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January 5, 2001

VIA FEDERAL EXPRESS

Dockets Management Branch
Food and Drug Administration, HFA - 305
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20857

Re: **PETITION FOR STAY OF AGENCY ACTION**
Docket No. 78N-0038 PSA2; Supplemental Submission

Dear Madam or Sir:

Morgan, Lewis & Bockius submits these comments on behalf of its client Playtex Products, Inc. ("Playtex") to reiterate and supplement the Company's request that the Commissioner of Food and Drugs stay the effective date of any pending, tentative, or final decision to exempt make-up, moisturizers or any other products used on the face or any other part of the body that include sunscreen ingredients, from the Food and Drug Administration's ("FDA's") over-the-counter ("OTC") and sunscreen drug labeling regulations. 21 C.F.R. §§ 201.66 and 352.52. A copy of the Petition for Stay (the "Stay Petition") is attached.

Playtex also submits these comments in response to comments filed by the Cosmetic, Toiletry, and Fragrance Association ("CTFA" or "the Association") on January 5, 2001 ("the CTFA comments") requesting that the Agency exempt from the OTC drug and sunscreen labeling requirements make-up products for the face and neck, and moisturizers for face, neck and hands contained in packages of 2 oz. or less, which also contain sunscreens ("face and hand sunscreens"). Although Playtex is a member of CTFA, it strongly disagrees with and objects to the Association's efforts to obtain an exemption for sunscreen make-up and moisturizer products from the OTC drug and sunscreen labeling requirements. CTFA's request for an exemption is not representative of the sunscreen industry's views on this issue; requires FDA to discriminate

arbitrarily among like products, requests an exemption which will violate the Administrative Procedure Act ("APA"), and most importantly, will adversely affect consumer health. Playtex therefore strongly urges the Agency to reject CTFA's request for an arbitrary exemption for face and hand sunscreen products from the OTC drug and sunscreen labeling regulations.

Playtex is the second largest U.S. manufacturer of sunscreen products, including Banana Boat and Biosun products and has been an active participant in the development of appropriate testing, compositional and labeling standards for sunscreen ingredients to ensure that consumers have access to and understand how to use properly sunscreen products that will protect them against exposure from harmful ultraviolet radiation ("UV rays"). Playtex, therefore, has legitimate and substantial concerns that CTFA's request for an overly-broad interpretation and expansion of the existing labeling exemption for small packages from the OTC drug and sunscreen labeling regulations will adversely affect consumer health and irreparably harm Playtex' ability to market effectively its sunscreen products.

A. CTFA's Proposed Exemption Does Not Protect Consumer Health

CTFA maintains that a labeling exemption for face and hand sunscreen products "puts the interests of consumers first." See CTFA Supplementary Comments Regarding Appropriate Labeling Requirements for Sunscreen Products, at 2 (January 5, 2001). CTFA's claims are inconsistent with its actions, however, because the exemption puts the cosmetic industry's economic interests in having reduced labeling and marketing costs for exempt products above the interests of consumers[1/]. The cost of such savings is consumers' health and the resulting consumer confusion and subsequent misuse of sunscreen products that will occur if FDA permits face and hand sunscreen products to have different labeling than other sunscreen products. If labeled differently, consumers will perceive and use these products like cosmetics, fail to apply adequate amounts of sunscreen, or reapply face and/or hand sunscreen products after engaging in activities that may eliminate or reduce the protective properties of sunscreen ingredients. This confusion and misuse will result in increased incidence of sunburn, melanoma and other face, hand and neck skin injuries. Therefore, FDA must deny CTFA's request for an expansion and overly broad interpretation of an exemption for sunscreen face and hand products from the OTC drug and sunscreen labeling regulations.

1/ CTFA cannot simultaneously claim that the sunscreen benefits from such products are secondary and at the same time maintain that the presence of sunscreen ingredients in these products is critical to public health.

CTFA in its comments has asserted that it intends for these products to be regulated as drugs. If this is the case, CTFA should also agree that the products should be labeled fully as drugs.

As FDA has previously stated;

> [R]egardless of what type of product a consumer chooses for sun protection, the essential information relevant to sun protection is the same. Thus, to ensure that consumers are adequately protected from overexposure to the sun, all products intended for use as sunscreens should have similar labeling requirements, irrespective of their method of use and irrespective of whether the sunscreen use is considered secondary or primary. 64 Fed. Reg. 27,666, 27,673 (May 21, 1999).

Only uniform labeling for all sunscreen drug products will adequately protect public health and continue the efforts of the sunscreen and medical communities to ensure that consumers take sun protection and the use of SPF products seriously.[2/]

CTFA also maintains that face and hand sunscreen products should be exempt from full labeling because consumers are well-versed in the safe and effective use of cosmetic products. Consumer experience with use of cosmetic make-up and moisturizing products, however, will not ensure that consumers will understand how to safely and effectively use drug products for sunscreen protection. On the contrary, consumers are likely to improperly use such products, consistent with customary use of cosmetic products and, thus, minimize or eliminate the effectiveness of these sunscreen products. It is just as, if not more, important that consumers consider face and hand sunscreen products to be an important component of their sun protection program, which can only occur if they contain full sunscreen drug labeling. Instead of reinforcing artificial distinctions between products which potentially jeopardize consumer health, FDA and CTFA should be striving for consistent, uniform OTC drug labeling which educates consumers about the safe and effective use of sunscreen products.

CTFA's suggestion that manufacturers will withdraw sunscreen ingredients from face products if FDA does not grant the exemption, is evidence that CTFA's sole motivation for the request is economic rather than consumer health. It is unpersuasive for the Association to suggest that the

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2/ Playtex continues to support a uniform exemption for all sunscreen products to ensure absence of consumer confusion and uniform consumer perception of these products and their appropriate use. See Playtex Petition for Stay at 9.

cosmetic industry will withdraw sunscreen ingredients from their products and simultaneously claim that its primary concern is public health.3/

Playtex also notes that the Agency has rejected similar requests for exemptions for other products from the OTC drug labeling requirements that were motivated by economic or other arbitrary considerations. See e.g., Letter to Whitehall-Robins Healthcare from Charles J. Ganley, M.D., Division of OTC Drug Products, Office of Drug Evaluation, Food and Drug Administration (Sept. 18, 2000) (denying a request for an exemption from certain labeling requirements for Chap Stick lip balm products and stating that the agency will not routinely grant an exemption for packages that are too small to meet labeling requirements or "grant exemptions based solely on financial considerations").

B. The Existing Small Package Exemption Must Be Construed Narrowly

As previously stated in Playtex's Stay Petition, and discussed above, the proper and routine use of sunscreen products can significantly reduce the adverse health risks associated with sun exposure. Therefore, to the extent that FDA agrees to provide for any exemption to the OTC drug and sunscreen labeling regulations it should be narrowly construed by FDA on a case-by-case basis to apply only to a limited number of sunscreen products that are marketed in small

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3/ Moreover, despite these implicit suggestions, it is highly improbable that make-up and moisturizer/sunscreen manufacturers will withdraw sunscreen ingredients from these products if subject to the same OTC drug and sunscreen labeling requirements that apply to other sunscreen products. Because of the increased health significance placed on sunscreen protection, market trends demonstrate that there is high consumer demand for face sunscreen products and a consumer willingness to pay higher prices for products that include sunscreen ingredients. See "Tick Tock: The Clock Stops For No One, But, New Ingredients, Formulas, Products and Technology Claims To Aid In The Ultimate Aging Of Skin," Global Cosmetic Industry (July 1, 2000) (noting that there is a "major thrust for skin-care products to include sunscreen" and an increased demand for sunscreens that block UVA and UVB rays.) Consequently, it is extremely unlikely that cosmetic manufacturers will choose to ignore this large source of revenue and profit and alienate consumers by choosing not to market these products if FDA denies CTFA's request for the exemption.

packages[4/] and intended and labeled for use only on small, discrete parts of the face on a non-routine use. For example, multifunction drug/cosmetic sunscreen products (e.g., make-up foundations, tints, blushes, rouges, moisturizers) which are intended to be used on a daily or frequent basis to protect against the adverse health and skin aging effects of acute and chronic sun exposure, must be labeled as drugs similar to other sunscreen products. Moreover, FDA should not automatically exempt products which are used on the nose, lips, ears or around the eyes, but rather on a case-by-case basis to determine the purpose of the product and its intended use prior to granting any exemption.[5/]

The current OTC and sunscreen drug labeling regulations were intended to exempt a very narrow category of products from the labeling requirements that apply to sunscreen products. See 21 C.F.R. § 201.66; 352.50; 352.52; see also 64 Fed. Reg. 13,254 (March 17, 1999) & 64 Fed. Reg. 27,666 (May 21, 1999). Specifically, the exemption applies to "products labeled for use only on specific small areas of the face (e.g., lips, nose, ears, and/or around the eyes)" and that meet the criteria established for small packages under 21 C.F.R. 201.66 (d)(10). 21 C.F.R. § 352.52 (emphasis added). CTFA maintains that face and hand sunscreen products which it proposes for exemption are "substantially equivalent to" products that are used in small limited areas around the face, eyes, nose, and ears. Nothing in the regulation or its preamble, however, suggests that FDA intended the exemption to apply broadly to make-ups, moisturizers, or other types of face or hand sunscreen products that are packaged in larger containers and used on large areas of the face and neck for color or products that are packaged in small containers but used routinely on multiple parts of the face, neck, and/or hands, including skin lotions, moisturizers, hand and eye lotions and creams. Face and hand sunscreen make-up and other moisturizer products are intended for use all over the face, neck and hands-- areas that are significantly larger than the

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4/ To qualify as a small package, the product must meet the criteria defined under 21 C.F.R. § 201.66 (d)(10). FDA should also construe the small package exemption narrowly because many of these products already are, or can be packaged in containers sufficiently large (e.g., blister cards or other outer or extended packaging) to accommodate full OTC drug labeling. FDA has taken a similar position in connection with its Aug. 28, 2000 rejection of Block Drugs' request for an exemption from OTC drug labeling for its BC analgesic product.

5/ Because of the significant development and marketing of new categories of cosmetic products which are intended only to be used on specific parts of the face, it is not possible or advisable to enumerate categories of "exempt" products.

small discrete areas around the eyes, nose, and ears which FDA initially intended to exempt from full labeling based on the extremely small packages in which these products are sold.

C. FDA Does Not Have the Legal Authority to Create Arbitrary Distinctions Between Similar Products

There is no rational basis and CTFA has articulated none, to expand the exemption to sunscreen products based on which parts of the body they are used, whether they provide some amount of some color, or the size of a package and, therefore, granting CTFA's requested exemption for face and hand sunscreens would be arbitrary and capricious and beyond the Food and Drug Administration's ("FDA's") statutory authority in violation of the Administrative Procedure Act ("APA") 5 U.S.C. § 706 (2)(A) and 706 (2)(C). In each case, the product is being used to provide sunscreen protection.[6/] Broad application of the exemption to the products identified by CTFA would be contrary to the purposes of the Act to protect consumers' health and to provide them with adequate information to properly self-medicate. For the reasons articulated in Playtex's Stay Petition, the need for such information is not lessened because the product is used or labeled for multiple purposes on specific parts of the face, hands or other parts of the body.

Despite there being no rational basis for a distinction among these products, CTFA attempts to distinguish among them on the grounds that such face and hand products only offer sunscreen drug features as a secondary benefit, are used primarily for color, consumers know how to use them, and/or because the products are packaged in 2 oz. containers. These distinctions, however, are legally irrelevant to the issue of whether FDA can properly regulate the labeling of such products differently than other sunscreens. These products are expressly marketed and purchased for their sunscreen drug properties. In many cases, consumers who purchase make-up and moisturizer face and hand sunscreen products use such products as their primary and only source of sunscreen protection for those areas of the body. Moreover, as stated in Playtex's Stay Petition, there is a longstanding precedent that products that include and are labeled and marketed for their drug properties are subject to regulation as a drug, including their labeling,

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6/ Consumers, for example, are more likely to rely on face and skin lotion sunscreen products to provide complete facial or other sunscreen protection than they would products that are intended solely for use on the discrete areas around eyes, nose, and ears. Consequently, public health concerns mandate that FDA require full OTC labeling for the safe and effective use of these products.

even if they have cosmetic properties. See attached Petition for Stay; see also 64 Fed. Reg. 27,666, 27,669 (May 21, 1999).

It is also a well-established administrative law principle that similarly situated products cannot be regulated differently based on arbitrary distinctions. Bracco Diagnostics, Inc. v. Shalala, 963 F. Supp. 20, 24 (D.D.C. 1997) (citing National Association of Broadcasters v. FCC, 740 F.2d 1190, 1260 (D.C. Cir. 1984); Doubleday Broadcasting Co. v. FCC, 655 F.2d 417, 423 (D.C. Cir. 1981)). CTFA cites several examples where FDA has permitted the labeling of certain subcategories of products to differ from other similar products and claims that FDA has the authority to allow variations in the labeling of certain drug products if there is a reasonable basis to conclude that certain characteristics distinguish them from other products in their class. We agree. However, despite CTFA's efforts to create distinctions among these sunscreen products, there is no legally appropriate, rational distinction between face and hand sunscreen products and traditional sunscreens on which to base any such exemption. The fact that a sunscreen product provides color, including potentially a bronzing color, is not a rational basis to assert the consumer does not also need full labeling about the product SPF effect. Similarly, the fact that a manufacturer chooses to market a sunscreen moisturizer in a 2 oz bottle and label it for use on the hands, rather than on the arms or legs, is not a rational basis to say the consumer does not need the full OTC labeling. Without such rational basis, FDA's granting of the exemption would be arbitrary and capricious, especially in view of FDA's prior finding of the need for uniform labeling for all such products.[7/] Moreover, the absence of a challenge to FDA's prior labeling exemptions for other OTC products does not confirm the legality of such actions.

E. Failure to Grant the Stay will Cause Irreparable Harm to Playtex

The failure of FDA to grant the stay requested in Playtex's petition will result in irreparable harm to Playtex. Playtex has a significant interest in ensuring that consumers are appropriately protected from harmful sun exposure and that they continue to have confidence in sunscreen products, including Playtex' products.

7/ Playtex also disagrees with CTFA's assertion that any decision by FDA to treat these products disparately relies on FDA's medical and other expertise and is entitled to substantial deference. In fact, CTFA's bases for the request is consumer convenience and cosmetic manufacturers' economic interests, neither of which requires FDA's medical or other expertise.

If the Agency grants an exemption for abbreviated instructions, warnings, and other drug facts for labeling for sunscreen face and hand products that are intended for use on multiple areas of the face and hands on a routine or daily basis, it will adversely affect consumer health and understanding of how to properly use all sunscreen products. Contrary to accepted medical recommendations about the critical importance of sunscreen protection for the face, consumers will interpret the disparate labeling to suggest that the sunscreen face and hand products have different conditions of use from other sunscreen products. Consumers will perceive and use such products like cosmetics based on their cosmetic experience, as acknowledged by CTFA, labeling, packaging and marketing and may fail to apply adequate amounts of sunscreen, will not reapply face and hand sunscreen products after bathing, exercising, or engaging in other activities that may eliminate or reduce the protective properties of such products, or combine the sunscreen product with other cosmetic products which reduce their effectiveness or fail to take other protective measures to reduce acute and chronic exposure. This confusion will result in increased incidence of sunburn, melanoma and other skin injuries. Further, consumers will improperly attribute the failure of such products to protect them to all sunscreen products, including similar types of Playtex products. As a result, Playtex can be expected to ultimately suffer an improper reduction in the use of its sunscreen products, and a resultant loss of sales.

In addition, consumers (especially female consumers) also will consider products which are labeled like cosmetics rather than drugs as more dermatologically appropriate for their faces or their children's faces, and forego traditionally packaged sunscreen products, such as Banana Boat Faces Plus Sunscreen (labeled for year round use on sensitive facial skin), or Biosun, which also are intended specifically for the face. Once such use trends are in place and reinforced by product advertising and label claims for the exempt products, Playtex will be competitively disadvantaged and irreparably harmed through lost customers and sales.

Playtex also will be competitively disadvantaged by the additional costs in labeling, and package design resulting from the more extensive full OTC drug labeling required on its products and in the amount of time required to change labeling. This injury will be ongoing and irreparable as long as the disparity exists between these similar products. Because Playtex will be irreparably

injured if the stay is not granted, FDA should deny CTFA's request to construe the small package sunscreen labeling exemption more broadly or to expand it to include sunscreen "make-up" or color products packaged in any size and/or face and hand lotions, moisturizers, or creams or other similar products that are contained in 2 oz. packages.

Respectfully submitted,

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