

11914 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

-- Development of short- and long-range plans and budgets necessary to assure the success of the quality assurance program.

-- Development of an evaluation activity to assess the effectiveness of the program as it is being carried out.

ACTION PLAN

FDA decided that due to the great diversity of medical products procured by the Federal Government, it would be best to develop first a quality assurance program covering drugs and biologics, and to include other medical products in a second plan. Specifically for drugs and biologics, FDA will:

-- Assume full responsibility for quality assurance of all drugs and biologics purchased under contract by DOD, VA, and PHS.

-- Assume full responsibility for any inspection of manufacturers required for the quality assurance of drugs and biologics purchased under Federal contracts; such inspections will be made to assure that manufacturers are in compliance with current Good Manufacturing Practice regulations promulgated under the Federal Food, Drug, and Cosmetic Act.