



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

MAR 16 2004

Thomas J. Donegan, Jr.
Vice President-Legal & General Counsel
The Cosmetic, Toiletry, and Fragrance Association
1101 17th St., N.W. Suite 300
Washington, D.C. 20036-4702

Re: Docket No. 78N-0038
Comment No. CP15

Dear Mr. Donegan:

This is in reference to your citizen petition (CP15) dated August 22, 2003, filed under Docket No. 78N-0038 in the Division of Dockets Management. The petition requests that FDA reopen the administrative record of the Final Monograph for Over-the-Counter Sunscreen Drug Products, 21 CFR Part 352, Subpart C and D. Your petition purports to provide scientific rationale why FDA should not restrict the labeling of high SPF sunscreen products that meet the testing requirements in the Final Monograph.

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.

If you have any questions regarding this matter, please refer to the docket and comment numbers noted above and submit all inquiries to the Division of Dockets Management (HFD-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

78N-0038

LET 178

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 16 2004

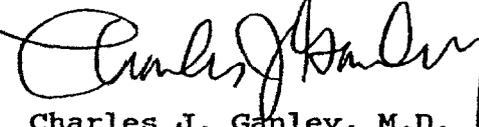
FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 78N-0038

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. CP15


Charles J. Ganley, M.D.

Attachment