



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

March 16, 2006

FILE COPY

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

Dear Mr. Rosen:

Your petition requesting the Food and Drug Administration to refrain from taking administrative action regarding the approval and/or the effective date of final approval of any and all abbreviated new drug applications for a generic version of Metrogel-Vaginal 0.75% was received by this office on 03/15/2006. It was assigned docket number 2006P-0114/CP1 and it was filed on 03/15/2006. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2006P-0114

ACK 1