

11912 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

On July 3, 1974, FDA formed an Executive Level Steering Committee, under the chairmanship of Mr. Sam D. Fine, Associate Commissioner for Compliance, to direct and oversee implementation of the Government-wide Quality Assurance Program. This committee meets regularly to evaluate the progress of the program, and to make decisions on FDA policy matters involving its implementation.

On August 28, 1974, I met with the principal Deputy Assistant Secretary of Defense (Health and Environment), Vernon MacKenzie, regarding the quality assurance program and we agreed to move forward as rapidly as possible with it. A similar spirit of total cooperation has enhanced our progress with the VA, and with other agencies in Health, Education, and Welfare (HEW).

Additionally, an executive level interagency liaison group representing the various agencies involved in the program was established. This group provides an effective means for the agencies to be in close and continual contact as the program is developed and implemented.

FDA's Steering Committee identified several aspects of a Government-wide Quality Assurance Program which required detailed study to assure successful implementation. They were:

- (1) product specifications,
- (2) manufacturing standards,
- (3) scope of inspectional coverage,
- (4) product testing, and
- (5) list of qualified firms.