DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

September 29, 2006

FILE COPY

Mr. Charles J. Raubicheck
Frommer Lawrence & Haug, LLP
745 Fifth Avenue
New York, New York 1 0151

Dear Mr. Raubicheck:

Your petition requesting the Food and Drug Administration to require all applicants for approval of generic or follow-on formulations of MEGACE ES (megestrol acetate oral suspension 625 mg/5 ml) to conduct bioequivalence studies, under both fed and fasted conditions and to demonstrate bioequivalence to MEGACE ES oral suspension in accordance with FDA's standard bioequivalence criteria, was received by this office on 09/29/2006. It was assigned docket number 2006P-0398/CP 1 and it was filed on 09/29/2006. 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,

Jennie Butler, Director
Division of Dockets Management
Office of Management Programs
Office of Management

2006P-0398

ACK 1