



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

May 5, 2005

FILE COPY

Edward John Allera
Buchanan Ingersoll
1776 K Street, N.W
Suite 800
District of Columbia 200006-2365

Dear Mr. Allera:

Your petition requesting the Food and Drug Administration to approve uniform professional labeling for Promethazine Hydrochloride Syrup, USP, was received by this office on 05/05/2005. It was assigned docket number 2005P-0173/CP1 and it was filed on 05/05/2005. 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,

Kyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2005P-0173

ACK 1