CHAPTER 5

OVERLAPPING QUALITY ASSURANCE ACTIVITIES AND OBSTACLES TO ELIMINATING THEM

FDA monitors the manufacturing practices and conditions under which drugs are made by inspecting the plants of drug firms, reviewing their quality assurance controls, and testing product samples. Under the Food, Drug, and Cosmetic Act (21 U.S.C. 301), antibiotics, insulin, and certain veterinary drugs may not be marketed until FDA has tested each batch for strength, quality, and purity and has issued individual certificates of approval to the manufacturer. For all other drugs, FDA periodically tests products through surveillance sampling programs to insure that the items meet the purity, strength, and identity standards provided in the act.

DPSC and VAMC also operate quality assurance programs to insure that the drugs they buy are acceptable in purity, safety, strength, and other considerations. These programs differ both in qualifying manufacturers as supply sources for drugs and in procedures for insuring that the respective supply systems accept only quality products.

In these circumstances, two or all three agencies could be conducting quality assurance inspections simultaneously at the same plant.

DIFFERENCES IN APPROVING FIRMS TO SUPPLY DRUGS AND IN INSPECTING PRODUCTS

Qualification of suppliers

The DPSC quality assurance program includes evaluating the contractor's ability to supply each required drug. This is done by surveying manufacturing plants and by testing product samples before awarding contracts.

Preaward plant surveys and preaward samples are generally required when a firm's ability to manufacture a specific drug is unknown or a doubt exists about the firm's quality control, housekeeping procedures, or financial position. A manufacturer may be disqualified for failing to satisfy certain requirements of quality control, housekeeping, acceptability of subcontractors, plant capacity, or