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

Re: Petition for Reconsideration and Stay of Action
Final Monograph for OTC Antiperspirant Drugs
68 Fed. Reg. 34273 (June 9, 2003)
Docket No. 78N-0064

Revlon, Inc., submits this petition in accordance with 21 C.F.R. 10.33(b) and 10.35(b) for reconsideration and stay of the 24-hour limitation on a duration claim in the Final Monograph on Antiperspirant Drug Products for Over-the-Counter Human Use.

A. Decision Involved

Based on an Advisory Committee Report, FDA published an advance notice of proposed rulemaking to establish a Monograph for over-the-counter (OTC) antiperspirant drug products in 43 Fed. Reg. 46694 (October 10, 1978). The Tentative Final Monograph was published as a proposed regulation in 47 Fed. Reg. 36492 (August 20, 1982). FDA published the final regulation in the form of a Final Monograph in 68 Fed. Reg. 34273 (June 9, 2003). The effective date for the Final Monograph is December 9, 2004.

This petition is directed at the failure of the Final Monograph to provide for antiperspirant "enhanced duration" claims that are longer than 24 hours. The 24-hour

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duration limitation is contained in 21 C.F.R. 350.50(b)(3) and (b)(5). In brief, FDA developed a testing protocol for duration claims. If a test in conformance with that FDA-approved protocol demonstrates that a company's product is effective for 24 hours, the company may make a 24-hour enhanced duration claim. The Final Monograph does not permit a company to make a truthful enhanced duration claim of more than 24 hours even if such a claim is fully supported by testing in conformance with the FDA-approved protocol.

B. Action Requested

Petitioner asks the Commissioner to reconsider and to revoke the 24-hour duration limitation in 21 C.F.R. 350.50(b)(3) and (b)(5). Petitioner also requests that the limitation on duration claims be stayed during this reconsideration.

C. Statement of Grounds

There are two bases upon which Petitioner challenges the limitation on duration claims. First, the limitation on duration claims violates the requirements of the Administrative Procedure Act (APA). Second, the limitation on duration claims violates Petitioner's First Amendment right to make truthful and nonmisleading claims about its product.

1. Administrative Procedure Requirements

The APA requires that a proposed regulation be published for comment, that the preamble to the final regulation contain a concise general statement of the basis and purpose of the regulation, and that the regulation not be arbitrary, capricious, or an abuse of

discretion. 5 U.S.C. 553, 706. In implementing these requirements, FDA's administrative procedure regulations in 21 C.F.R. part 10 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).

The Advisory Panel Report referred to the potential for duration claims without suggesting any limitations.[1] The FDA Tentative Final Monograph did not discuss this matter. In a written comment dated October 19, 1982, in response to the Tentative Final Monograph, the Procter & Gamble Company requested that:

> ". . . 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 preclearance since the Agency has already

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[1] The advance notice of proposed rulemaking published in 43 Fed. Reg. 46694 (October 10, 1978) noted that the Advisory Panel recommended that duration claims be classified as Category III. The Panel stated that "If a claim for a specific or prolonged duration of activity is to be made for an antiperspirant formulation it must be substantiated by a modification of the protocol described above for the measurement of effectiveness." Id. at 46728. The Panel went on to describe the modifications that would be required. The Panel drew no distinction between a 24-hour duration claim and longer claims.

> established that such a reduction in perspiration is evidence of antiperspirant efficacy."

FDA quoted from this comment in the preamble to the Final Monograph (68 Fed. Reg. at 34277) but addressed only half of the comment in its response. FDA agreed to a 24-hour claim but, without further discussion, dismissed claims of longer duration stating only that they are "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.

FDA's response to the comment by Procter & Gamble is not the "thorough and comprehensive" response required by its regulations, nor is it the "concise general statement of [the regulation's] basis and purpose" required by the APA, 5 U.S.C. 553(c). Indeed, it is not a substantive response to the comment at all.[2]

The approach adopted by FDA in the Final Monograph permits a manufacturer to make a 24-hour enhanced duration claim based upon its testing using the FDA-approved protocol and without submitting any data to FDA. But it prohibits, as "nonmonograph," a longer enhanced duration claim based upon its testing using the same FDA-approved protocol. Thus, without discussion or justification of any kind, the Final Monograph permits a duration claim based on the test results obtained from the FDA-

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[2] Cf. United States v. Nova Scotia Food Products Corp., 568 F.2d 240, 252 (2d Cir. 1977) ("It is not in keeping with the rational process to leave vital questions, raised by comments which are of cogent materiality, completely unanswered.").

approved protocol only up to 24 hours even if a company proves -- using the identical protocol -- that its product is effective for longer than 24 hours. This approach violates the APA and FDA regulations in three respects.

First, although the Advisory Panel recognized in its Report the potential for duration claims and placed no time limit on them, FDA did not address this issue in the Tentative Final Monograph and thus failed to provide notice that the agency might prohibit duration claims longer than 24 hours. In the intervening 21 years, product technology has advanced. Longer duration claims -- using the FDA-approved protocol -- can now be shown. By not identifying this issue in the Tentative Final Monograph and not requesting public comment on this matter, and relying on a stale record that is now a full two decades old, FDA has denied Petitioner the right to submit pertinent data and information for consideration in this rulemaking proceeding.[3]

Second, the preamble to the Monograph gives no justification for rejecting duration claims of longer than 24 hours that have been supported by testing in compliance with the FDA-approved protocol. FDA has failed to discuss why appropriate testing, using the FDA-approved protocol, is adequate for 24-hour claims but not 48-hour or other duration claims. The Procter and Gamble comment explicitly identified this issue and FDA did not respond. At no time in this rulemaking proceeding did FDA request data or

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[3] Cf. Chocolate Manufacturers Association of the United States v. Block, 755 F.2d 1098 (4th Cir. 1985).

information on 24-hour, 48-hour, or any other duration testing, and thus the FDA comment that the results of such testing for longer duration claims were not submitted to the agency is not an appropriate justification.

Third, the preamble to the Final Monograph does not attempt to argue that the FDA-approved protocol is applicable only to 24-hour tests and not to other duration testing. The Advisory Panel made no such distinction. The protocol is clearly applicable to all duration testing. Accordingly, there is no scientific basis for this arbitrary distinction.

For these reasons, the limitation on duration claims to 24 hours violates the APA, 5 U.S.C. 553, 706, and must be revoked.

2. First Amendment

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 enhanced 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 enhanced duration claims.

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.[4] 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 means of furthering that interest.

The Central Hudson test can be distilled into two principles. First, "only false, deceptive or misleading commercial speech may be banned."[5] Second, commercial speech that 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.[6]

As to the first principle, FDA has the burden to establish that a claim is false or misleading, before it may ban that claim.[7] As to second principle, FDA has the burden "of identifying a substantial interest and justifying the challenged restriction."[8] FDA may

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4 447 U.S. 557 (1980).

5 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)).

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

7 Cf. Ibanez, 512 U.S. at 142.

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

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.[9]

Any restriction on speech must be "narrowly tailored."[10] The "cost" of the restriction -- that is, the burden it imposes on the speech -- must be "carefully calculated."[11] 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.'"[12]

The Supreme Court strongly reaffirmed these First Amendment principles in last year's Western States decision.[13] As the Court stated, "if the First Amendment means anything, it means that regulating speech must be a last -- not first -- resort."[14]

Petitioner seeks to make truthful and nonmisleading claims about how long its 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

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

10 Fox, 492 U.S. at 480.

11 Id. at 480.

12 Id. at 478.

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

14 Id. at 373.

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.

D. Conclusion

For the reasons set forth above, Petitioner requests that FDA reconsider the limitations on a duration claim in the Final Monograph on OTC antiperspirant drug products. In the interim, Revlon asks that FDA stay the limitation portions of the regulations, 21 C.F.R. 350.50(b)(3) and 350.50(b)(5), so that a manufacturer may make duration claims of more than 24 hours if the claim is validated using the FDA-approved test protocol.

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