (October 10, 1978)

The FDA Tentative Final Monograph failed to address this issue. In response, a comment filed by a manufacturer stated:

"...if an antiperspirant product can be shown to provide the required 20% reduction in perspiration under hot room conditions 24, 48, etc. hours after application then the desired duration claims have indeed been substantiated and there is no need for FDA pre-clearance since the Agency has already established that such a reduction in perspiration is evidence of antiperspirant efficacy."²

FDA noted this comment in its review of the record and determined that a claim of 24-hour duration could be made if an "...antiperspirant product must reduce sweat production by at least 20 percent over a 24-hour period after application using the guidelines for effectiveness testing referred to in Section 350.60."

² Comment of the Procter & Gamble Company, October 19, 1982

However, the Agency then summarily dismissed duration claims of longer than 24 hours as “nonmonograph because the agency has not received any data to demonstrate antiperspirant effectiveness for more than 24 hours according to the Panel’s criteria.” 68 Fed. Reg. at 34278

We believe this is an arbitrary decision that fails to recognize the record in this rulemaking proceeding. The Agency acknowledges the Panel’s review of the issue and specification of the protocol for substantiating a duration claim without specifying any limit on the length of that claim; acknowledges a comment arguing for a duration claim longer than 24 hours; acknowledges that empirical data complying with the protocol is necessary and permissible to substantiate a 24-hour duration claim according to the Panel’s protocol; but then summarily closes the door on the possibility that a duration claim of longer than 24-hours could be substantiated by the same method.

The result of FDA’s decision is that a manufacturer could establish the basis for a duration claim of longer than 24 hours using the FDA-approved protocol and this claim would still be prohibited by the Final Monograph. However, at no time does FDA argue or attempt to justify that the protocol is only applicable to 24-hour claims.

We therefore believe that FDA has not met the requirements of the Administrative Procedure Act. A key issue – duration claims – was considered by the Panel and addressed in the Advance Notice of Proposed Rulemaking without any attempt to suggest any fixed limit on the duration of such claims; the issue was not addressed in the proposed rule; the validity of duration claims of 24-hours and more was raised in comments on the proposed rule; but then FDA has arbitrarily and without adequate explanation limited such claims to 24-hours in the final rule.

b. First Amendment

We also believe that FDA’s action in prohibiting duration claims in excess of 24-hours violates the First Amendment protections for commercial speech. As described above, the Agency has failed to adequately justify the drastic step of completely prohibiting a duration claim over 24 hours, despite a rulemaking record that establishes a protocol for substantiating duration claims without limitation on their length.

A long line of decisions culminating with the U. S Supreme Court decision in Thompson v. Western States Medical Center, 535 U.S. 357 (2002) have clearly established that the government has a heavy burden to justify any ban on truthful

speech.³ As the Court stated, “if the First Amendment means anything, it means that regulating speech must be a last – not first – resort.” *Id.* at 373.

This rulemaking record clearly establishes that duration claims are capable of being substantiated by a testing procedure reviewed and approved by FDA. That test was not limited to 24-hour claims. The Advisory Panel envisioned that such tests could be performed and could validate such a claim. FDA has done nothing to refute such an assertion. The Agency cannot and should not arbitrarily limit such claims to 24 hours.

Even if there were a basis for questioning such claims in the face of a properly conducted test substantiating them according to the FDA-approved protocol, Western States makes clear that FDA has the burden of demonstrating that there is no less restrictive means that the prohibition of truthful speech to further FDA’s interests of regulating these claims. FDA has made no effort to make such a showing. Under such a circumstance, FDA cannot categorically ban duration claims over 24 hours.

2. Warnings

Petitioner also urges the Agency to reconsider and eliminate the inhalation warning required in Section 350.50(c)(4)(i). FDA also has failed to meet its burden under the Administrative Procedure Act with respect to this requirement which differs substantially from the warning proposed in the Tentative Final Monograph. The basis for changing the required language of the warning has not been adequately explained.

The inhalation warning proposed in the Tentative Final Monograph was:

“avoid excessive inhalation.”⁴

Without justification or further comment, the inhalation warning required by the Final Monograph was changed to:

“When using this product (bullet) keep away from face and mouth to avoid breathing it.”

While we recognize that part of this change in language between 1982 and 2003 is to comport with the OTC Drug Labeling Regulation⁵, that fact does not explain

³ See also Central Hudson Gas & Electric Corp v. Public Service Commission, 447 U.S. 557 (1980)

⁴ 47 Fed. Reg. at 36504.

⁵ The application of the OTC Drug Labeling Regulation to antiperspirants is the subject of a Citizen Petition by CTFA dated April 11, 2002 and still pending before the Agency. CTFA seeks relief in the form of reduced labeling for these products.

the change in warning language nor does it relieve FDA of its burden to justify such changes or give the public adequate time to comment on such changes.

The change in the Section 350.50(c)(4)(i) becomes even more questionable when viewed in light of the requirement for the intentional inhalation warning requirement of Section 369.21 as imported into the Final Monograph and thus into the "Drug Facts" label through Section 350.50(c)(4)(ii). This requires the following warning:

"Warning – use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

The relationship of these two warnings and possible consumer confusion resulting from the obvious redundancy and overlap apparently was never considered by FDA, nor was there an opportunity for public comment on this issue with respect to the new wording of Section 350.50(c)(4)(i) added in the Final Monograph for the first time.

Space is scarce on the OTC drug label, especially for products such as antiperspirants which tend to be used in smaller sizes. If OTC Labeling in the "Drug Facts" format is required for some antiperspirants, a requirement that we do not believe to be appropriate or necessary, it is all the more important that redundant language be removed from all parts of the label, including the required warnings.

Whether or not the "Drug Facts" format is required, brevity and clarity are particularly important in enabling consumers to understand warnings – one of the most important parts of the drug label. Therefore, we urge FDA to reconsider the warning requirement of Section 350.50(c)(4)(i).

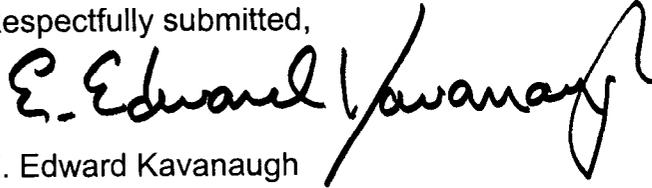
We question whether any additional inhalation warning is necessary in light of the warnings required by Section 369.21. However, if the agency believes additional language is required, we believe that greater brevity and clarity can be obtained by reinstating the language of the TFM – "avoid excessive inhalation" – and allowing this to be combined with the Section 369.21 warning in situations where that warning is required.

D. Conclusion

Petitioner requests the Commissioner to reconsider and revoke the Agency's decision in 21 C.F.R. Section 350.50(b)(3) and (b)(5) to limit duration claims for antiperspirants to 24-hours, and to reconsider and revoke the Agency's decision to require the inhalation warning contained in 21 C.F.R. Section 350.50(c)(4)(i). While this decision is pending, the Commissioner is requested to stay the effective date of December 9, 2004 for these provisions.

The Petitioner would be pleased to provide further information or clarification as needed.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "E. Edward Kavanaugh". The signature is written in a cursive style with a large, sweeping flourish at the end.

E. Edward Kavanaugh
President

cc: Charles J. Ganley, M.D. (HFD-560)
Gerald M. Rachanow, Esq. (HFD-560)
Daniel E. Troy, Esq. (GCF-1)