a New Drug Application is filed and is close to approval. We inspect the plant specifically for its capability to produce that drug.

Senator NELSON. You inspect the plants before they in fact produce that drug or before it is put into the marketplace, right?

Dr. JENNINGS. Yes, sir.

Senator NELSON. As to their capacity to produce that drug and meet USP standards?

Dr. JENNINGS. USP or NDA standards, whichever is in existence for that particular drug. Of course, in the course of such an inspection there will be a general appraisal of the plant's capabilities to produce other drugs. So, I think to say that we are aiming for only a visit, a housekeeping type of inspection of every plant every two years, is an oversimplification of the problem. There are different levels of inspection that are required for different purposes. I think we certainly could use more inspectors because as you are fully aware, the problems of drug quality control seem to become more complicated as time goes on. The more we know about drugs and possibilities for things going awry, the more complicated and the more intensive our inspection efforts must be. But I think the thing to remember is Dr. Schmid't testimony of a few weeks ago that as of now the prescription drug production inspection is essentially up to date. That is, something like 97 percent of the plants producing 95 percent of the prescription drugs in this country are currently in inspection.

Senator NELSON. I realize some plants you inspect very frequently, others not. Is it your view that once every 2 years or so is a fair assurance that a plant is in compliance or continues to be in compliance with good manufacturing practices?

Dr. JENNINGS. I would think that as a minimum a general inspection for the general capabilities of manufacturing every 2 years would provide adequate assurance, but I think, estimating manpower requirements, we would have to remember that there would be need for interim inspections.

Senator NELSON. There would be what?

Dr. JENNINGS. There would be a requirement for inspections between those biennial visits for special requirements, either because a new drug was to be produced and the capabilities for that particular production would have to be assessed, or because there was some indication that there might be a problem because of a complaint, because our surveillance activities had uncovered a defect. So that it isn't simply a matter of a rotation or inspections every 2 years. There is a need for capability for special, and sometimes very exhaustive, inspections in addition to the routine every-2-year visit.

Senator NELSON. Please go ahead.

Dr. EDWARDS. Just in conclusion on this particular issue, Mr. Chairman, we feel very strongly and Dr. Schmidt and the FDA certainly have the Secretary's and my support in their effort to move ahead rapidly on this pulling the inspectional capabilities of the Federal Government together.

As you know, the Department has also recently submitted to Congress a legislative proposal—the Food, Drug and Cosmetic Amend-