STATEMENT OF DR. HERBERT L. LEY, JR., COMMISSIONER OF FOOD AND DRUGS, CONSUMER PROTECTION AND ENVIRONMENTAL HEALTH SERVICE, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; ACCOMPANIED BY WILLIAM W. GOODRICH, ASSISTANT GENERAL COUNSEL, FDA; DR. JOHN J. JENNINGS, ACTING DIRECTOR, BUREAU OF MEDICINE, FDA; DR. FRANCES 0. KELSEY, BUREAU OF MEDICINE, FDA; AND DR. ALAN LISOOK, DIVISION OF SCIENTIFIC INVESTIGATION, FDA

Dr. LEY. Thank you, Mr. Chairman. I welcome this opportunity to appear before you and discuss drug-testing problems and the role of the Food and Drug Administration.

As you know, one of our major responsibilities is to oversee the interstate distribution and use of investigational new drugs.

Even before he Kefauver-Harris amendments were enacted in 1962, the Department had announced the proposed tightening of controls over investigational new drugs. The amendments strengthened the proposals and buttressed their legality.

Since the enactment of these amendments, we have taken numerous steps to implement the provisions of the 1962 act, making procedural changes as they became necessary.

On March 9, 1966, Dr. James L. Goddard, then Commissioner of Food and Drugs, outlined before a subcommittee of the House Committee on Government Operations the steps that the sponsor of any investigational new drug must take before he can proceed with drug testing on humans. These steps included:

1. The presentation to the Food and Drug Administration of an acceptable plan for the investigation. This plan must describe in adequate detail:

(*a*) What the drug is.

(*b*) How and where it is made.

(*c*) How it is controlled to meet appropriate standards of strength, quality, and purity to provide reasonable assurance of safety and to give significance to the investigations.

(*d*) What is known about it from preclinical and laboratory studies.

(*e*) What is known about it from clinical experience in other countries or from clinical experience with related drugs.

(*f*) What information is to be disseminated to investigators who are to use it.

(*g*) The names and experience of, and facilities available to the particular investigators who will be involved showing that they are qualified to conduct the study.

This submission is in the form of a claim for exemption from the requirement of the statute. As soon as it is submitted, the sponsor is free to ship the drugs to the investigators.

The second feature which must be reported to the FDA is a report from the sponsor of the results of studies with laboratory animals in adequate detail for scientific evaluation, together with the names and qualifications of the persons who evaluated the results and concluded