DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

OCT 28 2003

Patricia Saunders
10401 Grosvenor Place
North Bethesda, Maryland 20852

RE: Docket No. 78N-0064
Comment No. CP3

Dear Ms. Saunders:

This letter is in response to your citizen petition of December 21, 1992 on over-the-counter (OTC) antiperspirant drug products. Your petition was filed as CP3 under Docket No. 78N-0064 in the Dockets Management Branch (now the Division of Dockets Management).

In your petition, you requested that the Food and Drug Administration (FDA) take the following actions: (1) revoke its decision in the tentative final monograph to reclassify aerosol dosage forms of aluminum chlorohydrate antiperspirants from Category III to Category I, (2) reclassify non-aerosol dosage forms of aluminum-containing antiperspirants to Category III in order to permit a reevaluation of their potential for skin absorption or toxic systemic effects following long-term use, and (3) revise and expand the proposed warning for aluminum-containing aerosols that states "avoid excessive inhalation" in order to better clarify the safety concern.

In the FEDERAL REGISTER of June 9, 2003 (68 FR 34273), FDA published a final rule establishing a monograph for OTC antiperspirant drug products as generally recognized as safe and effective (copy enclosed). The safety issues raised by your petition are discussed in this final rule. By publishing this final rule, FDA has completed action on your citizen petition and does not intend to take any further action on the petition.

If you have any comments on the final rule, please reference the docket number above and submit them to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

Sincerely yours,

John M. Taylor, III
Associate Commissioner
for Regulatory Affairs

Enclosure

78N-0064

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

DATE: OCT 28 2003

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

SUBJECT: Material for Docket No. 78N-0064

TO: Dockets Management Branch, HFA-305

[X] The attached material should be placed on public display under the above referenced Docket No.

[X] This material should be cross-referenced to Comment No. CP3

Charles J. Ganley, M.D.

Attachment