14606 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

INTRODUCTION

Ionamin is the brand name of a generic drug known as phentermine, which is manufactured and marketed by Pennwalt Prescription Products, a Division of the Pennwalt Corporation, Rochester, New York.

On February 15, 1973, HEW originally recommended to BNDD that phentermine should be made a controlled substance in Schedule III. BNDD published such a recommendation in the Federal Register on May 9, 1973. However, in view of evidence which was presented in the resulting comments, DEA announced on July 6, 1973 that phentermine would be controlled in Schedule IV (not III) effective on July 6, 1973.

Ionamin is marketed in capsule form, in strengths of either 15 mg. or 30 mg. Cumulative Supplement 2 of the 1976 Red Book indicates that the wholesale prices of the different product sales units are as follows:

15 mg. Capsules	•
Bottles of	100 \$13.19
Bottles of	\$48.01
30 mg. Capsules	
Bottles of	100 \$14.55
Bottles of	400 \$52.71

Ionamin has a pharmacologic activity similar to that of the prototype drug of this class used in obesity, amphetamine (both d and 1 amphetamine). Actions include central nervous system stimulation and elevation of blood pressure. Tackyphylaxis and tolerance have been demonstrated with all drugs of this class in which these phenomena have been looked for.

Drugs of this class used in obesity are commonly known as "anorectics" or "anorexigenics". It has not been established, however, that the action of such drugs in treating obesity is primarily one of appetite suppression. Other central nervous system actions, or metabolic effects may be involved.

Whereas the natural history of obesity is measured in years, the available studies involving anorectic drugs are restricted to a few weeks or months in duration. Thus, the total impact of drug-induced weight loss over that of diet alone must be considered clinically limited.