

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 15285

Division of Medical Sciences

DRUG EFFICACY STUDY

Form A

(To be submitted in duplicate by applicant)

1. NDA Number 11-613 E-01 2. Date Originally Approved May 14, 1959 3. Rx ☒ OTC ☐ 1296 637
 4. Brand Name IONAMIN '15' & '30'
 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.)

IONAMIN '15'
 Phentermine 15 mg.
 as cation exchange resin complex of sulfonated polystyrene

IONAMIN '30'
 Phentermine 30 mg.
 as cation exchange resin complex of sulfonated polystyrene

7. Dosage Form (tablets, etc.) IONAMIN '15' Gray & Yellow Capsule IONAMIN '30' Yellow Capsule (2.25 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 The applicant is invited, if he so desires, to submit any unpublished material that is pertinent to the evaluation of the drug by the Academy—Research Council.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).

1. Double-blind comparative efficacy study (Kupperman). +
2. Double-blind comparative efficacy study (63-5-K).
3. Double-blind comparative duration of action study (63-3-L).

Blue copy is original
 White copy is duplicate

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