

15296 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

SUMMARY OF REPORTS

Date Summary Completed: 12/9/69

NDA # 11-613

Company: Strassenburgh Labs
Rochester, New York

ORIGINAL APPROVAL DATE: 5/14/59

NAME OF DRUG - Trade: Ionamin '15'
Ionamin '30'

Generic: phentermine resin

DOSAGE FORMS AND ROUTE OF ADMINISTRATION: 15 mg. and 30 mg. Capsules,
sustained release, for oral use.

CATEGORY OR USE OF DRUG: Anorectic

DATE OF REPORTS: February 28, 1969
September 15, 1969

REASON FOR REPORTS: Annual Report 2-28-69 (R-Ø7A)
Adverse Reaction 9-15-69 and 9-30-69

MATERIAL REVIEWED: Designated Reports

CLINICAL EVALUATION:

No clinical studies, pre-clinical studies, or animal studies were submitted with this report.

Bibliography:

Clinical references by author, title, journal and date are submitted on 32 items published 1966-1969. These studies are chiefly with amphetamines, obesity treatments, appetite suppressants, comparisons, adverse results, and various factors relating to anorectics. None deal individually with phentermine and their general approach makes them of dubious clinical significance. Reproduced copies of 6 of these references are submitted, but they provide no new information applicable to this review.