Information Required by Senator Nelson
from Department of Defense

16. QUESTION:

(a) Please state deviations from FDA's good manufacturing practices regulations which the DOD considers significant, and which are not considered significant by the FDA?
Please identify where there is a difference of opinion.

(b) Who in DPSC makes the determination whether the raw observations are significant?

(c) What criteria does DPSC use?

(d) Does DPSC relate the violation to a particular product? In other words, does the violation, for example, contribute to the contamination of the product?

ANSWER:

(a) The FDA Papers of April 1967 in an article "Good Manufacturing Practice" states the Food and Drug Administration is convinced that most, if not all, of the problems of drug quality can be solved by compliance with the minimum requirements of the Current Good Manufacturing Practice regulations. The article also states, "Analysis of the fiscal year 1966 recalls shows that 351, or 78 percent, were for reasons which would be related to a failure to observe GMP regulations." The FDA Handbook of Total Drug Quality of July 1971 states in an article: Case Studies of Drug Recalls, "We found that 75-80 percent of the errors contributing to drug recalls were due to deficiencies and failures to meet the requirements of the Current Good Manufacturing Practice regulations." The FDA Compilation of Case Studies of Drug Recalls of March 1973, lists case after case with the applicable GMP sections which relates to the apparent cause(s) of the recall.

All the GMP's are considered significant in order to manufacture quality drug products. The problem is that the FDA GMP's provide only general guidelines. This is recognized by FDA as in the Federal Register of January 15, 1971, it was stated, "In the Federal Register of August 22, 1969 (34 F. F. 13553) a notice was published proposing a revision of Section 133.1 - 133.14 to clarify, strengthen, and make more specific the good manufacturing practice regulations for drugs."

The DPSC Standards for the Manufacture and Packaging of Drugs, Pharmaceuticals and Biologicals were published in 1968. It was necessary to set these practices down in more detail and with a higher degree of specificity. This is absolutely necessary to accomplish the mission of DPSC -- to deal with our suppliers and potential suppliers in a contractual, not a regulatory capacity. A prime obligation of this relationship is that DPSC must deal with all on an equal basis and before this equality can be established it is essential that all suppliers and potential