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*Plough, Inc.*

MEDICINES  
COSMETICS  
BROADCASTING  
HOME PRODUCTS

P. O. BOX 377 MEMPHIS, TENNESSEE 38151 • 901/320-2011

November 2, 1982

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

Re: Docket No. 78N-0065  
Comments on Skin Bleaching  
Drug Products for OTC Human  
Use; Tentative Final Monograph  
(47FR39108, Sept. 3, 1982)

Gentlemen:

Plough, Inc. respectfully submits the following comments in response to FDA's publication of subject Tentative Final Monograph (TFM) which proposes to establish conditions under which over-the-counter (OTC) skin bleaching drug products are generally recognized as safe, effective and not misbranded. We market skin bleaching products and thus are directly affected by this notice.

I. Use of Drug and Cosmetic Claims on Product Labeling

In the preamble to the TFM, the Agency agrees that the Panel's jurisdiction extends only to drug claims made for skin bleaching products, and not to cosmetic claims. (Comments 1, 18, p. 39109, 39114). 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. (p. 39114.) We concur.

However, we do 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

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misleading. Cosmetic claims may appear elsewhere on the label." (Comment 18 p. 39114.) The Agency says this view is "(c)onsistent with the provisions of §701.3(d) [21C.F.R. §701.3(d)] regarding declaration in labeling of active drug ingredients and cosmetic ingredients." Plough disagrees. That section of the regulations merely prescribes the order in which ingredients are to be listed in the ingredient declaration for a cosmetic drug product, namely, that the 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 drug claims and cosmetic claims in the same portion of the label. This method of labeling permits the consumer to review information appearing in a central place and learn both the drug and cosmetic information about the product.

In fact, if the drug and cosmetic claims appear on entirely different portions of the label, the consumer could be confused as to what the product will do. For example, combining an appropriate drug claim -

Lightens dark spots such as age and  
liver spots...

with an appropriate cosmetic claim -

...to provide a healthier, younger  
looking skin

provides a clearer overall description of the intended result of product use, than if each were presented on separate parts of the label. Certainly, combining the two statements would not be misleading to the consumer. If the claims appear on different parts of the label, the consumer may well be confused and wonder which claims (drug or cosmetic) best describe the product, although both may be true.

Thus, Plough believes that the mere placement of cosmetic and drug claims on the same portion of the label does not, in and of itself, render the label misleading. So long as the label, taken as a whole, is 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.

II. Use of term "skin toning" in indications/statement of identity.

We agree with the Agency's belief (Comment 7, p. 39111) that "skin bleaching" accurately describes for consumers the pharmacologic results to be obtained from using these products. However, we disagree that such terms as "skin toner", "skin color toner" are any less accurate. We suggest that this and similar terms are, in fact truthful, meaningful descriptors of the action of these products. By definition, use of a product for "lightening of dark brownish discolorations, pigment, spots, blotches, or areas in the skin" [proposed §358.50(b)(1)] would result in a more even skin tone. Such terms have been used for years to properly describe these products and are readily understandable and meaningful. As has been repeatedly stated at the Agency's Exclusivity Hearings, September 29, 1982, companies should be allowed, and in fact have the legal right, to use a variety of terms to describe their products, so long as the terms are accurate and truthful.

Therefore, we request that other meaningful phrases such as "skin toner", "skin color toning", and "skin color toner", be included in the allowed statement of identity terms.

In addition, we request that for the same reason discussed above, the allowed indications be expanded to also include use of the concept of "even skin tone" which results from "gradual fading of dark brownish discolorations, pigment, spots, blotches, or areas in the skin." [§358.50(b)(1)].

III. Directions Statements.

- A. "Lightening effect of this product may not be noticeable on dark skin." [proposed 358.50(d)(1)]

Plough suggests that this term may well be confusing to the consumer since the intended affect of the product is to lighten dark spots. This statement is overbroad and is potentially confusing to consumers in that it could easily be construed to mean that hydroquinone will not lighten areas of darkened skin. Therefore, this statement should be deleted from the required Directions statements.

- B. "Sun exposure should be limited by using a sunscreen agent, a sun blocking agent, or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from reoccurring." [proposed 358.50(d)(2)]

This statement seems excessively wordy. A much more precise, and just as meaningful way to present the information could be -

Limit exposure to the sun to prevent skin darkening from reoccurring.

IV. Use of the signal words "Caution" and "Warning" in Labeling.

Plough objects to the proposed elimination of the term "Caution(s)" on the labeling of OTC products, as discussed in Comment 14, p. 39113.

To the lay consumer, there is a distinct difference between the term "Warning(s)" and the term "Caution(s)", with the "Warning" significantly harsher than "Caution."

It would undoubtedly dilute the impact of essential warning statements, if those cautions which require the consumer to take certain precautions while using the product were also included under the same signal word.

While both types of statements are usually used to call attention to danger, the distinction is important, particularly when products contain long lists of warnings. It is important for the consumer to be able to distinguish at a glance between cautions as to the use of the product and more serious warnings.

The distinction between Cautions and Warnings has its counterpart in the labeling for prescription drugs as set forth in 21CFR201.57:

(e) "Warnings" Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur." (Emphasis added)

The Precautions section as applied to the patient is similar to the concept of Cautions in labeling of OTC products.

(f) "Precautions": Under this section heading, the labeling shall contain the following subsections as appropriate for the drug:

(1) General: This subsection of the labeling shall contain information regarding any special care to be exercised by the practitioner for safe and effective use of the drug.

(2) Information for patients: This subsection of the labeling shall contain information to be given to patients for safe and effective use of the drug, e.g., precautions concerning driving or the concomitant use of other substances that may have harmful additive effects. (Emphasis added)

Therefore, we request that the distinction between "warnings" and "cautions" be retained.

V. Use in children under 12.

The Agency is proposing to include the "do not use on children under 12" statement in both the "Directions" and "Warnings" sections. (Comment 11, p. 39112)

Not only is it unnecessary to repeat the statement in two sections of the labeling, but with limited label space for products of this type, unnecessary repetition would tend to diminish space for and dilute the impact of other meaningful label copy. Therefore, it is requested that the statement be required to appear only once, and in the "Warnings" section.

VI. Category I Concentration of Hydroquinone.

The Agency continues to maintain that the upper limit for Category I concentration of hydroquinone is 2%. However, it is interesting to note that products continue to be available at concentrations up to 4%, with a low rate of reported reactions. In fact, a recent

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article by Drs. Maibach and Engasser [Engasser PG, Maibach HI: Cosmetics and dermatology: Bleaching creams. J. Am. Acad. Dermatol. 1981; 5:143-147.], reviewed the current thinking in the medical community and concluded that in 2.0% to 5.0% concentrations, hydroquinone is generally quite safe; allergic contact dermatitis may rarely necessitate stopping therapy. Therefore, we request that the Category I concentration be increased to 4%.

We thank you for the opportunity to present these comments.

Sincerely,



Kenneth R. Johannes  
Director Regulatory Affairs

KRJ:jp

Submitted in triplicate