As far as the statements he makes about bioavailability, we spoke of one or two or those already, and I will just say that he has really provided us with no specific special evidence of bioavailability problems that he has that we do not have. The drugs that he mentions as having bioavailability problems generally everybody knows and has known about the problems, and indeed, we have moved to correct the majority of those problems.

Mr. GORDON. Concerning the "definitive product specifications" he talks about, he says they often exceed official or commercial standards.

Now, on the basis of the material submitted to you, would you tell us the significance of these so-called extra requirements?

He makes a big deal out of this.

Dr. SCHMIDT. Well again, I would just divide them into two categories. There may be some that are required by the Department of Defense that do not relate to drug quality, but rather relate to shipping problems or maintenance problems in an extremely hot, humid atmosphere or some such. We would need to look at those carefully, and I think work out with their purchasing people the kinds of specs that are legitimately required by the DOD which do exceed compendial standards.

There is another group as I look at them, and I will ask Dr. Crout or Mr. Loftus to comment on this in a moment, that do not seem to us to relate to drug quality at all.

Do you have a comment?

Dr. CROUT. Yes. If we have to base an answer to your question on what was submitted to us through you, then it is quite clear that most of the violations of GMP's as we see them are relatively trivial and unrelated to the quality of the drug. It is quite clear that these specifications relate to the needs of a purchaser, rather than to a general assurance of quality. I think we are hesitant only in that, as Commissioner Schmidt mentioned before, our communications with DPSC have not been strong through the years. We are in many respects still in contact with them on the issue of what is it exactly they do.

I do not mean to quote back to you something that you already know about. But I think we can all read down here and read descriptions of violations. You know, washroom was not clean; no receptacle for used towels; a loose, slightly soiled roll of towels was available for drying hands; paint had flaked from the ceiling on many locations; dust and refuse was found on the floor in work areas.

Again, these are true. But an in-depth GMP inspection is quite a different thing. One is really interested in the recordkeeping of a firm; evidence of repeated weighings, of two people weighing something carefully and checking each other; evidence of analytical procedures at various steps along the way; evidence that the temperature during a cooking procedure was indeed maintained for the right number of minutes at the right temperature. Those are the kinds of information you get out of a GMP inspection.

Now, there is not anything like that in anything here. This is a superficial look in and glance kind of an operation. We are not say-