Procter&Gamble

Cosmetic and Fragrance Products

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

Re: Final Monograph for Sunscreen Drug Products for OTC Human Use; Docket No. 78N-0038; OTC Drug Labeling Requirements for Sunscreens

Dear Sir or Madam:

These comments are filed by The Procter & Gamble Company ("P&G") in response to the Petition for Stay of Agency Action filed by Morgan, Lewis & Bockius LLP on November 10, 2000 and supplemented on January 5, 2000, for Playtex Products, Inc. (the "Playtex Petition"). The Playtex Petition has been submitted as part of the Food and Drug Administration's ("FDA's") rulemaking in the above-referenced docket on the over-the-counter ("OTC") monograph for sunscreen products. Specifically, the Playtex Petition addresses the appropriate labeling of OTC sunscreens in conjunction with FDA's OTC Labeling Content and Format Rule (the "OTC Drug Labeling Regulation"), which is applicable to all OTC drugs, including sunscreens, pursuant to 21 C.F.R. sec. 201.66. For the reasons set forth in detail below, P&G objects to, and strongly disagrees with, certain of the claims and positions set forth in the Playtex Petition. P&G respectfully urges FDA to reject the claims made in the Playtex Petition in light of the full record on this matter and requests that the agency grant certain labeling modifications for specified types of sunscreen products consistent with this rulemaking and FDA's legal authority. P&G believes that the record on sunscreen labeling fully supports its request.

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P&G is a large, multi-national company that markets over 300 products to more than five billion consumers in 140 countries. Among the product categories marketed by P&G are skin care products such as lipsticks, hand and face moisturizers, foundations and other beauty regimen products that contain sunscreen ingredients and are regulated by FDA as both cosmetics and OTC drugs (hereinafter referred to as cosmetic-drugs or cosmetic-sunscreens). These products, purchased by consumers through a self-selection process, are mass marketed by P&G through large retail outlets, including drug and grocery stores. Cosmetic-sunscreens are an important part of P&G's health and beauty care business and the company has a vital interest in how they are labeled and thus, in the sunscreen labeling issues currently under consideration by FDA. Such products are lawfully marketed as both cosmetics and OTC drugs. FDA has full legal authority to balance the labeling requirements of both legal categories in a manner that fully conveys both the cosmetic benefit of these products (which is the principal reason why consumers purchase these products) as well as the OTC drug benefits in a way that ensures safe, appropriate use. P&G believes that the appropriate resolution of these issues is critical to its U.S. consumer's well-being and to their continued confidence in the beauty regimen effects associated with cosmetic-sunscreen products. The presence of sunscreens in the traditional easy-to-carry make-up and moisturizing products, provides continued availability to sun protection to those areas of the body not typically covered by clothing. In a society where time is a precious commodity, women want the convenience of both make-up/moisturization and sunscreen protection in one easy step.

BACKGROUND

P&G is a member of the Cosmetic, Toiletry, and Fragrance Association ("CTFA" or "the Association") and has actively participated in the Association's development of proposed labeling for cosmetic-sunscreens. Throughout the long history of the sunscreen monograph development process P&G is not aware that CTFA, on behalf of P&G and its other members, has ever requested or suggested

that FDA exempt cosmetic-drug products containing sunscreens from regulation as drugs. Rather, CTFA has always focused on the need for flexibility in the labeling of such products based on the dual nature of the benefits (cosmetic and therapeutic) for which they are relied upon by consumers. Currently, CTFA is requesting that FDA revise the final sunscreen monograph to incorporate changes to certain requirements of the OTC Labeling Content and Format Rule ("OTC Drug Labeling Regulation") applicable to cosmetic-sunscreens under 21 C.F.R. § 201.66. See CTFA comments of August 4, 2000 and January 5, 2001 submitted to Docket No. 78N-0038.[1] It is critical to understand that, if FDA accepts these suggestions, these products will lawfully remain labeled as OTC drugs (as well as cosmetics).

The modifications proposed by CTFA preserve the essential nature of FDA's OTC Drug Labeling Regulation. Thus, P&G objects to Playtex's constant reference to CTFA's request for modified labeling as one that would exempt cosmetic-sunscreens from FDA's drug and sunscreen labeling requirements. P&G also disagrees with the suggestion from Playtex that CTFA's request for modified labeling is not representative of the sunscreen industry's views on this issue.

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[1] Like CTFA, P&G is not requesting that FDA make any changes to the sunscreen labeling regulations already promulgated by FDA for products marketed as lipsticks or labeled for use on specific small areas of the face as set forth in 21 C.F.R. § 352.52.

DISCUSSION

1. Contrary to the Claims of Playtex, the Requested Labeling Modifications Preserve All of the Essential Information Required for the Safe and Effective Use of Sunscreens.

A. CTFA's Proposed Labeling for Cosmetic-Sunscreens

P&G is concerned that the Playtex Petition seriously misstates the sunscreen labeling proposal put forth by CTFA. The labeling modifications requested by CTFA for cosmetic-sunscreens, including sunscreens formulated as make-ups and as hand and face moisturizers, do not in any manner represent a radical departure from the currently required labeling established under FDA's final sunscreen monograph. The modifications represented by CTFA's proposed labeling for such products are limited to:

- Omitting the "Drug Facts" title;
- Omitting the separate "Purpose" heading;
- Omitting the "higher SPF gives more sunburn protection" statement (except for products with an SPF over 30);
- Omitting the "For external use only" statement;
- Eliminating certain format lines, and box enclosure; and
- Condensing the subheadings for certain Warnings into single statements (e.g., "Stop use and ask a doctor if rash or irritation develops and lasts" to "Stop use if skin rash occurs"); and
- Allowing for the off-label listing of inactive ingredients.

Each of these proposed modifications is addressed in detail in comments submitted to the sunscreen docket by CTFA on August 4, 2000 and January 5, 2001 and are incorporated herein by reference.

When compared against the labeling currently required under the final sunscreen monograph, it becomes clear that the modifications proposed by CTFA do not change the essential content or format of required information for such OTC drug products. Indeed, the modified labeling provides consumers with all of the

information required to ensure that they can use the applicable products safely and effectively.

B. The Directions For Use Do Not Change Under CTFA's Proposal

The Directions for Use under the labeling proposed by CTFA for cosmetic-sunscreens are exactly the same as those currently required under the final OTC sunscreen monograph. Thus, P&G regards the claim by Playtex that consumers will be confused regarding the proper use of cosmetic-sunscreens labeled according to CTFA's proposal to be totally unfounded. P&G believes, as evidenced by FDA's modified labeling for sunscreen products used on small areas of the face and formulated as lipsticks in the final sunscreen monograph (21 C.F.R. § 352.52(f)(1)), that it is entirely possible to effectively present all of the essential information required for the safe and effective use of cosmetic-sunscreens in a modified form.

C. There Is No Danger Of Consumers Misusing Cosmetic-Sunscreens

Thanks, in part, to efforts by public health authorities, consumers over the past several decades have become more educated about the dangers of sun exposure. P&G believes that two types of sun exposure are well-understood by consumers: that which occurs under extreme and prolonged sun conditions associated with specific outdoor activities; and that resulting from the brief, but more chronic daily activities that take consumers outdoors. It is the adverse health and beauty effects associated with chronic exposure that cosmetic-sunscreens are designed to protect against.

Despite claims to the contrary in the Playtex Petition, P&G is not aware, nor do we believe any evidence exists that consumers use cosmetic-drug products such as colored make-ups or moisturizers labeled for hand and face use as their primary or sole forms of sun protection. Rather, P&G's experience in this

segment of the sunscreen industry reveals that the marketing for these types of products has long focused on their supplemental role in a full beauty regimen. Thus, for example, the addition of sunscreen ingredients to these types of cosmetic-drug products are perceived by consumers as offering a relatively effortless method for achieving protection from incidental sun exposure on a daily basis. While consumers may purchase these products primarily for their cosmetic benefits, they have come to rely on the ability of such products to provide incidental sun protection as part of an overall program designed to avoid both the adverse health and beauty effects of sun exposure.

P&G strongly supports CTFA's position that the requested modifications reflected in the Association's proposed labeling will not result in consumer confusion about the safe and effective use of cosmetic-sunscreens.

2. ***Contrary To The Concerns of Playtex, The Requested Modifications Will Not Adversely Affect Consumer Health.***

Among the claims made in the Playtex Petition are that by allowing cosmetic-sunscreens to use the modified labeling proposed by CTFA, consumers will perceive and use these products like cosmetics. The health ramifications, according to Playtex, will be serious—with increased incidences of sunburn, melanoma and other face, hand and neck skin injuries. P&G does not believe that Playtex raises legitimate public health concerns. First, as noted above, the labeling proposed by CTFA requests certain content and format modifications but in no manner, as implied by the Playtex Petition, seeks a wholesale abandonment of FDA's current sunscreen labeling requirements. Thus, P&G finds it difficult to conceive that the requested modifications will result in the significantly altered perception of cosmetic-sunscreens and resulting adverse health consequences predicted by Playtex.

Second, P&G does not believe that the segment of the sunscreen industry responsible for marketing cosmetic-sunscreens has any intention of

misdirecting consumers in their use of such products. P&G does not believe any widespread effort exists to try to position cosmetic-sunscreens as replacements for products that provide full body sunscreen protection necessary for intense sun conditions. Beauty regimen products such as make-up foundations, face moisturizers and hand moisturizers typically are not available in package sizes that would facilitate such use and are not labeled to promote such use.

Finally, cosmetic-sunscreens have a significant marketing history. P&G is not aware that FDA or any other public health entity has expressed any concern that consumers do not properly use and understand the limits of cosmetic-sunscreens. Rather, increased use of cosmetic-sunscreens has been praised as an appropriate extension of sun protection by consumers who clearly understand the nature and proper use of such products. P&G fully supports CTFA's position that including sunscreen ingredients in make-up and hand and face moisturizers is an easy and extremely beneficial method of providing consumers with additional sun protection methods.

3. *A Decision By FDA to Grant CTFA's Request for Modified Labeling for Certain Sunscreen Products Would Not Violate the Administrative Procedure Act.*

Granting the labeling modifications requested by CTFA, and supported by P&G for sunscreens labeled as make ups and for use on the hands and face would not be arbitrary and capricious agency action under the Administrative Procedure Act ("APA"). 5 U.S.C. § 501 et. seq. As it has already done for lipsticks containing sunscreen and for products labeled for use on small areas of the face (21 C.F.R. § 352.52), FDA is fully within its authority to provide different labeling options that distinguish between categories of sunscreen products based on the nature of the products and how they are used by consumers. Indeed, P&G believes that sufficient basis exists under the current record, consistent with its rulemaking procedures, for FDA to propose modifications for the labeling of certain types of

cosmetic-sunscreens. Nothing in the principal case relied upon in the Playtex Petition, Bracco Diagnostics, Inc. v. Shalala, 963 F.Supp. 20 (D.D.C. 1997), dictates otherwise. In contrast to Bracco, the record in these circumstances provides ample basis for distinguishing between different categories of similar products.

Under the Federal Food, Drug, and Cosmetic Act, a drug will be deemed misbranded if, among other things, its labeling is false or misleading in any particular or, fails to bear adequate directions for use and adequate warnings against use. 21 U.S.C. §§ 352 (a) and (f). FDA's regulations reiterate these provisions specifically for OTC drugs. 21 C.F.R. § 330.10(a)(4)(v). FDA's interpretation of whether these requirements are satisfied for particular products is within its discretionary authority. The arbitrary and capricious standard of the APA is a narrow one that requires a finding that the agency has acted in a plainly erroneous fashion or inconsistently with the language of its regulations. See e.g., Zeneca v. Shalala, 213 F.3d 161 (4th Cir. 2000).

The long and detailed history of comments submitted to the public docket by CTFA more than adequately support the Association's proposed labeling and P&G's support for that modified labeling for certain cosmetic-sunscreens. For example, P&G agrees with CTFA that omitting the "Drug Facts" title from cosmetic-sunscreens is fully justified for such products because it unfairly emphasizes the therapeutic attributes of such products over their legitimate cosmetic uses. Moreover, given that the format and majority of content information would not change under CTFA's proposed labeling, P&G is confident that eliminating the "Drug Facts" title for certain categories of cosmetic-drugs will not adversely effect the conveyance of important information to consumers. Thus, P&G believes that the reasoning under which FDA will allow companies to omit the "Drug Facts" title for sunscreens formulated as lipsticks and limited to use on small areas of the face, is equally applicable to the cosmetic-sunscreen products identified herein.

The Playtex Petition acknowledges that "FDA has the authority to allow variations in labeling of certain drug products if there is a reasonable basis to conclude that certain characteristics distinguish them from other products in their class." Playtex Petition of January 5, 2001 at 7. Such a position is consistent with the decision in Bracco and with the APA. Moreover, as noted above, FDA has already exercised its authority with respect to sunscreen products labeled for use on small areas of the face and as lipsticks (21 C.F.R. § 352.52), recognizing that there is a reasonable basis for distinguishing them from other sunscreens. Granting similar labeling modifications to other cosmetic-sunscreens would be a logical extension of FDA's treatment of these products considered earlier in the rulemaking process and perfectly consistent with its prior distinctions.

The Playtex Petition fails to adequately refute the reasons set forth in the public sunscreen docket for allowing modifications to the labeling of cosmetic-sunscreens. Contrary to the picture painted by Playtex, a proposal by FDA to adopt modifications to the labeling of certain cosmetic-sunscreens would not represent a "sudden and unexplained change." See Playtex Petition of November 10, 2000 at n. 16. Rather, such a decision by FDA would represent a thoughtful decision by the agency to recognize that the information essential to the safe and effective use of certain products may be conveyed in a modified, and more condensed form.

4. *FDA Denials Of Exemptions From The OTC Drug Labeling Regulation Do Not Require Denial Of The Labeling Modifications Requested For Cosmetic-Sunscreens.*

The Playtex Petition equates the modifications requested by CTFA for sunscreens with the exemptions from the OTC Drug Labeling Regulation requested by Whitehall-Robins Healthcare for its Chap Stick lip balm. It is important to note, however, that unlike the exemption requests for Chap Stick, filed under 21 C.F.R. § 201.66(e) of the OTC Drug Labeling Regulation, CTFA's requested modifications are being made in the context of the final sunscreen monograph. P&G understands

that once FDA has finalized labeling requirements under a particular monograph, the agency will not routinely grant exemptions from any of the content or format requirements superimposed by the OTC Drug Labeling Regulation on the monograph requirements. While, however, issues regarding the finalization of an OTC monograph are still under consideration, the agency is perfectly justified in considering whether reduced content or format accommodations are warranted. Indeed, in its letter to Whitehall-Robins Healthcare on Chap Stick FDA points out that the skin protectant monograph is not yet final and that the agency has identified lip balm products among those that may be entitled to reduced content labeling. Thus, it is not certain, contrary to the implication of the Playtex Petition, that all of the modifications requested for Chap Stick will ultimately be denied.

5. *P&G Fully Supports Off-Label Disclosure Of Inactive Ingredients*

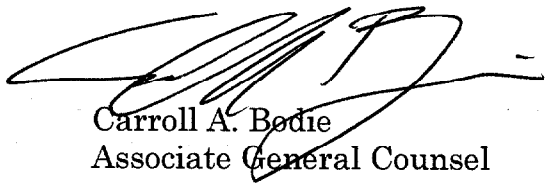
As part of its consideration of appropriate sunscreen labeling under the final monograph, P&G urges FDA to permit off-label listing of inactive ingredients. FDA's cosmetic regulations currently include a number of provisions that allow ingredient information to be conveyed other than directly on the label of such products under certain specified circumstances. 21 C.F.R. §§701.3(b), (i) and (r). P&G routinely utilizes the off-label provisions of the cosmetic regulations to provide consumers with inactive ingredient information for its cosmetics. No increase in adverse health reactions are attributable to the use of P&G products labeled in this manner. Thus, P&G sees no basis for FDA denying similar labeling flexibility for other OTC products and agrees with CTFA that FDA is fully authorized to allow similar labeling options under the FDA Modernization Act provisions requiring OTC drugs to provide inactive ingredient information.

CONCLUSION

P&G appreciates this opportunity to address the sunscreen labeling issues raised in the Playtex Petition and urges FDA to grant CTFA's request for

more flexible labeling for cosmetic-sunscreens and implement such requests in a manner fully consistent with the rulemaking requirement of the APA.

Respectfully submitted,



Carroll A. Bodie
Associate General Counsel

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