

11904 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

This task group met for the first time on 11 June 1974 with appropriate DoD agencies participating. Representatives of my office participated as observers in the task group deliberations. On 4 June 1974, OMB issued guidance on the procurement and distribution of medical supplies and nonperishable subsistence and tasked the Secretary DHEW with the responsibility of developing a quality assurance plan for medical materiel. A briefing for FDA representatives was provided by the DoD on 13 June 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 pre-award survey procedures for prospective contractors, quality assurance 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 14 July 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