

December 19, 2006

**VIA CERTIFIED MAIL/
RETURN RECEIPT REQUESTED**

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

**Re: Request for Extension of Time to Comment
Docket No. 1978N-0065 (RIN Number 0910-AF53)**

Dear Madam/Sir:

We write to request an extension of the comment period regarding the U.S. Food and Drug Administration's ("FDA") proposal that: (1) withdraws the tentative final monograph ("TFM") on skin bleaching drug products for over-the-counter "OTC" human use; and (2) would establish that all skin bleaching drug products (including those containing hydroquinone) are not generally recognized as safe and effective (GRAS/E) and are misbranded. Presently, the comment period is scheduled to end on December 27, 2006. We respectfully request that this period be extended until March 27, 2007 to ensure that all interested parties have sufficient time to assess the evidence relied upon by the agency.

As FDA notes, the effective withdrawal of the TFM and proposal that would prohibit the OTC sale of skin bleaching drug products containing hydroquinone would have a significant impact on sixty-five (65) manufacturers who produce in excess of one hundred products. In addition, removing these products from the marketplace will significantly impact the several thousand consumers who have safely used these products for generations to obtain a benefit not provided by any other substance.

The FDA's proposal is based upon "new data" from more than thirty (30) studies. The 120-day comment period, which ends on December 27, 2006, is not enough time to assess and comment upon these studies and to provide the agency with a comprehensive safety assessment prepared by independent experts with relevant expertise in the field. The agency has had several

78N-0065

EXT 4

FDA
December 19, 2006
Page 2 of 2

years to consider this data. Interested members of the public, patients, clinicians and businesses all should be provided more than three months to consider the adequacy of the data.

Given the impact upon all of these interested parties, the absence of alternative products, and the extensive data relied upon by the agency, we respectfully request that FDA extend the date by which comments are due until March 27, 2007.

Respectfully,



Claudia A. Lewis-Eng
Todd H. Halpern