Some of the changes proposed by the firm were merely editorial and were not the basis of any objection.

However, the firm proposed in some instances to minimize the adverse effects associated with their particular drug. Their proposed "drug dependence" suggestion was not satisfactory in this respect.

The reference to a study of 16 weeks in duration in the ACTIONS was also objectionable, since labeling for the class of drugs INDICATES USE FOR "A FEW WEEKS".

Some discussion was held about the use of the same labelling for all drugs in a class. The firm contends that individual drugs may have slightly different effects and should therefore have more individualized inserts.

The firm was requested to make a formal submission of the labeling and to address the issues to which we objected, since policy decisions at a higher level will have to be made.

They were also requested to submit material in advance for discussion at future meetings.

WILLIAM CRABBS,
Division of Neuropharmacological Drug Products, Office of Scientific Evaluation, Bureau of Drugs.

FOOD AND DRUG ADMINISTRATION,
April 10, 1975.

PETER E. MANNI, Ph. D.
Pharmaceutical Division,
Pennwalt Corp.,
Rochester, N.Y.

NDA 11-613/5-096, AF 13-450

GENTLEMEN: We acknowledge the receipt on March 17, 1975, of your communication dated March 14, 1975, enclosing printed labeling pursuant to your supplemental new drug application dated November 18, 1974, for Ionamin (phentermine resin complex) capsules.

The supplemental application provides for revised labeling.

We have completed the review of this supplemental application, and it is approved. This action approves your application, as supplemented, on the basis of effectiveness of the drug as well as safety. The enclosures summarize the conditions relating to the approval of this application.

Sincerely yours,

BARRETT SCOVILLE, M.D.,
Director, Division of Neuropharmacological Drug Products, Bureau of Drugs.

SUPERVISORY REVIEW OF REVIEW DATED FEBRUARY 17, 1976

Name of drugs: Trade; Ionamin; Generic; Phentermine resin.

Sponsor: Pennwalt Corp., Rochester, N.Y.

Subject review notes that an adverse reaction occurred in a nurse who took medication for 7 days and noted palpitation, restlessness, insomnia, and euphoria while receiving the drug and developed severe withdrawal symptoms of tremor, confusion, restlessness and severe depression following discontinuation. The nurse reporting the experience describes herself as a "sober alcoholic" for 1½ years.

Dr. Woo recommends that alcoholism should be added as a contraindication.

It appears to me that there is insufficient evidence that the reaction in this nurse was related to her prior history of alcoholism. It appears that there is an insufficient reason to include mention of alcoholism as a contraindication, based on available evidence at this time.

THOMAS A. HAYES, M.D.