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December 7, 2006

Food and Drug Administration
Attention: Division of Dockets Management
5630 Fisher Lane, Room 1061HFA-301
Rockville, Maryland 20852

Dear FDA:

It has come to my attention that the FDA plans to change the status of over the counter (OTC) hydroquinone to prescription only. Because I believe that such an action is both unwarranted and against the best interest of patients, and particularly effects individuals who are disadvantaged and that there is no factual basis for such an action, I am writing to you.

My opinions about the errors of such an action are based on my more than thirty years as an academic dermatologist, my service as a member of the FDA dermatologic and ophthalmologic drugs advisory committee including service as chair person from August 2001 to August 2004, and my knowledge of cutaneous medicine based on my years of clinical work and research.

I feel it is very likely that the proposed action is contrary to patients' best interest. I believe that before such a purposed rule is adopted, at the very least, an advisory committee meeting to fully consider the implications and scientific basis for the purposed action is warranted. To the best of my knowledge, I have no conflict of interest with respect to the above matter.

I hope that the FDA will reconsider its proposed actions.

Sincerely yours,

Robert S. Stern, M.D.

cc: Dr. Michael Bigby

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