We have undertaken several activities necessary for the successful implementation of the Government-wide quality assurance program. These include: The establishment of a medical products quality assurance staff in FDA's Office of the Associate Commissioner for Compliance. This staff is the coordinating unit between the contracting agencies and the involved FDA program units.

We have established similar operational staffs in the appropriate Bureaus and the Office of the Executive Director of FDA's Regional Operations.

The CHAIRMAN. How many people in DOD and VA now perform quality assurance functions?

Dr. SCHMIDT. We have not received that information yet. We have officially requested, as a necessary prerequisite to the implementation of this plan, such information in writing from the cooperating agencies.

The CHAIRMAN. Have you made any estimate of what manpower the FDA will need in addition to what it now has when it assumes the responsibility for all quality assurance for all Government-purchased drugs?

Dr. SCHMIDT. Yes. We have calculated roughly the cost in dollars and manpower of a program that we could do. What we need before we move ahead, is to go through a process of having the other agencies lay out in precise detail what they have been doing and resources that they have used to do those things. We can then match that against the program that we come up with. It is important to be very detailed and specific so that we are not accused later on of doing less than had been done with more resources, and this sort of thing, so that before I will commit the Agency to actually engage in these activities, I will need to see, very precisely laid out, the agreed to activities that we will undertake and the resources that everyone considers reasonable with which to do these activities.

I am sure this will be done, but it normally would occur later in the process and it has not been done as yet.

The CHAIRMAN. Please go ahead.

Dr. SCHMIDT. Under the activities is the identification and evaluation of other Government facilities and resources presently engaged—and this is really the point I just made—in medical products quality assurance programs, and I spoke to that issue.

We need to develop short- and long-range plans and budget projections that can assure the success of the quality assurance program. Finally, we need to put in place evaluation processes so that we can assess the effectiveness and success of the program as it is being carried out.

We felt that because of the great diversity of medical products procured by the Federal Government, it would be best to first develop a quality assurance program covering drugs and biologics, and to include other medical products in a second stage.

Specifically, under the plan now being developed FDA will assume full responsibility for quality assurance for all drugs and biologics purchased under contract by DOD, VA, and the Public Health Service.

We will assume full responsibility for any inspection of manufacturers required for the quality assurance of drugs and biologics