

facturers 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 examinations; 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 materiel. 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 FD&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 contacted FDA to report inspectional findings involving a drug firm violating the Current Good Manufacturing Practices Regulations. Their inspection was prompted by a complaint from a defense depot that two lots of epinephrine injections contained broken ampul 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.

Shortly thereafter DSA and FDA made a joint inspection of the firm. Following this inspection the company initiated a recall of the improperly sealed ampoules in the civilian market. At the same time,