MEDICAL SUMMARY OF NDA 11-613—SUPPLEMENT (S-004) AND ANNUAL REPORT R-10

Date summary completed *November 28, 1972.*
Sponsor: Penwalt Corp., Rochester, N.Y.
Name of drug—Trade: Ionamin; Generic: Phentermine Resin.

Dosage forms: each containing uationic resin complex equivalent to:

	Per capsule
Phentermine	15 mg; 30 mg

Category: Anorexigenic agent.
Route of administration: oral.
Material reviewed: Volume 11.1.
Reason for application: In response to DESI #5378, to demonstrate that Ionamin is "effective", rather than "possibly effective" as a "short term adjunct in a regimen of weight reduction based on caloric restriction."
Clinical evaluation—Studies Reviewed: (2) for Efficacy: #48613 by Eugene R. Jolly, M.D., Ph.D.; #49613 by Robin Shearer, M.D.
The subjects of the two studies were fat adults whose obesity had been caused by eating too much. They were randomly allocated to Rx groups as follows:
Group I—Placebo plus diet restrictions.
Group II—Continuous Ionamin plus diet restrictions.
Group III—Intermittent Ionamin plus diet restrictions.
The Rx phase was for 16 weeks.
Comments: In vitro studies purport to show that phentermine is released from the resin into the G.I. tract over a period of several hours, thus producing a release pattern intermediate between that of a classical salt and that exhibited by a "sustained-release" formulation.
In the 2 studies reviewed, the observed final adjusted difference in favor of Ionamin differed significantly from chance.
Recommendation: Ionamin (resin complex of phentermine) has been marketed for over a decade as an adjunct in the management of exogenous obesity. Pending declaration of FDA policy on the use of amphetamines in the Rx of obesity, no action need be taken.

THERESA T. WOO, M.D.

MEMORANDUM

FOOD AND DRUG ADMINISTRATION,
January 24, 1973.

(Supersedes Briefing Letter of May 14, 1970)

To: The Commissioner—Through: The Deputy Commissioner _____; The Associate Commissioner for Compliance _____.
From: Henry E. Simmons, M.D., M.P.H., Director, Bureau of Drugs (BD-1).
Subject: DESI announcement: Certain non-amphetamine, oral anorectic preparations—(DESI 11673)—action memorandum

Objective

To implement the Drug Efficacy Study by publishing in the Federal Register the enclosed announcement concerning seven reports of the National Academy of Sciences—National Research Council, Drug Efficacy Study Group, on certain non-amphetamine, oral anorectic preparations.

Background

Rating the drugs as effective, but . . ., the Academy's Panel for Psychiatric Drugs commented that sympathomimetic stimulants as a class have been shown