New Drug Approval

As you of course know, all new drugs introduced into the market since 1938 must be shown to be safe and effective. What is less well known, perhaps, is that the approval process also applies to quality control procedures and other manufacturing practices. Before a new drug application may be approved, our Bureau of Drugs must have assurance, through inspections, that the applicant can and will manufacture the drug under conditions of current good manufacturing practice. In addition, the new drug approval imposes requirements for the maintenance of certain records, including periodic reports regarding clinical experiences with the drug. Important changes in manufacturing processes or controls must be approved by the FDA before they can be implemented. The new drug approval process is therefore an important and essential part of our overall quality assurance program.

Drug Efficacy Study Implementation (DESI)

Under the Federal Food, Drug, and Cosmetic Act enacted in 1938, safety was the sole consideration for obtaining approval to market a new drug. The Drug Amendments of 1962 extended the requirements