

only one manufacturer who can meet it. Else why, or how, would they ever be able to decide what the specific gravity ought to be? They could decide what the specific gravity ought to be, and then ask for bids and find out that there is no manufacturer in America that produces one with that specific gravity. So I suspect what they actually do is to take a cough syrup and then test the specific gravity and the other aspects of taste and so forth and then write a spec and ask for bids. And what you have done is eliminate all of the competition.

Whether that is intentional or not, that would be the effect, would it not?

Dr. FELDMANN. Yes, it would appear to be, Mr. Chairman. I am not in a position to be able to draw a conclusion from these things, but I can certainly supplement what you have said with some rather dramatic examples, if you would care to have me do so.

Senator NELSON. We would like to have them for the record.

Dr. FELDMANN. I might simply mention several descriptions, purchase descriptions, which are the only things that we have gotten from DPSC prior to the material you supplied to me. I will be happy to submit approximately a half dozen or a dozen of these chosen simply at random from their listings, but they cover various things, such as optional rotation, specific gravity, very narrow pH limits and so forth.

Beyond this, however, they have some other very strange specifications. For instance, under ethynodiol diacetate with mestranol tablets, they require that the shape of these tablets shall be pentagonal, which is a rather unusual specification, I would think.

Senator NELSON. Do they identify the manufacturer who can meet that spec?

Dr. FELDMANN. No, and I am not able to, Mr. Chairman.

Senator NELSON. Can you see any therapeutic service or therapeutic benefit from the shape of the tablet?

Dr. FELDMANN. I am not aware of any, Mr. Chairman.

Senator NELSON. If you hear of any, would you please let us know?

Dr. FELDMANN. Under dimenhydrinate tablets, they require that the uncoated tablet shall be yellow in color. Well, this would be logical if the drug substance itself were yellow, but the USP XVIII description of this says that it is a white, crystalline, odorless powder. So, again, the fact that these tablets must be yellow in color would seem to be rather a peculiar requirement.

Similarly, the same can be said about ethinyl estradiol tablets, which, again, state that the sugar-coated tablet shall be light tan in color, and the article itself is colorless.

But I think that one that is really the epitome here is doxepin hydrochloride capsules, which specify that the capsules shall have a pink body and a blue cap.

Now, the message begins to come through here a little bit, when one reads their purchase description for clindamycin hydrochloride hydrate capsules, on which they issue a correction that under the assay the word lincomycin is deleted, and substitute clindamycin.