*Conclusions*

1. Initial weight comparisons indicate that the two treatment groups in each study did not differ substantially.
2. The observed final adjustment difference in favor of Biphetamine differed significantly from chance for 2 of the 3 studies.

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NEW DRUG APPLICATION No. 11-538

*Test drug(s):* Biphetamine-T (amphetamine and methoqualone) Code—BIPT.
*Manufacturer:* Pennwalt Corp.
*Studies reviewed:* (2) Albert Cohen, M.D. (Study #46538); Eugene Jolly, M.D. (Study #47538).

The first objective of these studies was to demonstrate that Biphetamine-T is truly effective rather than "possibly effective". In the two studies we reviewed, Biphetamine-T and plain Biphetamine are compared as adjunctive therapies. In another submission (NDA 10-093), plain Biphetamine was compared with placebo.

A three-week crossover pilot stage (Biphetamine-T, Biphetamine and placebo), and a week on placebo was followed by a 12-week parallel group trial. These studies were conducted in 1971.

The attached tables summarize the results for this NDA. Our conclusions are based on the covariate table. For our analysis, probabilities equal to or less than 5% shall be considered to differ significantly from chance.

*Conclusion*

1. On the basis of initial weight-comparisons, the groups appear not to differ significantly.
2. No differences greater than those expected by chance were found between the two treatment groups in both studies.

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NEW DRUG APPLICATION No. 11-613

*Test drug:* Ionamin (phentermine resin) Capsules, 30 mg., Code (0701).
*Manufacturer:* Pennwalt Corp.
*Studies Reviewed:* (2) Eugene Jolly, M.D. (Study #48613); Robin Shearer, M.D. (Study #49613).

The principal objective of these studies was to demonstrate that Ionamin is *truly effective*, rather than "possibly effective". The subjects of the 2 studies we reviewed were fat adults whose obesity had been caused by eating too much. They were randomly allocated to three treatment groups as follows: Group I-Placebo plus diet restrictions, Group II-Continuous Ionamin plus restrictions and Group III-Intermittent Ionamin plus diet restrictions and Group III-Intermittent Ionamin plus diet restrictions. The treatment phase was for 16 weeks and the studies were conducted in 1971.

The tables summarize the results for this NDA. Our conclusions are based on the covariate table. For our analysis probabilities equal to or less than 5% shall be considered to differ significantly from chance.

*Conclusions*

1. Initial weight comparisons indicate that the two treatment groups in each study did not differ substantially.
2. The observed final adjusted difference in favor of Ionamin differed significantly from chance for the two studies.

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MEMORANDUM

FOOD AND DRUG ADMINISTRATION,
*August 30, 1972.*

To: Barrett Scoville, M.D., BD-120; Division of Neuropharmacological Drug Products.
From: Walter Sloboda, Division of Statistic Evaluation Branch. BD-232.

ADDITIONAL WORK ON THE AMPHETAMINE-ANORECTIC PROJECT

1. As per your request, please find below some possible further analyses which would aid in summarizing the data so that the results may be published in one or more articles.