

# CONSUMER AFFAIRS

MANAGEMENT BRAND

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MARK GREEN  
COMMISSIONER

February 11, 1992

David A. Kessler, M.D., Commissioner  
Food and Drug Administration  
5600 Fisher's Lane  
Rockville, Maryland 20857

Dear Dr. Kessler,

The New York City Department of Consumer Affairs urges the FDA to act quickly to seize and then ban eleven skin-bleaching creams that are marketed primarily to African-Americans.

The products in question are Esoterica Regular, Artra Skin Tone Cream, Dr. Fred Palmer Ultra Bland and Tone, Dr. Fred Palmer Skin Whitener, Ambi Skin Tons Cream, Palmer's Skin Success, Porcelana Medicated Fade Cream, Porcelana Medicated Fade Cream Sunscreen Formula, Venus de Milo Complexion Cream, and Shirley Skin Litenor Cream. All contain hydroquinone (HQ) as the active ingredient.

Recent studies indicate that these products may be carcinogenic and can cause disfiguring skin diseases. In addition, my agency has just prepared its own report, "A Study in Hype and Risk: The Marketing of Skin Bleaches" (copy enclosed), which shows these skin care products to be blatantly mislabeled.

Specifically, these creams are variously advertised or labeled as able to "even skin tone," "brighten" the complexion, "remove pimples," "moisturize" the skin or function as "a make-up base." The truth is, the proper use of these over-the-counter skin bleaches should be limited to merely lightening certain darker areas of the skin. Skin bleaches must also be used with a sunscreen--usually not included in the product--to prevent the skin from redarkening and they must be used continuously, material facts that bleach packaging often fail to disclose. Some product packaging fails to indicate the level of HQ at 2% or less. Such deficient labeling may indicate a level of the active ingredient in violation of safety levels established by your agency.

The misleading, deficient and false labeling and directions on these products violate provisions of both the Federal Food, Drug, and Cosmetics Act (FDCA) and the Fair Packaging and Labeling Act (FPLA). Under the FDCA, 21 U.S.C.A., Section 334, the FDA has the power to seize any drug that is misbranded.

NEW YORK CITY DEPARTMENT OF CONSUMER AFFAIRS • 42 BROADWAY • NEW YORK, NEW YORK 10004 • TEL (212) 487-4444

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In 1978, recognizing a special problem in this area, your agency began the lengthy process of issuing specific regulations for skin bleach labeling. But under the Reagan/Bush Administrations, these proposed regulations gathered dust on a back shelf.

After more than ten years, the FDA was finally set to issue the labeling regulations this month. But now your agency talks of delaying issuance because of a 1989 study by the National Toxicology Program of the U.S. Department of Health and Human Services which suggests that HQ could be carcinogenic.

As our report points out, other studies link HQ to a skin condition, exogenous ochronosis, with symptoms of permanent, dark blue-black spots. In light of such information, the South African government banned the over-the-counter sale of HQ skin bleach in 1990. Because of serious concerns that skin bleaches can lead to a disfiguring skin disease and may be carcinogenic, the Department of Consumer Affairs is asking the FDA to ban HQ-based skin bleaches until all safety concerns have been resolved.

The time for the FDA to act is now. I am fully aware that President Bush is attempting to order a 90-day moratorium on new regulations, possibly further delaying the issuance of specific skin-bleach packaging. But the FDA does not need to promulgate additional regulations to seize these dangerously misbranded products because they clearly violate the more general provisions of the FDCA and the FPLA.

Last year, you seized "Fresh Choice" orange juice because its improper use of the word "fresh" constituted misbranding. Certainly, an even more serious misbranding is now occurring with these eleven skin bleach creams. Following seizure, the NYC Department of Consumer Affairs urges an FDA ban on all HQ-based skin bleaches until future studies establish the safety of that suspect chemical.

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Sincerely,

*Mark Green*

Mark Green  
Commissioner



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date . 2-19-92

From Director  
Division of OTC Drug Evaluation (HFD-210)

Subject: Material for Docket No. 78W-0065

To Dockets Management Branch (HFA-305)

The attached material should be placed on public display under the above referenced Docket No. *Three separate letters to go under the above Docket 100.*

This material should be cross-referenced to Comment \_\_\_\_\_.

William E. Gilbertson, Pharm. D.

Attachment