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ADMIN PROCEEDINGS STAFF

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Dockets Management Branch HFA 305  
Food & Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857

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

Dear Sir or Madam:

Norcliff Thayer, Inc. ("Norcliff"), a member of the Revlon Health Care Group, distributes an over-the-counter ("OTC") drug product, ESOTERICA, a member of the drug class which is the subject of the captioned Federal Register notice. Inasmuch as this rulemaking, if finalized as proposed, will have a substantial impact on the labeling of ESOTERICA, Norcliff respectfully submits these comments:

A. Statement of Identity

Norcliff urges that proposed 21 CFR 358.50(a) should be revised to include the term "medicated fade (insert dosage form, e.g. cream, lotion or ointment)".

Such Statement of Identity is neither false nor misleading. Just as with the term "skin lightener", the term "fade" accurately reflects the expected pharmacological action of the product. Indeed, the November 3, 1978 proposal of the Advisory Review Panel on OTC Miscellaneous External Drug Products (the "Panel") used the word "fade" when it recommended that the Indications section read "For the gradual fading of....." (43 Fed. Reg. 51554, emphasis added). Additionally, the word "fade" is probably

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more understandable to the consumer than the term "bleach", since it conveys a gradual lightening, while the latter connotes a harsh and more immediate effect.

Norcliff further believes that the addition of the word "medicated" indicates to the consumer that the product is a "medicine" which will produce a drug (therapeutic) effect, in contrast to a "cover-up" (cosmetic) effect. Thus, the term "medicated fade (dosage form)" tells the consumer that the product is a medicine which gradually lightens the color of brown spots, etc.

Norcliff has long used the term "medicated fade cream" and has no reason to believe that consumer confusion regarding the product will result from such term. This is evidenced by the offer to refund the purchase price of ESOTERICA upon return of the product with a brief explanation of customer dissatisfaction. Norcliff has never received a statement from a consumer indicating that he or she purchased the product under a mistaken notion regarding the term "medicated fade cream" or what such a cream is intended to do.

B. Indication

Norcliff believes that proposed 21 CFR 258.50(b)(1) should be revised by the addition of the words "and the prevention of their recurrence". The Panel determined that the depigmentation resulting from the topical application of hydroquinone is reversible, i.e., discontinuation of treatment with hydroquinone will permit melanonic cells to produce melanin in sufficient quantities such that lentigines will darken or reappear. (43 Fed. Reg. 51550, 51551) It is clear, therefore, that the consumer is faced with a chronic problem that will require long-term treatment. However, such treatment should not be at the risk of decreased safety.

With regard to that issue, the Panel concluded that 2 per cent hydroquinone may be safely used over limited areas of the body for extended periods of time. (43 Fed. Reg. 51551) Thus, the long-term use of such a product will effectively prevent the recurrence of undesirable lentiginos which were originally faded by that product while not compromising the safety of the self-medicating consumer.

C. Warnings

1. Norcliff believes that the warning found at proposed 21 CFR 358.50(c)(2) should be deleted. This warning is unnecessarily redundant inasmuch as the proposed Indications section includes the statement:

"Contains a sunscreen to help prevent darkening from reoccurring." (47 Fed. Reg. 39117)

Additionally, neither the proposed Indications section nor the proposed Statement of Identity section would permit the use of any term which would imply that such a product containing a sunscreen is intended for use in the prevention of sunburn. Furthermore, proposed 21 CFR 358.50(d)(3) would require a statement regarding use of sunscreens and the reason for such use.

2. Norcliff believes that proposed 21 CFR 358.50(c)(1)(iii) should also be deleted. This statement is redundant inasmuch as the Directions section would require the almost identical statement:

"Children under 12 years of age:  
Do not use unless directed by a  
doctor." (47 Fed. Reg. 39117)

Arguably, the Directions section will almost inevitably be read before use, while the Warnings section

may not be read by some consumers. Thus, placement of this statement in Directions provides the best assurance that the intended purpose of the statement will be achieved.

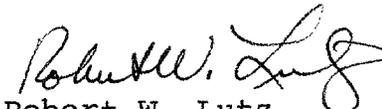
D. Directions

Norcliff believes that proposed 21 CFR 358.50(d)(3) should be rewritten to clarify the term "after treatment is completed". This statement is ambiguous; it could be construed to mean after each individual application of the product, or after the desired therapeutic effect has been achieved, i.e. after using the product for a period of time. Norcliff urges that if this phrase is intended to mean the latter, it should be eliminated for the following reason.

The presence of lentigines is a chronic problem which requires long-term treatment with hydroquinone, the discontinuance of which will lead to their recurrence. While the Panel determined that avoidance of exposure to the sun and the use of sunscreens for an indefinite period of time will help prevent that recurrence, as a practical matter, such measures serve only to delay the inevitable redarkening which naturally results from melanogenesis no longer under the inhibitory effects of hydroquinone. Therefore, Norcliff believes that any statement which implies to the self-medicating consumer with this condition that an end of treatment will be achieved and maintained with the use of sunscreens is scientifically invalid and misleading.

Norcliff appreciates the opportunity to submit its comments to the above-referenced Federal Register notice.

Respectfully,



Robert W. Lutz  
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