DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 6 2006

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

Re: Docket No. 2005P-0360/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 submitted on September 6, 2005. Your petition requests that the Agency not approve any abbreviated new drug application citing Miacalcin Nasal Spray as the reference listed drug, or any application submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act that relies on our findings of safety and effectiveness for Miacalcin Nasal Spray, unless certain conditions are met.

FDA has been unable to reach a decision on your petition because it raises 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 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

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