

15298 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

Dr. L. L. Phillips reviewed the pharmacology of phentermine resin, January 17, 1967 and recommended teratologic studies according to the 1966 guidelines.

CONCLUSIONS:

1. Efficacy is under NAS/NRC review.
2. Labeling revision is necessary to provide for safe use.

RECOMMENDATIONS:

1. Adequate animal reproduction studies should be performed in accord with our January 1966 guidelines, including adequate teratogenesis (Segment II) studies.
2. Labeling revision to comply with the current anorectic guideline label as follows:

Description

This drug is a sympathomimetic amine or chemically and pharmacologically related to the amphetamines.

Actions

This drug is a central nervous system stimulant; the precise mode of action is unknown. With respect to its anorectic effect it is generally accepted that this is of short term duration.

Indications

As an adjunct only in the initial treatment of exogenous obesity in order to facilitate adherence to diet. Anorectic agents are not a treatment of obesity when used alone.

Contraindications

Advanced arteriosclerosis, cardiovascular disease, moderate to severe hypertension, hyperthyroidism, known hypersensitivity or idiosyncrasy to the sympathomimetic amines, and agitated states.

Patients with a history of drug abuse.

During or within 14 days following the administration of monoamine oxidase inhibitors: hypertensive crises may result.