

The International Coalition Of Women Physicians, Inc.

Recd in Unit
6/30/92

May 12th, 1992

Dr. William Gilbertson, Pharm.D.
Director
Monograph Review Division
Office of OTC Drugs
Food and Drug Administration
7520 Standish Place
Rockville, MD 20855

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Billie Jean Pace, M.D.
Secretary/Treasurer • Orlando, FL

Dear Dr. Gilbertson,

In response to the recent controversy surrounding the use of Hydroquinone bleaching agents in African Americans, I would like to urge that the matter be dealt with scientifically, and not in a politically reactionary manner. African Americans deserve that health policy affecting us be formulated on accurate and sound medical evidence.

The time has come for well designed and controlled scientific studies to be conducted in the African American community to assess the safety of these products. The time has also come for exploration of the inappropriate use of these agents in our community. Given the complex psychocultural determinants of skin color, it is crucial that the African American medical and socio-behavioral community be included and represented in its diversity in this process. As a result of such a process, product manufacturers could market there products, if found to be safe, in a more culturally sensitive and responsible manner.

Yours truly,

Denese O. Shervington M.D.
Chairperson of Board of Directors
International Coalition of Women Physicians



Denese Shervington, M.D. • Chairwoman

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Pesabet (P-2-24-1)
Earliest known woman physician
3rd Dynasty of ancient Egypt

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 3 1992

Denese O. Shervington, M.D.
The International Coalition of Women Physicians, Inc.
4524 Bancroft Drive
New Orleans, LA 70122

Dear Dr. Shervington:

This is in reply to your letter dated May 12, 1992, expressing your concerns about the use of hydroquinone skin bleaching agents by African Americans. In your letter, you urged that present safety concerns regarding use of these products be dealt with scientifically, based on accurate and sound medical evidence.

I fully agree. The Food and Drug Administration is currently reviewing all available scientific data on the safety of hydroquinone, including data regarding appropriate use limitations. The FDA's future policy on OTC hydroquinone skin bleaching agents 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.

Thank you for letting the agency know your views.

Sincerely yours,

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

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