CONCLUSIONS AND PLANNED ACTIONS

Mr. Chairman, I would like now to state our present regulatory position in regard to the anorectics and to indicate our plans for future actions regarding these drugs.

The anorectic review of 1972 demonstrated that all these currently marketed drugs meet appropriate standards of effectiveness under the Federal Food, Drug, and Cosmetic Act. On the basis of the information available at that time, FDA also determined that this class of drugs meets the safety requirements of the Act and are, on a benefit-risk basis, appropriate for marketing for the indication of obesity on a short-term basis as adjunctive therapy. The most stringent controls possible under Federal law have been in place for five years on those drugs which demonstrate greater abuse risk than the others, and the remainder of the class of anorectic drugs has been controlled under other schedules of the CSA for three years.

Recent information indicates, however, that the Schedule II anorectics (amphetamine, dextroamphetamine, methamphetamine, and perhaps phenmetrazine) have continued to be abused at a relatively unchanging rate over the past three years. While there is considerable opinion that the current rate of abuse of amphetamines is well below that of the late 1960's, there is also evidence that the regulatory measures taken in the 1971-1973 period may have accomplished as much as they are going to accomplish. It also appears that the major residual problems of abuse and misuse involving anorectic drugs lie with those already in Schedule II and not those in Schedules III and IV.