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Dockets Management Branch (HFA-305)
Food & Drug Administration
Room 4-62
5600 Fishers Lane
Rockville, Maryland 20 857
UNITED STATES OF AMERICA

PO Medunsa 0204
Rep of South Africa
Tel (012) 58 2844 54 11011
Tel Ad Medunsa
Teletex 350079--MEDUNI
Telex 320580 SA
PK Medunsa 0204
Rep van Suid-Afrika
Tel (012) 58 2844 54 11011
Tel Ad Medunsa
Teleteks 350079--MEDUNI
Teleks 320580 SA

Dear Sir/Madam

COMMENTS ON TENTATIVE FINAL MONOGRAPH : SKIN BLEACHING PRODUCTS
FOR O-T-C HUMAN USE (21 CFR Part 358 : Docket No 78N-0065)

In terms of the above document, hydroquinone 1,5 to 2,0% appears as "active ingredient" (358.10). Since the tentative monograph was published however, a number of papers have appeared in the literature which indicate that the allowed concentrations of hydroquinone are not safe. In particular I draw your attention to the following reports on ochronosis which resulted from the use of skin bleaching preparations

1. Hoshaw R A, Zimmerman K G and Menter A, 1985, "Ochronosis-like pigmentation from hydroquinone bleaching creams in American Blacks", Arch Dermatol, 121, 105-108

**This paper implicates 2% hydroquinone-containing
preparations**

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2. Phillips U I, Isaacson J

in Black South Africans who used skin lighteners", Am J Dermatopath, 8, 14-21

This study was carried out when products containing

>2% hydroquinone were no longer available

3. Tidman M J, Horton J J and MacDonald D M, 1986, "Hydroquinone-induced ochronosis - light and electron-microscopic features", Clin Exp Derm, 11, 224-228

This paper implicates a 2% hydroquinone-containing product

4. Lawrence N, Bligard C A, Reed R and Perret W J, 1988, "Exogenous ochronosis in the United States", J Am Acad Derm, 18, 1207-1211

The 2 cases cited both implicate 2% hydroquinone-containing preparations

In view of these papers and a number of others which describe leucoderma as a consequence of the use of skin bleaching preparations, would it not now be advisable to reconsider the whole monograph, more especially the use of hydroquinone as the active ingredient

Thank you

Yours faithfully


PROFESSOR R S SUMMERS
HEAD : SCHOOL OF PHARMACY

23 November 1988

RSS/cm