

Food and Drug Administration Rockville MD 20857

January 30, 2001

Mr. Gary L. Yingling
McKenna & Cuneo, L.L.P.
1900 K Street N.W.
Washington, D.C. 20006-1108

Dear Mr. Yingling:

Your petition requesting the Food and Drug Administration to review and consider the additional information that your client intends to submit within the next 90 days, was received by this office on 01/17/01. It was assigned docket number 80N-0146/PRC 1 and it was filed on 01/10/01. 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.

Lyle D. Jaffe

Dockets Management Branch

80N-0146

ACK 1