

The overall review included not only a detailed statistical analysis of all of the controlled studies in our files relating to the effectiveness of these drugs in obesity but also meetings with consultants and advisory groups.

An obviously important consideration in reviewing this class of drugs was the general standard to be applied in determining effectiveness. It was well recognized then, as it is today, that permanent weight loss over the long term is the desired goal of any treatment program for obesity and that proof of such long-term effectiveness is lacking for any of the adjunctive measures used in treating patients with obesity. This does not imply that all adjunctive measures are necessarily ineffective -- only that proof of long-term effectiveness is not available from adequate and well-controlled trials. In the case of anorectic drugs, long-term trials would be very expensive and difficult to perform in view of the many other factors relating to patient motivation which would have to be controlled, or at least measured and accounted for in the statistical analysis of the results.

The problem of the standard of effectiveness to be required for marketing has been discussed repeatedly within the FDA and with our consultants. The standard we have adopted is that a demonstration of effectiveness should depend upon a finding in adequate and well-controlled trials that patients taking the drug sustain a statistically significant greater degree of weight loss than patients