

11738 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

drug specifications that will be done by FDA in collaboration with USP.

Mr. GORDON. How do you use the USP?

Dr. SCHMIDT. Sir?

Mr. GORDON. How will you use the USP, and does the recent merger between USP and the national formulary help the Food and Drug Administration?

Dr. SCHMIDT. We are assuming that the merger of what is often termed the two standard setting groups—the merger of these two into one—will be a helpful step. We will, as we have in the past—increasingly work with USP to develop standards to develop the testing methods and the other steps necessary in the standard-setting business.

We have worked with them in the past; we will be doing so increasingly as we are both working to be sure that there are adequate standards for all drugs.

The CHAIRMAN. How much progress has the USP made in revising its standards which I understood they were undertaking on a rather broader scale 2 or 3 years ago. Am I wrong in that?

Dr. SCHMIDT. They have had a continual process, in effect, their business is to make standards and then to review those standards and upgrade them as technology and need would dictate. I think it would be fair to say that there is a general consensus that some of their activities could be stepped up and broadened, and this is really part of the merger in their future planning. I think they will be increasing their activities, both in setting standards and in reviewing old standards, to be sure that they are adequate to today's problems and technologies.

I think everyone agrees that there is some work to be done—and this is referring back to my earlier statement that I think standards naturally will improve over the next few years.

The CHAIRMAN. Please proceed.

Dr. SCHMIDT. All right.

Moving back to the middle of page 7 in my list of things that we will develop with DOD and the VA; an information exchange mechanism which will cover contract administration; new data which may impact adversely on quality assurance of a product or firm; specific requests for inspectional or analytical work; and drug defect reporting systems.

As you have heard this morning, the proposed plan has been discussed with VA and the Department of Defense, and based on these discussions, we have drafted proposed interagency agreements which have been submitted to VA, Public Health Service, and DOD for their preliminary review.

We are optimistic that these draft agreements will receive favorable consideration. We will then formally transmit the plan to HEW and OMB for their final approval. We are hopeful that approval by all parties can be obtained so that our projected implementation date of July 1, 1975 will be met.

And moving to the top of page 9.

Meanwhile, one interagency agreements between DOD and FDA has already been finalized. It provides for FDA inspection of foreign drug manufacturers upon the request of DOD. FDA's inspectional