There are no published regulations within the Federal Government which require other Federal agencies to report to FDA the identity of foods and drugs which they reject.

However, FDA has initiated and entered into agreements and memorandums of understanding with other agencies providing for exchanges of knowledge and information to strengthen programs of mutual concern in the public interest. The Food and Drug Administration also provides resources and facilities to assist other agencies as our program capabilities and legislative authority permit.

At the present time, these agreements with other governmental agencies include working arrangements with the Department of Agriculture, Department of Defense, and the Veterans' Administration—which are the agencies directly involved in the purchase of foods and drugs for Federal use.

Briefly stated, our agreements with the Department of Agriculture deal with the disposal of Agricultural Stabilization and Conservation Service products which have become adulterated or misbranded; promotion of greater sanitation in the warehousing, transportation, and milling of food grain; coordination of the activities of the Departments of Agriculture, Interior, and HEW pertaining to pesticides and the establishment of a joint contract with the Department of Agriculture for Salmonella research by the National Research Council.

We have an agreement with the Defense Medical Supply Center of the Department of Defense establishing policy and procedures for FDA inspections and tests relative to certain pharmaceuticals manufactured in foreign countries. We also have an agreement to provide the Defense Supply Agency information on food and drug manufacturers being prosecuted under the Federal Food, Drug, and Cosmetic Act.

We have an agreement with the Veterans' Administration establishing policy and procedures for FDA testing of VA drug samples.

The FDA also has agreements with the Public Health Service to provide testing services for items in the civil defense medical stockpile.

In 1963, the Intra-Governmental Procurement Advisory Council on Drugs (IPAD) was formed, consisting of representatives of the various Departments, agencies, and offices of the Federal Government concerned with the procurement of drugs for Federal use. Its purpose was to provide a forum for the timely interchange of procurement information and, through cooperative efforts, to improve the quality of products purchased by the Government.

IPAD representatives agreed to exchange full information whenever any agency encountered a defective drug posing a potential hazard to health.

Under the IPAD charter, FDA maintains contact with the Defense Supply Agency drug purchasing and utilization activities. The Director of our Bureau of Regulatory Compliance is FDA's IPAD representative and several FDA employees are members of various IPAD working groups. Where requested, FDA furnishes the Defense Supply Agency information to assist in the establishment of drug specifications, methods of analysis, results of sample examination, findings developed in factory inspections, and routinely supplies them with information about recalls, seizures, and injunctions. We also work with DSA in the development of standards for medical material DSA, in turn, notifies FDA of adverse drug reactions and informally informs us of suspected violations of the Federal Food, Drug, and Cosmetic Act. In serious cases, information is exchanged by telephone or telegram, usually between DSA's Directorate of Medical Materiel in Philadelphia and FDA's Bureau of Regulatory Compliance or Bureau of Medicine.

DSA has notified FDA of serious deviations from good manufacturing practices encountered during its preaward surveys of drug manufacturers, and has reported to FDA on preaward samples which failed to comply with the F.D. & C. Act. In addition, DSA sends us copies of its "not qualified suppliers" list each month.

Mr. Chairman, I would like to cite some specific examples of the type of cooperation that exists between the military and FDA:

Recently the Defense Supply Agency contracted FDA to report inspectional findings involving a drug firm violating the Current Good Manufacturing Practices Regulations. Their inspection was prompted by a compaint from a defense depot that two lots of epinephrine injections contained broken ampoule tips and rusty ampoule opening files, and were discolored. A sample was turned over to the FDA laboratories which confirmed these findings. At about the same time, DSA received another complaint involving the same manufacturer's menadione sodium bisulfite injection.