



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 25 2003

6381 '03 SEP 29 A9:37

David M. Fox
Hogan & Hartson L.L.P.
555 Thirteenth Street, NW
Washington, D.C. 20004

Re: Docket No. 2003P-0140/CP1

Dear Mr. Fox:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your petition dated April 7, 2003, requesting, among other things, that the FDA refrain from approving abbreviated new drug applications for topical mupirocin ointment products where the applicant cannot support all elements of the labeling approved for the reference listed drug, Bactroban Ointment.

FDA has been unable to reach a decision on your petition because it raises issues that 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
Associate Director for Policy
Center for Drug Evaluation and Research

03P-0140

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