

The third item that they list is an ophthalmic ointment, containing three antibiotics. And since this is an antibiotic, it is covered by the FDA's certification regulations, and the compendia do not provide separate standards for those in addition to FDA's, so this would not be higher than compendia standards.

Mr. GORDON. If this is a form 6 drug, that is an antibiotic subject to batch testing, the requirements are set by the FDA. And, as I understand it, additional requirements cannot be set up by the DPSC.

Is that correct?

Dr. FELDMANN. I am afraid I cannot answer that question. Perhaps the FDA would be able to. I am afraid I cannot.

Mr. GORDON. Because if they batch test it, they have to meet certain FDA requirements.

Dr. FELDMANN. I would think if they meet the FDA requirements, I know of no case where additional requirements above and beyond those should be necessary for an article marketed in this country for public consumption.

The final example that they listed for you. Mr. Chairman, is hyaluronidase for injection, which they list that they have certain color limits. The NF states that the article shall be colorless, which in essence is saying the same thing.

Senator NELSON. The National Formulary says that?

Dr. FELDMANN. Yes, the NF states that it shall be colorless.

DPSC also states a solubility time limit, which, again, the National Formulary requires that the article completely dissolve in solution; and DPSC lists a content uniformity test.

Now, this may, on the surface, appear to be a substantial added requirement, above and beyond the NF requirement. Well, as it so happens, back in the late 1960's, I had correspondence at that time, when I was director of the National Formulary, with personnel in the DPSC. And in three pages, I tried to explain to them that a content uniformity test in this particular case was entirely superfluous, that the assay and the other provisions of the monograph were such that they assured content uniformity of the article.

And, again, Mr. Chairman, I would be pleased to submit this correspondence for your record.

Senator NELSON. If you would.

[Testimony resumes at page 10217. The information referred to follows:]