

15290 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

DRUG EFFICACY STUDY

686

Form A

(To be submitted in duplicate by applicant)

1295

1. NDA Number 11-538 E-C / 2. Date Originally Approved April 25, 1961 3. Rx ☒ OTC ☐

4. Brand Name BIPHETAMINE-T '12½', BIPHETAMINE-T '20'

5. Applicant's Name Strassenburgh Laboratories Div. Wallace & Tiernan Inc.

and Address 755 Jefferson Road, Rochester, New York 14623

6. Quantitative Formula

Published (Non-Proprietary) Name of Active Ingredients (in order shown on label)

Amount (per tablet, per ml., etc.)

BIPHETAMINE-T '12½'

d-Amphetamine 6.25 mg.
 dl-Amphetamine 6.25 mg.
 Methaqualone 40 mg.
 all as cation exchange resin complexes of sulfonated polystyrene

BIPHETAMINE-T '20'

d-Amphetamine 10 mg.
 dl-Amphetamine 10 mg.
 Methaqualone 40 mg.
 all as cation exchange resin complexes of sulfonated polystyrene

7. Dosage Form (tablets, etc.) BIPHETAMINE-T '12½' Black & Green Capsule, BIPHETAMINE-T '20' Black & Red Capsule (20 mg)

8. Route of Adm. (Oral, etc. Where a new drug application covers different routes of administration, separate forms should be used.) Oral
9. Therapeutic Claims—Attach 10 labels and 10 package inserts (if used) to original form A (blue) and 1 copy to duplicate form A (white).
10. List of literature references most pertinent to an evaluation of the effectiveness of the drug for the purposes for which it is offered in the label, the package insert, or brochure. Approximately 5 to 10 key references are requested, if available. (Attach 10 copies to original form A (blue) and 1 copy to duplicate form A (white).) See reverse side.
11. The applicant is invited, if he so desires, to submit any unpublished material that is pertinent to the evaluation of the drug by the Academy—Research Council. This supplementary material should be packaged with form A (white). A single copy of this material is requested.
12. In this space, please list and describe briefly the supplementary material that is submitted with form A (white). See reverse side.

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 used if additional space is needed