



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Rockville MD 20857

MAR 23 2004

E. Edward Kavanagh  
The Cosmetic, Toiletry, and Fragrance Association  
1101 17th Street, N.W., Suite 300  
Washington, D.C. 20036-4702

Re: Docket No. 78N-0064  
Comment No. PRC1

Dear Mr. Kavanagh:

This is in reference to your petition (PRC1) dated July 8, 2003, filed under Docket No. 78N-0064 in the Division of Dockets Management. The petition requests that FDA reconsider and stay two provisions of the Final Monograph for Antiperspirant Drug Products for Over-the-Counter Human Use. Those provisions are: (1) the 24-hour limitation on a duration claim for antiperspirants; and (2) the requirement that the following warning appear on the label of antiperspirant products in an aerosolized dosage form: "When using this product [bullet] keep away from face and mouth to avoid breathing it."

The procedures governing the review of citizen petitions are set out in regulations found at 21 CFR 10.30. The regulations provide, among other things, that the Commissioner shall furnish a response to a petition within 180 days of the petition, as FDA resources and priorities permit. [See 21 CFR 10.30(e).] This is to advise you, pursuant to 21 CFR 10.30(e)(2), that because other priorities exist, FDA is unable to provide a response to the petition at this time. We have also received another petition concerning the 24-hour duration claim limitation and will respond to both petitions at the same time.

If you have any questions regarding this matter, please refer to the docket and comment numbers noted above and submit 3 copies of all inquiries to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, Maryland 20852.

Sincerely yours,

Steven Galson, M.D.

Acting Director

Center for Drug Evaluation and Research

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

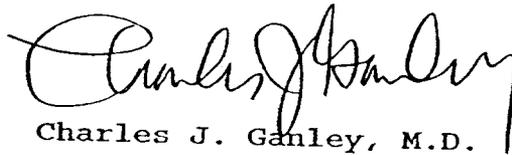
DATE: MAR 23 2004

FROM: Director  
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 78N-0064

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 No. PRC 1

  
Charles J. Ganley, M.D.

Attachment