These studies were then evaluated by our medical staff to determine whether there was, for each drug entity, substantial evidence that patients taking the drug sustained on the average a greater degree of weight loss over a twelve-week period than patients on a placebo. The twelve-week period was selected because it was the longest period for which there was reasonably comparable data on all of the drug entities in the review.

The results of this review were presented to FDA consultants during two meetings in 1972. This group was chaired by Dr. Thaddeus E. Prout, Professor of Medicine at Johns Hopkins University School of Medicine. Their recommendations were, among others, as follows:

1. The single-entity anorectic drugs including the amphetamines should "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."

2. The future approval of anorectic drugs should be "based on demonstration of efficacy or measured by statistical superiority of the drug over placebo in trials using FDA recommended protocols." The group did not recommend that demonstration of a long-term effect on the natural history of obesity be necessary for marketing.