I would like to discuss this if you wish, in some detail, because I know it is a point of interest to the committee.

This is your third issue, consolidation of quality assurance in FDA. The truth is we have substantially relied upon the FDA for quality assurance in our drug procurement program for many years. Our position is—and has consistently been—that we are willing to rely upon FDA for a comprehensive quality assurance program, providing FDA makes the necessary information available to us in a reliable and timely manner.

Senator NELSON. Do they?

Dr. LEE. They have in many instances. In some they have not, and we have had discussions with FDA officials in recent weeks to indicate our VA requirements. It looks as though we can have them met in each instance, yes, sir.

For the past 15 years, we have relied upon the FDA laboratories to perform drug assay and testing of those drugs VA procures. Those items we identify as requiring testing before issue to our hospitals are received at our supply depots and placed in quarantine. Random samples are selected by VA personnel from each lot or batch and sent to FDA laboratories, usually the one in Cincinnati, Ohio, for assay and testing. After the results are reported to us, we either remove the drug from quarantine and place it in stock for issue, or, if the report is unfavorable, return the drug to the vendor as rejected merchandise. We also select random samples from items delivered under Federal Supply Schedules and submit them for test in a similar manner. Currently, we are sending about 1,400 items a year to FDA for laboratory testing. We reimburse the FDA for this service.

We rely on both FDA and DOD inspections made by those agencies for their own purposes where feasible. We attempt to determine from them or from prospective contractors if either of these two agencies has inspected the contractors' plants within the past 12 months. We receive copies of inspection reports from DOD, but not from FDA. Current discussions will, we believe, develop increased information exchange with FDA that has not been routine up to now. To supplement FDA and DOD information, we employ two pharmacists at our Marketing Center, each of whom devotes approximately one-half his time to performing plant inspections and quality control.

If neither FDA nor DOD has inspected a facility in which we are interested in the past 12 months, we conduct our own inspections, using the inspection guidelines developed from material obtained from DOD and from Good Manufacturing Practices published by FDA. In addition, we also review the vendor's capacity, performance and delivery capability as well as other matters related to contract administration. During the first 4 months of the current fiscal year, VA officials inspected 23 plants. We declined to contract with six firms because of our findings. We did not find evidence in these cases of production of adulterated or dangerous drugs. We would, of course, have reported any such instances to the FDA had we encountered them.