



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

November 1, 2006

**FILE COPY**

Kalpana Rao  
Taro Pharmaceuticals USA, Inc.  
3 Skyline Drive  
Hawthorne, New York 10532

Dear Mr. Rao:

Your petition requesting the Food and Drug Administration to make a determination of ANDA Suitability for Phenergan Promethazine Hydrochloride Suppositories USP, 12.5 mg and 25 mg, were voluntarily withdrawn from sale for reasons other than safety and effectiveness, was received by this office on 11/01/2006. It was assigned docket number 2006P-0446/ CP 1 and it was filed on 11/01/2006. 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 procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Gloria Ortega, Deputy Director  
Division of Dockets Management  
Office of Management Programs  
Office of Management

2006P-0446

ACK 1