

MEDICAL OFFICER'S REVIEW OF NDA 11-613  
(Annual Report: R-13 of 5-28-75)

FEB 17 1976

Date review completed: 2-12

SPONSOR: Pennwalt Corporation  
Rochester, N.Y.

NAME OF DRUG:

TRADE: Ionamin 15 and 30 (CIV)  
GENERIC: phentermine resin

MATERIAL REVIEWED: in volume 12.1

PREVIOUS MEDICAL REVIEWS: 11-28-72; 10-2-73; 3-12-74; 1-15 &amp; 3-26-75.

## PUBLISHED ARTICLES (translations):

a. Backmann, R. et al: Primary vascular pulmonary hypertension (PVPH).  
Verh. Dtsch. Ges. Kreislaufforsch. 38:134-141, 1972.

A workshop was held at the Med. Coll. of Hanover in Feb. 1970 to discuss the increased incidence of PVPH related to the use of aminorex fumarate (AF). The following conclusions were drawn from the evaluations of the commission of the German Society for circulatory research:

- (1) In a retrospective study of PVPH patients, and selected controls, there is a significant relationship ( $p < 0.001$ ) between AF ingestion and PVPH.
- (2) With the exception of 9 cases, there is a close chronological relationship between AF ingestion and the appearance of PVPH in all the patients.
- (3) There is an increase in the incidence of PVPH for 1968 and 1969 and a decrease in the incidence since 1970. The chronological relationship between the introduction, expanded usage, and decline of AF is given.
- (4) A dosage dependence of the path risk with respect to PVPH after AF ingestion could be demonstrated.
- (5) The fact cannot be excluded that other amphetamine-like anorectics and stimulants may cause PVPH.
- (6) Besides AF, no other factors that might be responsible for PVPH could be identified.

The Commission is of the opinion that the use of amphetamine-like anorectics and stimulants, for which PVPH is suspected can no longer be justified.

b. Parwadesh, M. R. et al: Tissue alterations in exp animals after chronic administration of anorectics. Verh. Dtsch. Ges. Kreislaufforsch. 56: 513-517, 1972.