Dr. LEY. I believe the panel met in the intervening period between the passage of the bill and the date it went into effect.

Mr. Goodrich, would you fill in the details here?

Mr. GOODRICH. There was a lagtime, Senator, between the enactment in 1962 and 2 years later, October 10, 1964, when the new effectiveness provisions went into effect. This panel did recommend changes in the labeling for these combination products. The statement will show in the next paragraph that those changes were made. The particular one discussed here is Mysteclin-F, I take it, or that type of product which has not been acted on until quite recently.

Senator NELSON. But the law was in effect, and it provided, as I recall, that the companies were given 2 years in which to produce controlled studies to prove efficacy; is that not correct?

Dr. LEY. Quite right. And after the passage of the 2 years, in October 1964, the agency had the legal authority to move ahead. It did not move ahead until 1966, when Dr. Goddard obtained the assistance of the National Academy of Sciences to review the effectiveness, and in effect there was a further lag on our part of that 2 years.

Senator NELSON. The fact is, though, that the Congress amended the statute—in October, was it?

Mr. GOODRICH. October 10, 1962, when it became effective, with a 2-year lagtime for review of effectiveness.

Senator NELSON. So it is now 6½ years after the act was passed; is that correct?

Mr. GOODRICH. Yes.

Senator NELSON. On October 10 this year it will be 7 years. So all companies have had 6½ years' notice and opportunity to produce well-controlled studies that meet the statutory requirement to prove efficacy of the drugs; is that not correct?

Dr. LEY. That is perfectly correct, Senator.

As a result of the proposal and the comments received, significant labeling changes were made. The recommended dose of the antibiotic was increased to therapeutic level and a labeling statement was added recommending that the patient be switched from the combination drug to the antibiotic alone after fever and other symptoms had subsided.

The action of these medications for colds, however, was just a small step in dealing with antibiotic combinations. Many other combinations remained to be considered as part of the overall review of the efficacy of pre-1962—and subsequent to 1938—drugs. Moving forward with this gigantic task was one of the first problems that confronted Dr. Goddard when he became Commissioner of Food and Drugs in January 1966.

Senator NELSON. So there was a 2-year period in which the Food and Drug Administration was not taking any action under the law?

Mr. GOODRICH. May I say one thing on that. Dr. Jennings reminds me that the first thing we did was to require in 1964, soon after the effectiveness provisions came into effect, an initial report from the drug companies on the products they marketed certifying that the claims were supported by the clinical experience with the drug known to the company. In other words, this step called on the companies to make a self-appraisal and to eliminate unwarranted claims.

Senator NELSON. And when was this?