Concurrent with these actions, FDA has carried out an active program of surveillance over the advertising of these drugs. Since May 1966, thirty-eight legal, regulatory, and advisory actions related to their promotion have occurred. Of these actions, twenty-seven have been initiated in the last four years. These have included two product seizures, three remedial "Dear Doctor" letters; and one remedial advertisement. Common causes of actions by FDA in regard to the advertising of these drugs have been inadequate prescribing information; unwarranted extension of the indications to special groups of patients such as hypertensives, diabetics and teenagers; implied claims of usefulness beyond the indicated short-term use of a few weeks; and misleading promotion which attempts to understate the potential for abuse.

The FDA advertising rules require that all promotional labeling and advertisements for these drugs meet the usual requirements for prescription drugs and, in addition, display the appropriate CSA control symbol.

FDA ACTIONS FROM 1972 TO THE PRESENT: THE ANORECTIC REVIEW

Mr. Chairman, as you know, the Kefauver-Harris Amendments required that FDA review for effectiveness all drugs previously approved on the basis of safety between 1938 and 1962. For the anorectic drugs the Agency elected to review the whole class at one time so that the same standards would be applied to each drug. The amphetamines were included in the review even though they had been marketed prior to 1938.