

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 15235



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

NDA 11-538/S-004

APR 29 1971

Stranzenburgh Laboratories
Division of Penwalt Company
Attention: W.F. Head, Jr., M.D.
P.O. Box 1710
Rochester, New York 14603

Gentlemen:

Reference is made to your supplemental new drug application of October 7, 1970 submitted pursuant to section 505 (b) of the Federal Food, Drug, and Cosmetic Act for Biphetamine-T. (d-amphetamine, di-amphetamine and methaqualone) capsules.

The supplemental application provides for labeling revised in accord with the Federal Register Statement of August 8, 1970.

We have concluded our review of the submitted labeling and find it inadequate to provide for safe use of the drug. Accordingly, we recommend that the labeling be revised substantially as represented by the following suggested labeling:

Biphetamine-T: Proposed Labeling:

AMPHETAMINES HAVE A SIGNIFICANT POTENTIAL FOR ABUSE. IN VIEW OF THEIR LIMITED SHORT-TERM ANORECTIC EFFECT AND RAPID DEVELOPMENT OF TOLERANCE, THEY SHOULD BE USED WITH EXTREME CAUTION AND ONLY FOR LIMITED PERIODS OF TIME IN WEIGHT REDUCTION PROGRAMS.

DESCRIPTION:

Biphetamine-T-12½		Biphetamine-T-20	
Each capsule contains cationic resin complexes equivalent to:		Each capsule contains cationic resin complexes equivalent to:	
d-amphetamine	6.25 mg.	d-amphetamine	10 mg.
di-amphetamine	6.25 mg.	di-amphetamine	10 mg.
Tuazole		Tuazole	
(methaqualone)	40 mg.	(methaqualone)	40 mg.

The Empirical Formula of methaqualone is 2-methyl-3-O-tolyl-4 (3H)-guanazoline.