

14652 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

3. All drugs in the anorectic class except fenfluramine should "be placed in Schedule II on the basis of abuse potential."

As a result of this review, the following actions were taken by FDA in 1972-1973:

1. FDA required that the anorectic drugs be relabeled to emphasize necessary warning information about their potential for abuse, and also to reflect accurately the indications for which they were judged to be effective and to have an acceptable benefit-to-risk ratio, i.e., narcolepsy, minimal brain dysfunction, and short-term adjunctive therapy in obesity. These conclusions were published in the December 1972 issue of the FDA Drug Bulletin which was distributed to some 600,000 health professionals.
2. We determined there was no place for parenteral amphetamines in medical practice and these products were removed from the market in 1973.
3. We took the position that preparations containing amphetamines in combination with other drugs (such as barbiturates, vitamins, and tranquilizers) failed to meet FDA's combination drug policy and were, therefore, ineffective as fixed combinations. Beginning in March 1973, procedures were begun to remove these from the market. A group of small manufacturers brought legal