DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 28 2003

Peter S. Reichertz, Esq.
Sonnenschein Nath & Rosenthal
1301 K Street, N.W.
Suite 600 East Tower
Washington, D.C. 20005

Re: Docket No. 02P-0431/CP1

Dear Mr. Reichertz:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your petition received on October 1, 2002. Your petition requests that FDA determine whether Delcobese (amphetamine adipate, amphetamine sulfate, dextroamphetamine adipate, dextroamphetamine sulfate) tablets and capsules were withdrawn from sale for safety and efficacy reasons.

FDA has been unable to reach a decision on your petition because it raises issues that require additional review and analysis by the Agency. 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 we have reached a decision on your request.

Sincerely yours,

For Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

02P-0431

LET2