

15292 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

BIPHETAMINE-T "12 1/2", "20"
NDA 11538
LOG 666 1295

DOCUMENTATION:

1. Fazekas, J. F. Anorexigenic agents. New Eng. J. Med. 264:501-503, 1961.
2. Harris, S. C., A. C. Ivy, and L. M. Searle. The mechanism of amphetamine-induced loss of weight; a consideration of the theory of hunger and appetite. J.A.M.A. 134:1468-1475, 1947.
3. Kinard, S., L. C. Mills, J. Terrell, and J. H. Moyer. Use of d-amphetamine to curb the increased appetite and over-eating induced by reserpine therapy. J. Amer. Geriatr. Soc. 4:1073-1077, 1956.
4. Thorn, G. W., and P. K. Bondy. Obesity, p. 398. In T. R. Harrison, R. D. Adams, I. L. Bennett, Jr., W. H. Resnik, G. W. Thorn, and M. M. Wintrobe, Eds. Principles of Internal Medicine. (5th ed.) New York: McGraw-Hill Book Co., 1966.

- II. Biphphetamine-T effects: 10-12 hr of appetite appeasement with mild invigoration and reduction of anxiety.

EVALUATION: Possibly effective.

COMMENTS: Inadequate documentation regarding blood levels of the preparation following the use of the sustained-release capsule is available to the Panel; the Panel suggests that further studies be conducted to demonstrate the superiority of the sustained release form to the usual form of administration.

See also comments for Indication I.

DOCUMENTATION: Clinical experience and judgment of the Panel.

- III. Biphphetamine-T utilizes a 1:3 ratio of levoamphetamine to dextroamphetamine. This ratio has been shown to have better anorectic activity than the dextroform alone.

EVALUATION: Possibly effective.

COMMENTS: Documentation in support of this assertion is inadequate.

DOCUMENTATION: Clinical experience and judgment of the Panel.

GENERAL COMMENTS

The Panel suggests the deletion from the package insert of the following unsupported statement:

Both the appetite-curbing action of Biphphetamine and the calming action of Tuazole (methaqualone) are released simultaneously at a predictable rate.