



Food and Drug Administration
Rockville, MD 20857

November 16, 2004

Andrew D. Gall
Executive Vice President
ACIC Fine Chemicals, Inc.
81 Sinclair Blvd
Brantford, Ontario, CANADA N3S 7X6

Dear Mr. Gall:

Your Suitability Petition Requesting the Food and Drug Administration to Change from the Reference Listed Drug (New Strength) Methacholine Chloride 1280 mg/vial, was received by this office on 11/16/2004. It was assigned docket number 2004P-0511/CP 1 and it was filed on 11/16/2004. 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,

/s/

Gloria Ortega, Deputy Director
Division of Dockets Management
Office of Management Programs
Office of Management