Now, everybody must do a couple of things at this point. They must enter a certification program, and they must submit to us an ANDA stating that they are going to do bioavailability testing within 180 days. We do not know yet how many manufacturers are going to submit ANDA's, but we would assume that it is on the order of at least 20.

Senator NELSON. What do they have to put into the abbreviated NDA?

Dr. CROUT. I beg your pardon?

Senator NELSON. What do they have to include in their abbreviated NDA?

Dr. CROUT. They have to include evidence of bioavailability. They have to include their specific procedures for making digoxin. They have a plant inspection and so on, which is part of the usual procedure of approving an ANDA.

Senator NELSON. What about your batch testing?

Dr. CROUT. Batch testing will go on for as long as necessary, but we assume that as the bioavailability data come in and as manufacturers demonstrate repeatedly that they can make a good batch, they will drop out of this certification program. So we view this certification program as a transient and not a permanent phenomenon on the digoxin scene.

Senator NELSON. You stated you discovered the problem in 1969.

Dr. CROUT. Yes.

Senator NELSON. The Defense Personnel Support Center state they learned about the problem in 1965. They have no record of ever having informed the FDA about that.

Do you have such a record?

Dr. CROUT. No, and I am not certain what the problem could have been, because the problem discovered in 1969 required a methodology by which you could analyze individual tablets.

That methodology was not available in 1965, so whatever problem you are referring to was not the problem that I am discussing.

Senator NELSON. Because the technique was not available?

Dr. CROUT. The technique was not available in 1965.

Senator NELSON. Since it is a very important drug and its availability may very well be critical to patients, should the Defense Supply Center not have notified the FDA of whatever problem it was they said they discovered at that time?

Dr. CROUT. I would have thought so. As you know, I was not at the agency in 1965. I do not know what the communication channels between the two agencies were at that time.

Senator NELSON. Well, has any system now been established which would require any agency that discovered a problem with any drug to notify the Food and Drug Administration, which has the most significant responsibility for assuring quality?

Dr. CROUT. I think there are several systems established which the Commissioner deals with in his testimony coming up.

Dr. SCHMIDT. I might say that when we heard of some criticism by the Agency, we took a look at the communications link, and I asked