I previously stated that if we are assured of adequate and timely information, we can accept GAO's recommendation to rely upon FDA for quality assurance—both for plant inspections and laboratory testing. We mentioned preliminary discussions with HEW and FDA officials to accomplish this. We expect the discussions to result in early implementation.

In 1973, VA did 130 inspections and our rejection rate was 32 percent.

Senator NELSON. For failure to meet manufacturing requirements?

Mr. COOK. For a variety of reasons, for contractual requirements as well as those reasons going to the heart of the drug; quality. Some of them were what we felt were not adequate good manufacturing practices. We did not find any that were gross violations of manufacturing practices.

Senator NELSON. When you say contract reasons, they could not meet the contract schedule?

Mr. COOK. In some instances we felt they were unable to meet the delivery schedule they had said they could meet.

Senator NELSON. Do you have a breakdown of the reasons that could be submitted for the record?

Mr. COOK. It will be submitted for the record.

[The information referred to follows:]

REASONS FOR REJECTION OF CONTRACTORS' FACILITIES BY VA INSPECTORS FISCAL YEAR 1973

1. Two firms failed to demonstrate operation capacity to produce in accordance with VA delivery requirements.

2. Forty firms were rejected for the following reasons. Most of the firms were rejected for more than one reason:

QUALITY CONTROLS

(*a*) Commingling of processed materials with raw materials and/or tested and quarantined items—23
(*b*) Incomplete listing of chemical components of raw and finished materials—14
(*c*) Lack of labelling controls—9
(*d*) Equipment not calibrated—8
(*e*) Stability program lacking—8

HOUSEKEEPING

No specific requirements for cleaning processing equipment—10
Inadequate air exhaust—1
Floors encrusted with materials and peeling paint in processing area—2
Lack of screening of windows and doors—2

Mr. GORDON. Do you have any problems which are considered serious?

Mr. COOK. We had a few that we considered serious, one a couple of weeks ago on the west coast in which we found that there were capsule problems in this case. They were contaminated.

Mr. GORDON. What company was that?

Mr. COOK. Syntex, I believe.

Mr. GORDON. What about your other serious problems?

Mr. COOK. And recent problem with Abbott Laboratories which we felt were serious.