--Provide a means for measuring changes in the quality of drugs and the relationship of such changes to FDA actions.

--Provide a statistically valid evaluation of the quality of selected drugs under study.

The analytical work under this program is carried out by FDA's National Center for Drug Analysis in St. Louis or one of our 18 field laboratories. Where feasible, drugs of similar composition are assigned to a single laboratory for analysis, increasing laboratory efficiency by permitting use of mass production techniques. During FY 73, we analyzed over 9,000 human drug samples. During the current fiscal year, we plan to analyze 15,000 samples of human drugs. In general, we have found that only a small percentage of drugs analyzed are defective. All those that are defective are followed-up by our field offices to remove them from the market and to ascertain the cause of the defect. Also, we publish the results of our drug quality surveys in the FDA Drug Compliance Information Letter, a copy of which I would like to submit for the record.

When our monitoring activities reveal problems with an entire class or type of drug, specific intensive programs are established. Our recent efforts to assure digoxin content uniformity and dissolution and sterility of large volume parenteral solutions (LVP) are examples of such programs.

In 1970, to assure digoxin content uniformity, we established an industry-wide voluntary certification program. Until a firm