Mr. Chairman:

We are pleased to have this opportunity to appear this morning to discuss Food and Drug Administration drug quality assurance programs and the effect these programs may have on other Government agencies involved in drug procurement and reimbursement.

FDA QUALITY ASSURANCE PROGRAMS

Let me begin by stating that the pharmaceutical industry must bear the primary responsibility for assuring the production of high quality drug products. The Food and Drug Administration's (FDA) role is to assure that manufacturers meet this responsibility. We do so by setting appropriate standards for the manufacture of drugs, and by carrying out surveillance activities such as factory inspections and analysis of selected products. When firms do not meet their responsibilities, the Federal Food, Drug, and Cosmetic Act (FDC Act) provides us with authority to take certain measures to bring about correction and/or to remove offending products from the market.

Our quality assurance programs for drugs are aimed at providing optimal assurance of drug quality to all physicians and consumers. These programs employ a major portion of our field manpower available for drug work and range in approach from continuing surveys of the manufacturing practices of selected drug firms, to intensified targeted programs such as certification of specific products or plant inspection and analyses involving a certain product with identified problems.