

15280 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

NATIONAL ACADEMY OF SCIENCES—NATIONAL RESEARCH COUNCIL

Division of Medical Sciences

DRUG EFFICACY STUDY

Form A

(To be submitted in duplicate by applicant)

271

1290

1. NDA Number 10-093 E-01 2. Date Originally Approved September 23, 1955 3. Rx ☒ OTC ☐

4. Brand Name BIPHETAMINE '7½', '12½', '20'

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

and Address 755 Jefferson Road, Rochester, New York 14623

6. Quantitative Formula

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

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

BIPHETAMINE '7½'
d-Amphetamine 3.75 mg.
dl-Amphetamine 3.75 mg.
both as cation exchange resin complexes of sulfonated polystyrene

BIPHETAMINE '12½'
d-Amphetamine 6.25 mg.
dl-Amphetamine 6.25 mg.
both as cation exchange resin complexes of sulfonated polystyrene

BIPHETAMINE '20'
d-Amphetamine 10 mg.
dl-Amphetamine 10 mg.
both as cation exchange resin complexes of sulfonated polystyrene

7. Dosage Form (tablets, etc.)
Biphetamine '7½' White Capsule, Biphetamine '12½' Black & White Capsule, Biphetamine '20' Black Capsule

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 entered 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 The applicant is invited, if he so desires, to submit any unpublished material that is pertinent to the evaluation of the drug by the Academy—Research Council.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).

1. Double-blind, cross-over in mentally retarded obese subjects.
2. Double-blind study in obese subjects.
3. Double-blind study to determine duration of action.

Blue copy is original
White copy is duplicate

The back of this form may be used if additional space is needed