DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 20 2007

1507 7 MAR 22 P3:07

Mr. Charles J. Raubicheck
Frommer Lawrence & Haug LLP
745 Fifth Avenue
New York, NY 10151

Re: Docket No. 2006P-0398/CP1

Dear Mr. Raubicheck:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on September 29, 2006. Your petition requests that the Agency require all applicants for approval of generic or follow-on formulations of MEGACE ES (megestrol acetate oral suspension 625 mg/5ml) 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.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2006P-0398

LET 1