



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

August 10, 2000

Eric M. Mittleberg, Ph.D.
Vice President, Scientific Affairs
Zenith Goldline Pharmaceuticals, Inc.
140 Legrand Avenue
Northvale, NJ 07647

Dear Dr. Mittleberg:

Your petition requesting the Food and Drug Administration to stay the effective approval of any ANDA for Alendronate Sodium Tablets, 5 mg, 10 mg, 40 mg, until effective approval is granted to Zenith Goldline's ANDA 75-711 was received by this office on 08/09/00. It was assigned docket number 00P-1443/PSA 1 and it was filed on 08/10/00. 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,

A handwritten signature in black ink, reading "Lyle D. Jaffe". The signature is written in a cursive style with a large, prominent "L" and "J".

Lyle D. Jaffe
Dockets Management Branch

00P-1443

ACK 1