DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 11 2006

David L. Rosen, B.S. Pharm., J.D.
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Washington Harbour
3000 K Street, N.W., Suite 500
Washington, D.C. 20007-5143

Docket No. 2006P-0114/CP1

Dear Mr. Rosen:

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 March 15, 2006. You request that FDA refrain from taking administrative action regarding the approval and/or the effective date of final approval of any and all abbreviated new drug applications (ANDAs) for a generic version of Metrogel-Vaginal 0.75% (metronidazole vaginal gel) until certain showings are made by an ANDA applicant.

FDA has been unable to reach a decision on your petition because it raises significant and complex issues requiring extensive review and analysis by Agency officials. 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 possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad

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

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