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NONPRESCRIPTION DRUG MANUFACTURERS ASSOCIATION

March 30, 1992

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

Dear Dr. Gilbertson:

Further to our conversation concerning our request for a meeting with FDA on hydroquinone and your scheduling the meeting for April 8, 1992, I would like to request on behalf of NDMA's Hydroquinone Task Group a brief postponement of the meeting until later in April or early in May, 1992.

The reasons for this request stem from our understanding that the meeting will likely extend into areas pertaining to hydroquinone's safety that are beyond the specifics of the NTP study and our research plans related to that study. We therefore want to involve additional expert consultants, who are not available for April 8. Our task group very strongly believes that it would be appropriate to extend the date for a meeting with FDA so that all of the issues pertaining to hydroquinone can be fully elaborated. We then could have greater assurance that all of our consultants will be able to attend the meeting and that we will be able to provide the agency with specific materials before the meeting which are pivotal to a discussion of hydroquinone.

I look forward to your response. The meeting dates that we would like the agency to consider are April 28 or 30, 1992 or May 1 or 5, 1992. We urge that this meeting take place before the agency finalizes its review of hydroquinone as an OTC skin lightening ingredient.

Sincerely yours,

R. William Soller, Ph.D.
Senior Vice President and
Director of Science & Technology

78N-0065

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

DATE: 4-2-92

FROM: Director
Monograph Review Staff (HFD-810)

SUBJECT: Material for Docket No. 78N-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. _____.

W. E. Gilbertson

William E. Gilbertson, Pharm. D.

Attachment