15212COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

For your information, of the volume of data submitted to the Food and Drug Administration to establish efficacy of Biphetamine, Ionamin and Biphetamine-T only a few specific points were questioned. We are confident that we will be able to supply the Food and Drug Administration with the data requested and establish the efficacy of these products to their satisfaction.

2. Amphetamines

The National Academy of Sciences and the National Research Council evaluated amphetamines as generally effective for shortterm anoretic action. The Food and Drug Administration is thus requiring all manufacturers of amplietamine preparations to change their labeling to conform with the findings of the academy. As soon as the new labeling is available, it will be forwarded to you. As far as we are concerned, there is nothing objectionable in the labeling suggested by the Food and Drug Administration for these products.

The above information is not the best news we could have received nor is it the worst. For the past three years many of the so-called experts have declared amphetamines worthless for the treatment of obesity. We now have recognition from the National Academy of Sciences and the National Research Council that amphetamines are generally effective in the treatment of obesity for a limited period of time. We certainly can not disagree with these findings. In fact, the National Academy of Sciences and the National Research Council endorse our "four essentials" for treating obesity with the following statement which appears in their report -

"Anoretic agents supress appetite. They are not a treatment of obesity in themselves and should be used as an adjunct to a total program of weight reduction for obese patients that includes patient education, motivation, caloric restrictions and exercise. The anoretic effect of anoretic agents often plateaus or diminishes after four to six weeks. The dosage of the drug must be individually titrated

Thus, our complete program of "Are You Really Serious" and Biphetamine, Ionamin and Biphetamine-T fulfills the overall treatment design of the National Academy of Sciences and the National Research Council for the treatment of obesity.

DO YOU HAVE SOMETHING TO SELL?

Cordially yours,

Isaac R. McGyaw, II

Vice President

IRM/sw