



Dobbs

Food and Drug Administration
Rockville MD 20857

JUN 24 1992

Joan A. Kuriansky
Executive Director
Older Women's League
666 11th Street NW, Suite 700
Washington, DC 20001

Dear Ms. Kuriansky:

Your letter dated May 19, 1992, addressed to Dr. David Kessler, Commissioner, Food and Drug Administration (FDA), was directed to our office for response. In your letter, you express your organization's support for FDA's review of 2% hydroquinone skin bleaching drug products, because these products are used by many older women. You state that your organization believes it is important that consumers' input be included in the review and you are hopeful that skin bleaching drug products will continue to be available over-the-counter (OTC).

The FDA is currently reviewing all available scientific data on the safety of hydroquinone, including data regarding hydroquinone's history of safety and effectiveness and hydroquinone's medicinal importance to the consuming public. The FDA's future policy on OTC hydroquinone skin bleaching drug products is expected to be published in the FEDERAL REGISTER later this year. At that time, all interested persons will be invited to submit comments regarding the FDA's proposed actions. I have directed that your letter be included in the administrative record for the agency's current rulemaking for OTC skin bleaching drug products.

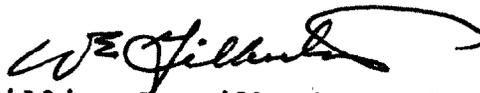
For your reference, I have enclosing a recent letter sent to the Office of OTC Drug Evaluation from Dr. Denese O. Shervington, Chairwoman of the International Coalition of Women Physicians, Inc. In this letter, Dr. Shervington urges that the recent safety concerns surrounding the use of hydroquinone skin bleaching products in African Americans be dealt with scientifically, based on accurate and sound medical evidence. She also expresses concern about the inappropriate use of these products in the African American community, although she does not address misuse by any specific age group.

78N-0065

*D
C20 /ANS*

Thank you for letting the agency know your league's views.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "W.E. Gilbertson".

William E. Gilbertson, Pharm. D.
Director, Monograph Review Staff
Office of OTC Drug Evaluation
Center for Drug Evaluation and Research

Enclosure