



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

SEP 25 2002

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

Re: Docket No. 78N-0064/CP4

Dear Mr. Kavanaugh:

This is in reference to your citizen petition (CP4) dated April 11, 2002, filed under Docket No. 78N-0064 in the Dockets Management Branch. The petition requests, among other things, that the Agency amend the tentative final monograph for over-the-counter (OTC) antiperspirant drug products to permit the use of modified labeling in order to comply with the requirements of the general OTC drug products labeling regulation (21 CFR 201.66) for antiperspirant drug products. In the alternative, the petition requests that the agency "reopen the final monograph to consider the relief requested" if the agency publishes a final OTC antiperspirant drug products monograph before acting on the petition.

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, agency resources and priorities permitting. See 21 CFR 10.30(e). This is to advise you, pursuant to 21 CFR 10.30(e)(2), that because of the existence of other priorities, the Agency is unable to provide a response to the petition at this time.

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

Sincerely yours,


for Janet Woodcock, M.D.

Director
Center for Drug Evaluation and Research

78N-0064

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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:

9/30/02

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. CP4


Charles J. Ganley, M.D.

Attachment