



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

MAY - 5 2004

Dennis L. Lott
Vice President-Technical Affairs
Tanning Research Laboratories, Inc
1190 U.S. Highway 1 North
Ormond Beach, Florida 32174

Re: Docket No. 78N-0038
Comment No. CP16

Dear Mr. Lott:

This is in reference to your citizen petition (CP16) dated October 14, 2003, filed under Docket No. 78N-0038 in the Division of Dockets Management. The petition requests that the Commissioner of Food and Drugs amend 21 CFR Part **352**, Sunscreen Drug Products for Over-The-Counter Human Use. Specifically this petition requests the FDA to remove the maximum SPF value on sunscreen products, or raise the limit for SPF values.

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,

A handwritten signature in black ink that reads "Steven Galson".

Steven Galson, M.D.
Acting Director,
Center for Drug Evaluation and Research

78N-0038

LET179