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Food and Drug Administration
Rockville MD 20857

JUN 24 1992

William J. Haskins
Vice President of Programs
National Urban League, Inc.
500 East 62nd Street
New York, NY 10021

Dear Mr. Haskins:

Your letter dated May 18, 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 views on FDA's review of over-the-counter (OTC) skin bleaching drug products containing hydroquinone. You state that the National Urban League believes these products to be both safe and effective because of past medical evidence assembled from over fifty years of use by tens of millions of American consumers. The National Urban League also believes that these products serve an important role by allowing African Americans to treat common instances of hyperpigmentation, and you encourage the continued availability of OTC hydroquinone skin bleaching drug products.

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, especially to the African American 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 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

The International Coalition Of Women Physicians, Inc.

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

Denese Shervington, M.D.
Chairwoman • New Orleans, LA
Arike Logan-Kusald, M.D.
President • Atlanta, GA
Jessie Sherrod, M.D.
Vice-President • Los Angeles, CA
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

4524 Bancroft Drive • New Orleans, LA 70122 • (504) 282-2227

Peseshet (P-s-sh-t)
Earliest known woman physician
3rd Dynasty of ancient Egypt

The International Coalition Of Women Physicians, Inc.

May 12th, 1992

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Chairwoman • New Orleans, LA
Arlke Logan-Kusaldi, M.D.
President • Atlanta, GA
Jessie Sherrrod, M.D.
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Dr. William Gilbertson, Pharm.D.
Director
Monograph Review Division
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Food and Drug Administration
7520 Standish Place
Rockville, MD 20855

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Chairperson of Board of Directors
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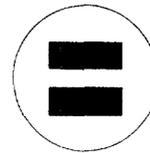
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National Urban League, Inc.

The Equal Opportunity Building
500 East 62nd Street, New York, N.Y. 10021
Telephone (212) 310-9000

May 18, 1992

HPD-500

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

Dear Dr. Kessler:

We understand that the Food and Drug Administration is reviewing the regulatory status of 2% Hydroquinone as the active ingredient in over-the-counter fade creams.

We believe that the medical evidence assembled from over fifty years of use by tens of millions of American consumers indicates that these products are safe and effective. Further, these products serve an important role by allowing African-Americans to treat the very common instances of hyperpigmentation caused by acne scars, razor bumps, mosquito bites, and other skin irritations.

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Dr. David A. Kessler
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May 18, 1992

The National Urban League supports further FDA approved research and encourages the FDA to continue to classify hydroquinone as a Category I (generally recognized as safe and effective) drug and to continue to permit hydroquinone to remain available in its present over-the-counter status.

Sincerely,



William J. Haskins
Vice President
Programs

WJH/nh

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE:

FROM: Director
Monograph Review Staff (HFD-810)

SUBJECT: Material for Docket No. 78 IV - 0065

TO: Dockets Management Branch (HFA-305)

- The attached material should be placed on public display under the above referenced Docket No.
- This material should be cross-referenced to Comment(s) No. _____.



William E. Gilbertson, Pharm. D.

Attachment