DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 13 2007

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Emil A. Tanghetti, M.D.
Center for Dermatology and Laser Surgery
5601 J Street
Sacramento, California 95819

Re: Docket No. 2006P-0524/CP1

Dear Dr. Tanghetti:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received December 20, 2006. In the petition you raise concerns about the use of Ziana (clindamycin phosphate 1.2% and tretinoin 0.025%). Specifically, you state that Ziana presents safety hazards secondary to the development of antibiotic resistance. You request withdrawal of approval and recall of Ziana or, at a minimum, the initiation of long term safety studies evaluating the incidence and prevalence of antibiotic resistance associated with Ziana usage.

FDA has been unable to reach a decision on your petition because of the need to address other Agency priorities and the complexity of the issues raised by your petition, which require additional review and analysis by the Agency. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2006P-0524 LET2