

December 22, 2006

Food and Drug Administration
Attn: Division of Dockets Management
5630 Fishers Lane, Room 1061, HFA-301
Rockville, MD 20852

DOCKET NUMBER: 1978N-0065, RIN 0910-AF53
Against Proposed Change in HQ Use

I am writing to express my sincere concern over FDA's proposal to ban hydroquinone formulations. As a long-time dermatological researcher and dermatopharmacologist, I do not support this ban and encourage FDA to allow use of hydroquinone as it is currently being used, in accordance with the OTC monograph and as a prescription for concentrations exceeding 2%.

It appears the main concerns of FDA is the risk of ochronosis following topical application of hydroquinone. Research has shown that this risk is extremely rare and is usually related to use of high concentrations of hydroquinone in combination with extreme sun exposure. The concentrations allowed by the OTC monograph (2%), and those of prescription products (up to 4%), are generally not associated with ochronosis, particularly in the United States with consumer awareness and more limited sun exposure relative to other countries.

I have been informed that NeoStrata company had worldwide sales of over 1.8 million units of 2% hydroquinone skin lightening products over the past years. The adverse event data revealed fewer than 5 cases of reported mild pigment darkening, and these cases had been resolved upon discontinuing usage. This represents an incidence rate of less than 0.001 percent. It is known that post-inflammatory pigment darkening can result in prone individuals following topical application of any product that irritates the skin, and they suspect that these few cases merely reflect some sort of irritation response that likely resolved themselves upon discontinuation of use, similar to other cases of post-inflammatory hyperpigmentation.

Hydroquinone is one of the most effective chemical substances for the treatment of dark discoloration over the past 40-50 years and has been used in millions of people. It is used to treat the top concerns among patients including melasma, lentigines, photo-aging, post-inflammatory hyperpigmentation, medically and cosmetic disfiguring dyschromias. Furthermore, since 1961, hydroquinone has demonstrated a safe and effective profile among clinicians prescribing or recommending hydroquinone products. In spite of humans' exposure to natural sources of hydroquinone in wheat, pears, berries, coffee, tea, onions, rice and red wine, there is not an association with carcinogenicity. There have been no reported cases of related malignancies in more than 50 years of manufacture and use of HQ.

In summary, based upon my extensive experience in dermatological research and skin biochemistry, I strongly urge FDA to reconsider its proposed ban of hydroquinone. It has an important place in the treatment of medically relevant skin dyschromias, and should remain available to all patients via both OTC and Rx distribution.

Sincerely,

Ruey J. Yu, Ph.D., O.M.D.