



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Dobbs

Food and Drug Administration
Rockville MD 20857

JUN 24 1992

Mrs. Frances D. Hooks
National Coordinator
WIN (Women in the NAACP)
4805 Ben L. Hooks Drive
Baltimore, MD 21215

Dear Mrs. Hooks:

Your letter dated May 14, 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 association's concerns about the FDA's review of over-the-counter (OTC) skin bleaching drug products containing hydroquinone. You state that your association believes these products to be both safe and effective because of their long history of medical success and their long history of use by millions of American consumers, the majority being African Americans. Your association also believes it is important that skin bleaching drug products continue to be available 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.

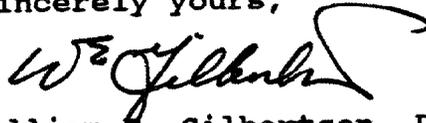
For your reference, I am enclosing a recent letter sent to the Office of OTC Drug Evaluation from Dr. Denese O. Shervington, Chairwoman of the International Coalition of Women Physicians, Inc. In this letter, Dr. Shervington urges that the recent safety concerns surrounding the use of hydroquinone skin 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.

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

Sincerely yours,

A handwritten signature in black ink, appearing to read "W. E. Gilbertson". The signature is fluid and cursive, with a large, sweeping flourish at the end.

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

Enclosure



WIN (Women in the NAACP)
 National Association for the Advancement of Colored People
 4805 Ben L. Hooks Drive - Baltimore, MD 21215 - (410) 358-8900

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Frances D. Hooks
 WIN National Coordinator

May 14, 1992

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 FDH

Dr. David A. Kessler, M.D.
 Commissioner
 Food and Drug Administration
 5600 Fishers Lane
 Rockville, MD 20857

Dear Dr. Kessler:

It has come to our attention that the Food and Drug Administration is reviewing over-the-counter fade creams that contain Hydroquinone.

These creams have been used by tens of millions of American consumers, especially African-American consumers, for over fifty years to treat skin discolorations. Because of the medical success of these products over such a long period of time, and by such a large number of people, we believe them to be both safe and effective.

The recent publicity given Hydroquinone has evidently caused concern within your agency. We believe it is important that these products continue to be available "over-the-counter".

Thank you for your consideration.

Sincerely,

Frances D. Hooks

Mrs. Frances D. Hooks
 National Coordinator
 WIN (WOMEN IN NAACP)

FDH/kw

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"The Struggle Continues..."

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