



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

September 6, 2005

FILE COPY

Mr. David L. Rosen
Foley and Lardner LLP
3000 K Street, N.W.
Suite 500
Washington, DC 20007-5143

Dear Mr. Rosen:

Your petition requesting the Food and Drug Administration not to approve Abbreviated New Drug Applications (ANDAs) or New Drug Application under 505(b)(2) NDAs for Salmon Calcitonin Products unless certain conditions are met, was received by this office on 09/02/2005. It was assigned docket number 2005P-0360/CP 1 and it was filed on 09/06/2005. 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

2005P-0360

ACK 1