

3. That amphetamines prepared for or in a form suitable for parenteral use not be approved for use in the treatment of obesity.

4. That single-entity oral "anorectic" preparations including the amphetamines be permitted to be labeled for restricted use in obesity provided that they are used in association with a specific weight reduction program and that the clinically trivial contribution of these drugs to the overall weight reduction is properly emphasized. To carry out the latter recommendation, a statement such as that made in the conclusions drawn from this review must be included in all labeling and promotional products. This statement should include the following points:

Studies of the effect of "anorectic" drugs in the treatment of obesity when compared with the effects on patients treated in a similar manner without the use of the drugs demonstrate that the magnitude of weight loss of drug treated patients over non-drug treated patients was only a fraction of a pound a week. The rate of weight loss was greatest in the first weeks of study for both the drug and the non-drug treated subjects and tended to decrease in succeeding weeks. The natural history of obesity is measured in years whereas the studies offered for review are restricted to a few weeks duration. Thus, the total impact of "drug induced" weight loss over that of diet alone must be considered clinically trivial. The limited usefulness of these agents must be measured against any possible risk factors such as nervousness, insomnia and drug habituation that might be inherent in their use. Moreover, these agents can only be recommended for use