DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

305

JAN 25 2006

1906 6 JAN 27 P1:47

Jasmine Shah, M.S., R.Ph.
Director, Regulatory Affairs
Amide Pharmaceutical, Inc.
101 East Main Street
Little Falls, NJ 07424

Re: Docket No. 2005P-0300/CP1

Dear Ms. Shah:

I am writing to inform you that the Food and Drug Administration (FDA or Agency) has not yet resolved the issues raised in your citizen petition dated July 28, 2005, submitted on behalf of Amide Pharmaceutical, Inc. Your petition requests that the Agency determine whether Phenergan (promethazine hydrochloride) tablets, 12.5 mg and 50 mg, were voluntarily withdrawn from sale for reasons other than safety or effectiveness.

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 we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

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

2005P-0300

LET 1