



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

June 26, 2001

Nicholas M. Fleischer, R.Ph., Ph.D.
Director of Biopharmaceutics
The Weinberg Group Inc.
1220 Nineteenth Street, N.W., Suite 300
Washington, DC 20036-2400

Dear Dr. Fleischer:

Your petition requesting the Food and Drug Administration to make a determination that an Abbreviated New Drug Application may be submitted for Pentoxifylline Extended-release Tablets, 500 mg. was received by this office on 06/26/01. It was assigned docket number 01P-0283/CP 1 and it was filed on 06/26/01. 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.

Sincerely,

Lyle D. Jaffe
Dockets Management Branch

01P-0283

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