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Department of Dermatology

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

To Whom It May Concern:

In August, the Food and Drug Administration (FDA) proposed a rule change to over-the-counter (OTC) skin bleaching products containing hydroquinone based on new evidence of carcinogenicity in rats and mice. Therefore, the FDA stated that it cannot rule out the potential carcinogenic risk from topically applied hydroquinone in humans. In addition, the FDA cited hydroquinone as having been shown to cause ochronosis after use of concentrations as low as 1 to 2 percent. Based on these data, the FDA has tentatively concluded that there is no health benefit of OTC skin bleaching products that would justify their continued marketing.

The FDA also stated that skin bleaching products sole purpose is for cosmetic improvement. Consequently, the health risks outweigh the benefits. Therefore, the FDA's position is that OTC hydroquinone products are no longer recognized as safe and effective and their use cannot be justified. The FDA proposed that hydroquinone in skin bleaching products be restricted to prescription use only, and users of such products should be closely monitored under medical supervision.

As a member of the American Society for Dermatologic Surgery (ASDS) I oppose the FDA's proposed rule changes for the following reasons:

- Dermatologists frequently use hydroquinone-containing products both to treat and prevent post inflammatory hyperpigmentation, which is common after resurfacing procedures in darker skin types.
- Abnormal pigmentation of the skin, also known as dyschromia, is an important cutaneous disorder with significant patient morbidity.
- Dyschromias affect millions of Americans including those from minority groups including African Americans, Latinos, and Asians.
- Treatments for dyschromias, whether self-treatment by patients with OTC hydroquinones or by dermatologists with prescription hydroquinones, should not be denied to the American population.
- 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.

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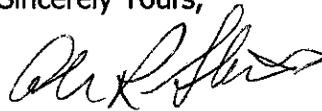
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- In marked contrast to the African experience, in the United States, exogenous ochronosis is a remarkably uncommon adverse event from the use of hydroquinone containing products, and the exceedingly low risk does not support removal from the market.
- 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.

As a practicing dermatologist who regularly treats dyschromia patients with hydroquinone products, I strongly believe the FDA has underestimated the health benefit of OTC and prescription hydroquinone treatments.

I urge the FDA to reconsider its position on withdrawing OTC and limiting prescription hydroquinone treatment. If this proposal is passed it will have deleterious effects for dyschromia patients. The action is in many respects punitive in nature for dyschromia patients and is potentially inequitable for patients of various minority groups.

Sincerely Yours,



Alan R. Shalita, M.D.
Distinguished Teaching Professor &
Chairman

ARS:bhr