

Senator NELSON. How do you find out whether or not they follow their own written procedures?

Mr. FEINBERG. We have—this is what our inspector does, one of the things he does, when he visits a plant to determine the qualifications of a low bidder.

Senator NELSON. What other significant differences are there?

Mr. FEINBERG. Well, we require, for example, calibration and standardization of equipment and instruments so that you would—so that it is established that the balances that are used and the instruments that are used are accurate, that the weights are. This is again a normal operating thing and it is required that they check it periodically.

Senator NELSON. Have you ever done any tests to find out whether or not the drugs that you are purchasing are superior in any way to those of other manufacturers—in other words, do you know whether yours meet certain standards, USP or NF standards, and others don't?

Mr. FEINBERG. We have not made comparisons with material on the market, no, sir. We have, of course, tested the material that we have purchased.

Senator NELSON. Well, let's assume that the FDA adopted these written procedures that you are talking about. Is there any reason why they shouldn't do the inspection for DOD and VA, then?

Mr. FEINBERG. Well, Mr. Nelson, we have not delved into the subject really at this point to discuss it at length.

General HAYES. I think I should answer part of that, Mr. Chairman. The FDA inspects for some things, and we set standards in some areas that are higher than the FDA's of necessity. As I mentioned in the statement, we have drugs that go all over the world, under adverse circumstances, and we have had to set certain standards of packaging, for instance, certain standards of stability under adverse circumstances.

Therefore, our standards are even, if you shifted all of this around, our standards would have to be somewhat different along the line.

Senator NELSON. What are some of the standards of stability? You say you are buying a drug in tablet form. It is going to go to some other country. What is it you require that is different?

General HAYES. Well, Mr. Feinberg is going to amplify but I am going to start it off a little bit.

If you decide that you want a tablet at the end-using site, if the case that the tablet started out in has been brought from the manufacturer to the depot, thrown from the depot into a truck, from the truck to a ship, from the ship to the dock, from the dock to a truck, the tablet off-loaded into something else, then juggled around in a jeep and finally set out in a field unit for awhile, you want to be sure at the end of all of that mechanical stress, and that is all we are talking about fundamentally in this discussion, you want to be sure that you still have an intact tablet, that it hasn't fallen apart and you have only an amorphous mass of powder in the bottle.

Senator NELSON. You aren't talking about a different quality tablet. It is the same tablet the company is selling to the general public in this country.