

# The Cosmetic, Toiletry and Fragrance Association, Inc.

1110 VERMONT AVENUE, N.W., WASHINGTON, D.C. 20005 • 202/331-1770 • TELEX 89-2673

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November 2, 1982

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
Room 4-62  
5600 Fishers Lane  
Rockville, Maryland 20857

Re: Skin Bleaching Drug Products for Over-the-Counter  
Human Use; Tentative Final Monograph  
Docket No. 78N-0065

ADMIN PROCEEDINGS STAFF  
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Dear Sir or Madam:

I have enclosed an original and three copies of comments in the above-entitled matter. Please file the original and two copies, stamp the third copy as filed, and return it to us through the messenger.

Thank you.

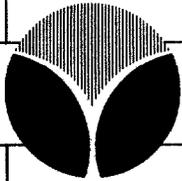
Sincerely,

Eve E. Bachrach  
Assistant General Counsel

Enclosures

78N-0065

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Docket No. 78N-0065

Dear Sir or Madam:

The Cosmetic, Toiletry and Fragrance Association, Inc. (CTFA)\*<sup>/</sup> submits these comments in response to the Agency's publication of a Tentative Final Monograph (TFM) that would establish conditions under which over-the-counter (OTC) skin bleaching drug products are generally recognized as safe and effective and are not misbranded. 47 Fed. Reg. 39108 (September 3, 1982). Many CTFA members market skin bleaching products, which are frequently used because of their cosmetic effects. The TFM also addresses broader issues, including the distinction between cosmetic and drug labeling claims made for a product, and the appropriateness of warnings. Accordingly, CTFA has a keen interest in this matter.

\*<sup>/</sup> Founded in 1894, CTFA is the national trade association representing the cosmetic, toiletry and fragrance industry. CTFA has an active membership of more than 240 companies that manufacture or distribute approximately 90 percent of the finished cosmetic products marketed in the United States. In addition, CTFA includes more than 220 associate member companies from related industries, such as manufacturers of cosmetic ingredients and packaging materials.

Labeling of Cosmetic Claims and Drug Claims

In the preamble to the TFM, the Agency agrees that the Panel's jurisdiction and the proposed monograph extend only to drug claims made for skin bleaching products, and not to cosmetic claims. 47 Fed. Reg. 39109, 39114-39115. The Agency states that cosmetic labeling may appear on skin bleaching products that are also drugs so long as the required drug labeling appears and the products conform to the cosmetic labeling requirements of the Federal Food, Drug, and Cosmetic Act. 47 Fed. Reg. 39114. CTFA agrees with these views.

However, CTFA does not agree with the Agency's stated view that "cosmetic claims appearing in any portion of the labeling that is required by the monograph could be misleading. Cosmetic claims may appear elsewhere on the label." 47 Fed. Reg. 39114. The Agency says this view is "[c]onsistent with the provisions of §701.3(d) (21 C.F.R. §701.3(d)) regarding declaration in labeling of active drug ingredients and cosmetic ingredients." Id. CTFA disagrees. That section of the regulations prescribes the order in which ingredients are to be listed in the ingredient declaration for a cosmetic drug product, and it requires that drug and cosmetic information appear together on the label: the ingredient declaration first shall express the active drug ingredients, to be followed by the cosmetic ingredients. The section does not support the assertion that cosmetic and drug claims should not appear on the same portion of the labeling.

Indeed, the cited section supports the opposite proposition: that is, the preferred method of cosmetic drug labeling is to express related drug and cosmetic information in the same portion of the labeling. This method of labeling permits the consumer to review information about the usefulness of a cosmetic drug product at a central location on the label and to learn both the drug and cosmetic effects that can be expected from the product.

In fact, if the drug and cosmetic claims were to appear on entirely different portions of the label, e.g., different panels, the consumer could be confused as to what the product will do. Surely, for example, FDA does not mean to prevent the label of an anticavity toothpaste from advising the consumer on the principal display panel both that it is useful for cleansing the teeth and freshening the breath (cosmetic claims) and that it may help to reduce tooth decay (a drug claim).

CITFA believes it is clear that the placement of cosmetic and drug claims on the same portion of a label does not necessarily render the label misleading. So long as the labeling is truthful and not false or misleading, the Agency should not object to the practice of placing cosmetic and drug claims on the same portion of the label.

Moreover, from a practical standpoint, if cosmetic claims could not appear on the same part of the label as drug claims, this could mean that no cosmetic claims could appear on the product at all. A review of

the TFM reveals that a single container of a skin bleaching product may be required to contain, at a minimum, as many as nine separate representations, including statement of identity, indications, numerous warnings, and lengthy directions for use. In addition, the Federal Food, Drug, and Cosmetic Act requires a tenth declaration, that of the active ingredient(s). Containers for skin bleaching products are relatively small and expression of all required monograph information may leave no portion of the label available for cosmetic claims only, which the Agency properly assures are permitted to be declared. 47 Fed. Reg. 39109, 39114-39115.

Warning for Skin Bleaching Products that Contain a Sunscreen

The Agency proposes to require a warning for skin bleaching products that contain a sunscreen as an active ingredient to retard repigmentation of bleached skin: "Warning: This product is not for use in the prevention of sunburn." Proposed 21 C.F.R. §358.50(c)(2), 47 Fed. Reg. 39117. CIFA believes this warning is unwarranted and that it could be unduly alarming to consumers.

The sunscreen's limited function of retarding reversal of the skin bleaching effect is amply conveyed by four separate proposed labeling requirements of the TFM, so that a warning is not required:

First, the required statement of identity makes clear that a skin bleaching product, even one containing a sunscreen, is for skin bleaching

purposes only. "Statement of Identity" labeling clearly informs consumers that the product is a "skin bleaching" product, and not a sunburn prevention product:

- (a) Statement of identity. The labeling of the product [shall contain] the established name of the drug, if any, and identif[y] the product as a "skin bleaching agent," "skin lightener," "skin bleaching (insert dosage form, e.g., cream, lotion, or ointment)," or "skin lightening (insert dosage form, e.g., cream, lotion, or ointment)."

Proposed 21 C.F.R. §358.50(a), 47 Fed. Reg. 39117.

Second, review of the required label "Indications" makes clear that a skin bleaching product, even one containing a sunscreen, is not indicated for sunburn prevention. "Indications" labeling, proposed 21 C.F.R. §358.20(b), 47 Fed. Reg. 39117, addresses the process of skin bleaching only, and not sunburn prevention:

- (b) Indications. The labeling of the product [shall contain] a statement of the indications under the heading "Indications" that is limited to the following phrases:
  - (1) For products containing the ingredient identified in §358.10 or any combination identified in §358.20. (Select one of the following: "For the gradual fading of" or "Lightens") "dark (brownish)" (select one of the following: "discolorations," "pigment," "spots," "blotches," or "areas") "in the skin such as" (select one or more of the following: "freckles," "age and liver spots," or "pigment in the skin that may occur in pregnancy or from the use of oral contraceptives.")

Third, a skin bleaching product containing a sunscreen would be required to include additional labeling language under "Indications" that the product "Contains a sunscreen to help prevent darkening from reoccurring." Proposed 21 C.F.R. §358.50(b) (2), 47 Fed. Reg. 39117. This clearly informs the consumer of the limited purpose of the sunscreen.

Fourth, these products would be required to include language under "Directions" instructing consumers to use a sunscreen or other sun protection method despite the presence of sunscreen in the formula: "Sun exposure should be limited by using a sunscreen agent, a sun blocking agent, or protective clothing to cover bleached skin after treatment is completed in order to prevent darkening from reoccurring." Proposed 21 C.F.R. §358.50(d) (3), 47 Fed. Reg. 39117.

Furthermore, a warning is not justified under the Agency's own rationale for use of warnings, as discussed in the preamble. The Agency determined not to propose the Panel's recommended "WARNING: Sun exposure should be avoided indefinitely by using a sunscreen agent...to cover bleached skin in order to prevent darkening from reoccurring," 47 Fed. Reg. 39112, on the ground that the language relates substantially to the effectiveness of the product rather than to a safety problem. The Agency concluded that while it is appropriate to advise consumers to "limit exposure" or "avoid over-exposure" to the sun by using a sunscreen, this information more appropriately belongs under "Directions for Use." Similarly, informing consumers that a skin bleaching product containing a sunscreen is not for sunburn prevention is more generally a question of efficacy than safety. Because of the undue alarm that a warning could engender, manufacturers may choose not to include the useful sunscreen ingredient at all. Such a result surely is not desired by the Agency.

Accordingly, we propose that the Agency delete the proposed sunscreen warning, proposed 21 C.F.R. §358.50(c) (2), 47 Fed. Reg. 39117. If the

Agency nevertheless concludes that additional sunscreen information should be included on the label, which we believe is not necessary, at most the information (that a skin bleaching product is not for sunburn prevention) belongs in the Indications, proposed 21 C.F.R. §358.50(b)(2), 47 Fed. Reg. 39117, which already address the sunscreen issue, and not in the Warnings. Thus, if the Agency declines to delete the proposed sunscreen warning altogether, CTFA suggests that proposed 21 C.F.R. §358.50(c)(2) be deleted, and that proposed 21 C.F.R. §358.50(b)(2), 47 Fed. Reg. 39117, be revised to read:

- (2) For products containing any combination identified in §358.20. "Contains a sunscreen to help prevent darkening from reoccurring; not for prevention of sunburn."

This statement fully informs consumers in a succinct and unified way of the presence of the sunscreen, and what it will and will not accomplish, without creating the unnecessary alarm that a warning could produce.

#### Warning to Discontinue Use in Event of Irritation

CTFA believes that the proposed Warning concerning skin irritation, proposed 21 C.F.R. §358.50(c)(ii), 47 Fed. Reg. 39117, is unduly alarming in its directive to consult a doctor, and that it should be revised.

The section would require the Warning to read:

Some users of this product may experience a mild skin irritation. If skin irritation becomes severe, stop use and consult a doctor.

Id. In the preamble to the TFM, the Agency points out not only that "a mild skin irritation is [to be] expected," from use of the product but also that the "occurrence of inflammation makes subsequent lightening more likely," 47 Fed. Reg. 39113. [Emphasis added.] However, the proposed Warning's admonition to "consult a doctor" may make consumers extremely wary of any irritation, even the mild variety that forebodes the desired lightening effect, such that they may unnecessarily stop using the product, and so not gain its benefits.

Accordingly, CITFA suggests that the section be revised to eliminate the unduly alarming reference to consulting a physician, as follows:

- (ii) "Some users of this product may experience a mild skin irritation. If skin irritation becomes severe, stop use immediately."

If the Agency nevertheless is unwilling to delete all reference to consulting a doctor, CITFA suggests as an alternative that the section be amended to read:

- (ii) "Some users of this product may experience a mild skin irritation. If skin irritation becomes severe, stop use or consult a doctor."

Use of the term "or" in referring to consulting a doctor serves to remove the element of undue alarm.

#### Statement of Identity Labeling

CITFA believes that the Statement of Identity section of the TFM, proposed 21 C.F.R. §358.50(a), 47 Fed. Reg. 39117, should be amended to

permit use of the terms "Skin Tone Cream" and "Fade Cream" as acceptable descriptions of the product.

The terms "skin bleaching" and "skin lightening" as the sole permissible descriptions for these products are not only offensive to many black consumers, but also may cause them mistakenly to believe that these products are not useful for black skin, when in fact they can be. Indeed, insofar as black consumers are concerned, the terms "Skin Tone Cream" and "Fade Cream" may more accurately describe the action of the product than the TFM terms "skin bleaching agent" and "skin lightener."

The Agency states in the preamble to the TFM that it rejected terms such as "Skin Toner" as a Statement of Identity because the term may mislead consumers to expect improvement in skin elasticity or resiliency, rather than change in skin color. 47 Fed. Reg. 39111. CITFA disagrees with this statement.

The term "Skin Tone Cream" is a well-established statement of identity for this type of product. Black and other consumers are familiar with the term, so it is not reasonable to expect they would be misled to believe that a product so designated is being represented to improve skin elasticity or resiliency. Moreover, the other labeling statements proposed to be required -- e.g., Indications and Directions, which all refer to 'fading' 'lightening,' 'discolorations,' and so forth -- make it abundantly clear that the "Skin Tone" product is intended to produce a change in skin color, not in skin elasticity or resiliency.

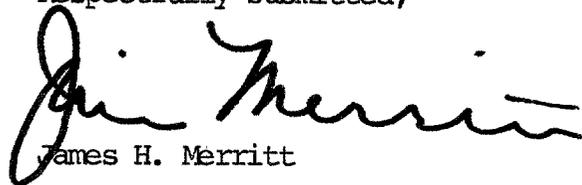
Similarly, the term "Fade Cream" is also a well-recognized statement of identity for this type of product. Amending the proposal to permit its use would be appropriate also because it would provide consistency with the proposed Indications section, which includes as a permissible statement: "For the gradual fading of" the skin. [Emphasis added.]

Therefore, we request that the Agency revise proposed 21 C.F.R. §358.50(a), 47 Fed. Reg. 39117, Statement of Identity, to read:

(a) Statement of Identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as a "skin bleaching agent," "skin lightener," "skin tone (insert dosage form, e.g., cream, lotion, or ointment)," "skin fade (insert dosage form, e.g., cream, lotion, or ointment)," "skin bleaching (insert dosage form, e.g., cream, lotion, or ointment)," or "skin lightening (insert dosage form, e.g., cream, lotion, or ointment)."

We hope these comments are helpful.

Respectfully submitted,

  
James H. Merritt