



# THE CITY OF NEW YORK

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Michael R. Bloomberg  
Mayor

Thomas R. Frieden, M.D., M.P.H.  
Commissioner

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United States Food and Drug Administration  
Silver Spring, Maryland

Comments from the New York City Department of Health and Mental Hygiene on FDA's  
Proposed Rule: Skin Bleaching Drug Products for Over-the-Counter Human Use

The New York City (NYC) Department of Health and Mental Hygiene (DOHMH) is writing to comment on the Federal Drug Administration's (FDA) proposed rule to ban over-the-counter (OTC) skin bleaching products because these products are not "Generally Recognized As Safe and Effective" (GRASE) and are misbranded. This new rule will also require *all* skin bleaching drug products, even those currently marketed on a prescription basis, to undergo new drug application approval for continued marketing. The DOHMH supports FDA's decision to limit access to these products and is in agreement with the agency's proposed approach. In addition to our agreement in the inherent lack of adequate safety of hydroquinone, we write to suggest that there are likely to be important secondary benefits from the removal of skin lightening creams for OTC store shelves.

The New York City Health and Nutrition Examination Survey (NYC HANES), conducted in 2004, evaluated mercury exposure among a representative group of 2,000 adult New Yorkers. This survey discovered a significant number of people who had elevated urine mercury levels due to the use of mercury-containing skin lightening products illegally imported, but nonetheless available in many New York City beauty supply stores. An intensive investigation by DOHMH ultimately discovered seven mercury containing skin lightening products sold in New York City.

At NYC's request, the FDA's laboratory analyzed the mercury content of several of the products. The products' mercury content ranged from 4,700 to 41,600 parts per million; equivalent to 0.47% mercury to 4.16% mercury. (See Table 1, attached). A total of 12 participants, out of approximately 2,000 total participating in the survey, had significantly elevated urine levels attributable to the use of mercury containing skin lightening creams. Because NYC HANES drew a representative sample of the entire adult population of NYC, these numbers suggest that as many as 24,900 New York City adult residents may have had elevated mercury level due to use of mercury containing skin lightening products.

During our intensive store investigation and enforcement actions, DOHMH determined that the majority of skin lightening products sold on stores shelves listed hydroquinone (of

differing percentages) as the active ingredient. Several manufacturers produced products with similar product names but with different active ingredients.

DOHMH believes that the availability of legal OTC skin lightening creams enables illegal products to continue to be sold without notice or consumer concern. The implied safety of OTC products reinforces the already questionable ability of consumers to read and understand labels to determine whether products are legal, or illegal for sale. Our interviews with people with elevated mercury levels from the use of skin lightening creams also revealed that many use skin lightening products over significant portions of their body (e.g., entire backs, face and necks, arms and legs), with great frequency (e.g., twice daily) and for long periods of time (e.g., several years). This wide variability in quantity, frequency and duration of use demonstrates that an approach that aims to limit exposure based on limiting the permitted percent of an active ingredient is inadequate to limit actual exposure to any purportedly safe level.

Children are also unintentionally exposed to hydroquinone from the presence of these products. A review of calls between January 2000 and September 2006 to the NYC Poison Control Center found 26 calls reporting exposure to “skin-lightening” products or “hydroquinone”. While not a large number of calls, more than half of these reports were for exposure to children (younger than 5 years old) who had accidentally ingested these products. We reiterate that the implied safety of these products by their legal presence on beauty store shelves keeps consumers from recognizing their potential health hazards.

In summary, the NYC DOHMH agrees with FDA’s proposed approach to limit access to skin lightening products by removing them from OTC availability for reasons that acknowledge the inherent unsafe qualities of hydroquinone, but also for the likely secondary benefit of ensuring that mercury-containing skin lightening creams do not find their place next to legal products on stores shelves. A complete prohibition on OTC sale will make it easier for store owners to ensure that no skin lightening products appear on their shelves, and for DOHMH and other health and consumer product enforcement agencies to identify illegal products available for sale. We also recommend to FDA that following its adoption of this proposed regulation, it promote public awareness among importers, distributors and retail store owners to ensure compliance.

Thank you for the opportunity to comment on the proposed amendment. If you have any questions, please contact me at 212-442-2638, or by email at [dkass@health.nyc.gov](mailto:dkass@health.nyc.gov).

Sincerely,

/s/

Daniel Kass

Assistant Commissioner

Bureau of Environmental Surveillance and Policy

New York City Department of Health and

Mental Hygiene

**Table 1 Skin-Lightening products sold in New York City containing mercury**

<b>Name of Product</b>	<b>Manufacturer</b>	<b>Place of manufacture</b>	<b>Active Ingredient</b>	<b>Mercury (ppm)</b>
Crema Santa Germicida	Lab. Lobefer	Dominican Republic	Unknown	4,700
Crema Santa	Laboratorios Contifarma, C. por A.	Dominican Republic	Mercury oxide	6,200
Miss Key Crema	Blanqueadora Laboratorios Key, C. por A. R.I.	Dominican Republic	Amide Chloride of Mercury	9,100
Dermaline Skin Whitening Cream	Leivon Cosmetics, Inc. Div. of Laboratorios Contifarma, C. por A.	Dominican Republic	no mercury listed	13,600
Magia Blanca de Michelle Marie Crema Blanqueadora	Productos Portela, SA	Unknown	Unknown	18,500
Dermaline Skin Cream	Leivon Cosmetics, Inc. Div. of Laboratorios Contifarma, C. por A.	Dominican Republic	Amide Chloride of Mercury	21,100
Recetas de la Farmacia Normal--Crema Blanqueadora	Infaca for Farmacia Normal	Dominican Republic	Ammoniated mercury	41,600