DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

FILE COPY

September 3, 2003

William A. Rakoczy
Lord, Bissell & Brook LLP
115 South LaSalle Street
Chicago, IL 60603

Dear Mr. Rakoczy:

Your petition on behalf of TorPharm, Inc. requesting the Food and Drug Administration to immediately withdraw final approval of Synthon's NDA 21-299 for Asimia (paroxetine mesylate) 10 mg, 20 mg, 30 mg and 40 mg tablets was received by our office on 09/03/2003. It was assigned docket number 2003P-0408/CP 1 and it was filed on 09/03/2003. 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 procedure matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management

2003P-0408

ACK1