CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40231

ADMINISTRATIVE DOCUMENTS

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 40-231 Date of Submission: March 5, 1998

Applicant's Name: Pharmaceutical Associates, Inc.

Established Name: Chlorpromazine Hydrochloride Oral Concentrate USP, 30 mg/mL

Labeling Deficiencies:

1. CONTAINER - Satisfactory

2. CARTON - Satisfactory

3. INSERT

   a. GENERAL COMMENT

      Due to changes in the approved insert labeling of the listed drug (Thorazine® - SmithKline Beecham; revised June 1989; approved April 22, 1998), we ask that you revise your package insert labeling as follows:

      i. PRECAUTIONS

         A) Revise the first sentence of the second paragraph to read, ...cardiovascular, liver, or renal disease.

         B) Revise to add the following as the 9th paragraph of your submission which should follow the paragraph that begins, "Neuroleptic drugs elevate prolactin levels;":

            Chromosomal aberrations in spermatocytes and abnormal sperm have been demonstrated in rodents treated with certain neuroleptics.

ii. ADVERSE REACTIONS (CNS Reactions: Motor Restlessness)

Revise the second paragraph to read, ...reduction of dosage or change of drug. Treatment with anti-parkinsonian agents, benzodiazepines or propranolol may be helpful.

In addition,

b. DESCRIPTION

Please revise your structural formula to be the same as Thorazine.

Please revise your insert labeling, as instructed above, and submit in final print.

Please note that the Agency reserves the right to request further changes in your labels and/or labeling based upon changes in the approved labeling of the listed drug or upon further review of the application prior to approval.

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

/S/

Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research