

these were 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.

(d) With respect to problems of digoxin tablets -- "This was no surprise to the drug specialists in DPSC because we know of many other examples demonstrating that compliance with laboratory standards is not necessarily indicative of clinical effectiveness."

When did the DPSC drug specialists first learn about the problem with some digoxin tablets on the market?

Was the FDA informed of this problem by your organization and if so, when and how?

Which of your drug specialists first became acquainted with the problem?