

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10039

Information Required by Senator Nelson
from Department of Defense

16. ANSWER: (Cont'd)

suppliers fully understand the requirements that must be met. The DPSC Drug Standards with their definitiveness are very essential for the continued support of quality procurement. It has been announced that the following proposed revisions in GMP's will be made in 1974:

- a. Add a section on Sanitation.
- b. Personnel responsible for Quality Control shall not also be responsible for production.
- c. Requirement that all production and control procedures be reduced to writing.
- d. Provision for the establishment of definitive records of all tests and assays.
- e. A written record shall reflect which pieces of equipment within each operation are or were in operation at any point in time.
- f. Establish a requirement for the formal training of employees.
- g. Each container sampled shall be suitably identified.
- h. Require reserve samples of inactive ingredients shall be retained.
- i. Qualifications of consultants.

(b) A brief explanation of the scope and effectiveness of the pre-award survey is as follows:

The Armed Services Procurement Regulation (ASPR) requires that the contracting officer shall make a determination of responsibility or non-responsibility of the prospective contractor. If the information available to the purchasing office is not sufficient to enable the contracting officer to make a determination regarding a prospective contractor, a pre-award survey is conducted by the Contract Administration Office.