Drug Product Surveillance Program

A second basic approach to assuring the quality of drugs is the FDA's surveillance program of marketed drugs to determine their adherence to compendial standards or standards established in new drug applications.

The analytical work under this program is carried out by FDA's National Center for Drug Analysis in St. Louis and its 19 field laboratories. Where feasible, drugs of similar composition are assigned to a single laboratory for analysis to permit the use of modern automated testing methods and thus increase laboratory efficiency and reliability. During fiscal year 1975, the FDA will analyze over 20,000 human drug samples, requiring approximately 250,000 individual assays. In general, FDA has found that only a small percentage of drugs are not in compliance with official standards and require regulatory action.

Old Drug Monographs

The Federal Food, Drug, and Cosmetic Act provides for a category of drugs which are "generally recognized as safe and effective" and are popularly known as "old drugs" to distinguish them from "new drugs" as defined in the Act. Those drugs in the old drug category include most over-the-counter preparations and most older prescription drugs. The law has always permitted any registered manufacturer to market these well-established old drugs without obtaining preclearance from the FDA. However, these drugs are subject to full regulatory control by the FDA in terms of their labeling and manufacture. The FDA has