

10016 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

Information Required by Senator Nelson
from Department of Defense

14. QUESTION:

Number of drug contracts in Europe for the past year?
Number of DOD representatives in Europe that inspect drug facilities.

ANSWER:

During the past year DPSC did not have any contracts in Europe.

Surveys of overseas drug firms are conducted by a DPSC Liaison Officer.

15. QUESTION:

In the past several months Mr. Feinberg of the DPSC has publicized certain problems for which the Subcommittee is very anxious to secure additional information. His statement and our questions are as follows:

(a) "The rejection rate of DOD plant inspections is 45 percent and the rejection rate on pre-contract award sample inspections is 42 percent."

Would you please explain exactly how these figures were derived?

(b) "Based on my experience of drug plants, it is my firm conviction that the primary problem lies in the fact that many producers in the business today are in gross violation of FDA's good manufacturing practices regulations. Those same firms are manufacturing drugs on a daily basis."

Will you please supply: (1) the names of the firms; (2) the dates of the "gross violations" of FDA's good manufacturing practices regulations; (3) were these reported to the FDA and other government purchasing agencies, and if so, when and in what detail; (4) the exact description of the violation (not a general statement like "poor housekeeping," etc).

(c) "We have seen totally unacceptable housekeeping conditions involving dirt, filth, and rodents. We have reviewed production records that showed noncompliance with the companies' own standards. We have found instances where ingredients and finished products are not adequately tested."

As in the previous question, please supply the names of the companies involved; dates on which violations were found; were these reported to the FDA and other government agencies, and if so, when and how; and the exact description of the violation.