

T I D E W A T E R D E R M A T O L O G I C A L S O C I E T Y

December 22, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

Subj: DOCKET NUMBER 1978N-0065

Dear Sir or Madam:

On behalf of the approximately fifty physician members of the Tidewater Dermatological Society, an academic society of dermatologists from the Tidewater Virginia area, I am writing to comment upon the proposal to remove the Generally Accepted as Safe and Effective category from OTC hydroquinone products. We believe that the implications of such a change are great and may significantly limit access to a very valuable drug for our patients afflicted with disfiguring hyperpigmentation, many of whom are ethnic minorities.

We recognize that there is concern about the potential for carcinogenicity in found in laboratory animals fed large oral doses of the drug. Additionally valid concerns exist regarding the potential for cutaneous ochronosis based upon international data. but with over fifty years of experience of clinical use in the United States, dermatologists have noted extremely few side effects. All drugs must be evaluated with a view towards risk and benefit. If the medication is considered only cosmetic, then no risk would be tolerated. However, dyschromia can be disfiguring and socially isolating in the same way as acne and therefore carries a medical burden. It seems that when facial dyschromia is considered in this light, the risk to benefit ratio greatly favors continuation of hydroquinone and a Generally Accepted as Safe and Effective Drug. Please also consider:

- Eliminating safe, effective, readily accessible and affordable OTC hydroquinone products is injurious to millions of dyschromia patients particularly those from minority groups who are less likely to see a dermatologists for treatment.
- Requiring a new drug application for all prescription hydroquinone products would severely limit treatment for more severe dyschromias.
- In marked contrast to the African experience, in the United States, exogenous ochronosis is a remarkably uncommon adverse event from the use of hydroquinone containing products, and the exceedingly low risk does not support removal from the market.
- The association of cancer in humans from the use of hydroquinone is unproven and existing animal data do not support removal of these products from the market.

After consideration of the available data a the FDA proposal, a resolution expressing the sense of the Society was passed unanimously by the present members at the December 12, 2006 meeting which opposed the current proposal and which urges restraint by the FDA in limiting access to this valuable drug.

Please do not hesitate to contact me with any questions at JSAnthony@VBDERM.COM or at 757.481.4422. Thank you for your kind attention.

Sincerely

A handwritten signature in black ink, appearing to read "John S. Anthony", enclosed within a hand-drawn oval.

John S. Anthony, M.D.
President