Defense is that it shall be done by X-ray fluorescence. Again, it is a question of shooting down a dragonfly with antiaircraft artillery. And at the end of it all, you ask what you wanted to bring down the dragonfly for in the first place. These are really superfluous.

This is not to say that all of their suggestions are of the same nature. When there are good suggestions that will improve the quality of the drug or the language of the standards, we do proceed to adopt these recommendations.

Senator NELSON. Have you adopted any of their recommendations?

Dr. BANES. Yes, indeed we have.

Senator NELSON. In what nature?

Dr. BANES. With respect to constituted solutions of injectables. In one of their comments, the Department of Defense said that they favored a specific statement in the Pharmacopeia that these materials, which are prepared for injections or dried powders to be dissolved, dissolve completely and be colorless and be free of significant particulate matter. Well, we have adopted that statement and it will be included in all of the pertinent monographs in the USP.

There was a statement with respect to ophthalmic ointments, that all of these be sterile. The Department of Defense stated that in 1966 and 1971—I am paraphrasing—they asked for sterile ophthalmic ointments, and in 1973 finally the USP and the NF and the FDA took action.

Well, the fact of the matter is that while I was with the Food and Drug Administration, the divisions under my supervision were doing the research on which that sterility test is based, that in 1970 when the 18th revision of the USP was published there was still doubt about the adequacy of the equipment available and the reagents, so that the USP did not contain the statement that ophthalmic ointments be sterile, but that as soon as a collaborative study in which FDA participated, and in which I think in fact FDA led, when these difficulties were resolved, a method of sterility was adopted. In 1971 the USP came out with a requirement that ophthalmic ointments shall be free of certain microorganisms, staphylococcus and pseudomonas, and in 1972 the interim revision said that hereafter all ophthalmic ointments in the USP will be sterile, because by now we had confidence that the method would work. As a matter of fact there are still criticisms of the method and we are still purifying the reagents.

But this is a mode of improving standards which is progressively pursued by the national compendia, by the USP and the National Formulary.

Now, the Department of Defense had the idea that these things should be sterile. FDA wanted them sterile and certainly tested all antibiotics to make sure that they were. As soon as the standards, as soon as the methods of analysis were available, the standards were promulgated. So here is an example of where DOD says we should have sterile ointments, everybody agrees we should, and as soon as scientifically we can support that position we adopt a standard, and there it is.

Senator NELSON. Thank you.