

8048 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

The quality assurance program at the Defense Personnel Support Center includes an evaluation, through pre-award surveys of the plant and pre-award testing of product samples, of the contractor's ability to supply a specific drug item.

Pre-award surveys and pre-award samples may be generally required when (1) the contractor has never before furnished the item being procured; (2) a doubt exists as to the quality control, housekeeping procedures, or financial position of the prospective contractor; or (3) the item is to be furnished from or manufactured in a different plant.

The Defense Contract Administration Service has about 80 quality assurance representatives, who are either chemists, chemical engineers, or pharmacists, and function as drug inspectors. They perform pre-award surveys at the request of the Defense Personnel Support Center and are charged with the responsibility for inspecting and approving all drug items manufactured under Defense contracts. In performing their inspections the quality assurance representatives are required to inspect each drug lot.

During fiscal year 1969 a total of 168 pre-award surveys were made--149 of which were performed on domestic manufacturers which were classified as either small or large business. Sixty-two small business firms were subjected to 90 surveys. Forty-seven of these surveys resulted in disqualifications. Twenty-six large businesses were subjected to 59 surveys, 25 of which resulted in disqualifications. Reasons for disqualification included poor quality control; poor housekeeping; sample failure; unacceptable subcontractor; and inadequate capacity.

The Veterans Administration inspects each contractor plant with regard to its entire operation and for its entire