



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

96 SEP 25 PM 12:52

Food and Drug Administration
Rockville MD 20857

Harold Minus, M.D.
Professor, Former Chairperson
Howard University
2400 6th Street NW
Washington, D.C. 20059

RE: Docket No. 78N-0655

Dear Dr. Minus:

This letter is in response to your letter of May 22, 1996 regarding the safety of hydroquinone as an over-the-counter (OTC) drug for the treatment of hyperpigmentation. Thank you for sharing your views and clinical experience with us. I have directed that your letter be made part of the official record for this rulemaking.

We note your experience that patients' desire to remove "ugly disfiguring dark spots" often outweighs their concern over other dermatologic problems and appreciate your sharing your experience regarding the challenges of treating hyperpigmentation.

We greatly appreciate your sharing your views and experience regarding the long and extensive safe use of hydroquinone in OTC drugs in the United States and the relative rarity of reported cases of hydroquinone induced ochronosis. We also appreciate your sharing your views with respect to the benefits and risks of continued OTC availability of hydroquinone.

We are currently in the process of evaluating all submitted data concerning both the question of ochronosis and other potential risks of hydroquinone. We hope to be able to clearly address and answer these potential safety questions in the very near future. Until we can more clearly determine the extent of the risk, we cannot completely assess the benefit-risk of hydroquinone availability.

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Thank you again for your interest and for sharing your experience and expertise.

Sincerely yours,



Debra Bowen, M.D.

Director

Division of OTC Drug Products

Office of Drug Evaluation V

Center for Drug Evaluation and Research