Mr. McKENZIE. The DSA organized a DOD task group to conduct negotiations with the FDA. This task group met for the first time on June 11, 1974, with appropriate DOD agencies participating. Representatives of my office participated as observers in the task group deliberations. On June 4, 1974, OMB issued guidance on the procurement and distribution of medical supplies and nonperishable subsistence and tasked the Secretary of HEW with the responsibility of developing a quality assurance plan for medical materiel.

A briefing for FDA representatives was presented by DOD on June 13, 1974. This briefing provided officials of FDA with an analysis of our quality assurance program for drugs. It provided information concerning our requirements for drugs, their specification development and use, and the relationship of our quality assurance procedures to the DOD drug procurement program. It also highlighted our preaward survey procedures for prospective contractors, our quality assurance program as it affects contract administration, and the quality assurance of drug supplies in government storage.

As a result of this briefing, FDA representatives requested that they be afforded an opportunity to visit a representative Defense Contract Administration Services Region and some selected drug firms to witness the DOD quality assurance program in practice. During the week of July 14, 1974, a visit was made to our New York office and three pharmaceutical firms whose DOD contracts are administered by the New York office. This provided FDA with further insights into DOD purchasing procedures, related contract administration and quality assurance.

On August 6, 1974, the Commissioner and senior officials of FDA met with me and selected senior officials of Defense agencies to discuss the quality assurance subject. On September 19, 1974, the FDA conducted a briefing and discussion for senior officials involved in Federal contracting.

Again, as Dr. Lee has indicated, five interagency task groups were organized on September 24, 1974, to review all aspects of Federal purchasing of drugs and to make appropriate recommendations that would offer a government-wide quality assurance program plan for drugs. These were Task Group 1, Specifications, chaired by DOD; Task Group 2, Standards, Good Manufacturing Practices and related material, chaired by FDA; Task Group 3, Pre-award Surveys and On-Site Inspections, chaired by FDA; Task Group 4, Product Testing, chaired by DOD; and Task Group 5, Certification Lists, chaired by FDA.

A sixth task group on nondrug items was recognized but not established at this time. However, on April 2, 1975, this task group was activated under the chairmanship of DOD. The completion of the implementation plan being developed by this last group is expected by September 1, 1975.

The interagency groups were requested to cover the assigned areas in considerable depth and to complete their task by the 15th of January. Each group was required to describe the quality assurance systems now in existence and to include the manpower and other resources required to operate these systems. Each group was also charged with the responsibility to design or describe a conceptual system as it would operate under the FDA's direction and to include