DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 23 2007

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Kalpana Rao
GVP, Regulatory Affairs (Global)
Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Drive
Hawthorne, NY 10532

Re: Docket No. 2006P-0446/CP1

Dear Ms. Rao:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated October 31, 2006. Your petition requests that FDA determine whether it is suitable to file an abbreviated new drug application based on the reference products Phenergan (promethazine hydrochloride) Suppositories, USP, 12.5 milligrams (mg) and 25 mg, that were voluntarily withdrawn from sale by Wyeth Pharmaceuticals, Inc.

FDA has been unable to reach a decision on your request because of 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 yours,

Jane A. Axelrad

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

2006P-0446

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