

15334 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

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In summary, then, we have 6 out of 7 well-controlled studies that do not support the efficacy of fenfluramine in this dose when given as an adjunct in a weight-reducing program. The data cannot be considered adequate.

Conclusion: The application is incomplete and not approvable.

RECOMMENDATIONS

The firm perform two more well-controlled studies, using the above-suggested guideline criteria. One study would use the dose of 40 mgs 3 times a day. The other study would use 30 mgs 3 times a day. Each dose regime is to be double-blind, randomized, using a placebo. This should measure the ability of fenfluramine to reduce the desire for eating when subjects are placed on a low calorie diet. The claim that fenfluramine is less stimulating to the central nervous system than the amphetamines is justified and should be included in the labeling.

Perhaps a combination of fenfluramine and amphetamines would be worth studying.

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MEDICAL OFFICER'S REVIEW OF NDA 16-618

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Product: Fenfluramine.

Trade name: Ponderex.

Sponsor: A. H. Robins Co., Richmond, Va.

ADDENDUM

The firm has submitted an amendment to their new drug application dated November 25, 1969. This material contains the results of clinical studies by eight different investigators, all of whom evaluated the appetite suppressant effect of Fenfluramine Hydrochloride according to the same study plan.

The amendment also contains a revised package insert.

LIST OF INVESTIGATORS

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