Information Required by Senator Nelson
from Department of Defense

15. QUESTION: (Cont'd)

(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?

Please name the "many other examples" mentioned. Was the FDA informed? When and how? Give name and title of drug specialists who discovered these problems?

(e) "We develop definitive product specifications which often exceed official or commercial standards."

Please name each product for which such specifications have been developed; the significance for each product of these extra requirements; and the medical purpose served by these extra requirements.

ANSWER:

(a) The 45 percent rejection rate in plant inspections refers to our FY 1973 responses to the contracting officer regarding award or no award recommendations resulting from pre-award surveys of manufacturers of drugs and devices. There were 216 such responses where an award/no award recommendation was made as a result of a pre-award survey. Of those, 97 or 44.9% recommended no award.

The 42 percent rejection rate on pre-award samples refers to our FY 1973 responses to the contracting officer regarding award or no award recommendations resulting from the evaluation of pre-award samples from manufacturers of drugs and devices. There were 320 where an award/no award recommendation was made as a result of evaluation of a pre-award sample. Of those, 136 or 42.5% recommended no award.