

balanced scales were to be utilized; appointments were to be made at approximately the same time of day; shoes were to be removed during the weighing; ordinary clothing would be worn otherwise; and, weight was to be recorded carefully to the nearest quarter of a pound.

2. Blood pressure and pulse rate were taken while subjects were at rest and in a sitting position.

3. At the initial interview, the subject was told to look for but not to expect the following adverse effects: nausea, vomiting, diarrhea, constipation, tenseness, abdominal discomfort, nocturia, urinary frequency, visual disturbances, daytime drowsiness, headache, dizziness, insomnia, fatigue, depression of mood, irritability, and rash. At each subsequent visit, the investigator would merely ask: "In general, how have you felt this last week?"

4. Subjects were also questioned as to whether it had been easier or more difficult than usual to control their appetite, whether they had more or less daytime energy, whether they had been more or less drowsy in the daytime, and whether their sleep at night had been easier or more difficult.

COMMENT AND EVALUATION

This protocol seems adequate and is acceptable to this reviewer.

However, Division of Statistical Analysis will be requested to review this protocol and comment on any deficiencies they may find.

REVIEW OF INDIVIDUAL STUDIES

Study No. 2536 by H. L. Fred, M.D.

Drug—6 effective, 6 not effective, and 4 dropouts.

Placebo—6 effective, 7 not effective, and 3 dropouts.

Conclusion.—Not favorable.

Study No. 2537 by G. C. Gremmel, M.D.

Drug—10 effective, 3 not effective, and 3 dropouts.

Placebo—5 effective, 9 no effective, and 3 dropouts.

Conclusion.—Favorable.

Study No. 2538 by R. S. Gutin, M.D.

This study is of no value due to lack of sufficient number of patients completing the study.

Study No. 2539 by J. C. Esposito, M.D.

Drug—22 effective, 9 not effective, 1 dropout.

Placebo—6 effective, 8 not effective, 2 dropouts.

Conclusion.—Favorable.

Study No. 2540 by S. B. Stern, M.D.

Drug—6 effective, 6 not effective, 4 dropouts.

Placebo—3 effective, 9 not effective, 4 dropouts.

Conclusion.—Favorable.

Study No. 2541 by A. J. Hadler, M.D.

Drug—5 effective, 6 not effective, 4 dropouts.

Placebo—6 effective, 7 not effective, 3 dropouts.

Conclusion.—Not favorable.

Study No. 2543 by A. Gattereau, M.D.

Drug—7 effective, 2 not effective, 7 dropouts.

Placebo—3 effective, 2 not effective, 9 dropouts.

Conclusion.—Favorable.

Study No. 2544 by R. E. Noble, M.D.

Drug—9 effective, 2 not effective, 5 dropouts.

Placebo—3 effective, 4 not effective, 9 dropouts.

Conclusion.—Favorable.

Study No. 2545 by R. E. Noble, M.D.

Drug—13 effective, 0 not effective, 3 dropouts.

Placebo—7 effective, 4 not effective, 5 dropouts.

Conclusion.—Favorable.