us from divulging information of this kind. Also, there is provisions in the Federal Food, Drug, and Cosmetic Act about trade secrets.

Now, these provisions collectively were the basis for the policy established some years ago. It has been followed. We have said in 1962, and repeat here again today, that if Congress wishes us to make that information available generally to other manufacturers, we are prepared to do that. But we think it was presented to us as business and commercial information and thus we have not made it generally available. We do, however, accept in New Drug Applications scientific data about these drugs which is reported in the open literature and allow other firms to rely on that.

Senator NELSON. Have you been advised by the Attorney General's office that it would be illegal for you at the expiration of a patent, when all legal protection is ended under the law, to disclose everything you know about a drug?

Mr. GOODRICH. We have not. We have asked them several times their interpretation of title 18, section 1905, I believe it is, how they interpret that. We have not received an awful lot of help from them.

Senator NELSON. You have not had an answer?

Dr. GODDARD. They have not told us that we could do it and in the recent Attorney General's manual on the Freedom of Information Act, there is a discussion of commercial and business information which covers this kind of information. That is an exception to the open disclosure.

Senator NELSON. You mean commercial and business information that the Government picks up from a business you are not permitted to reveal to his competitors?

Dr. GODDARD. Right.

That is what we are talking about here.

Senator NELSON. It is really not the same question where a patent is involved, is it?

Dr. GODDARD. I think it is broader than the patent policy. This is the very point.

Senator NELSON. This does not seem to me to be a very sound public policy position. The Congress gave a 17-year exclusive right of protection under a patent. I do not think anybody intended that such protection should continue beyond that time.

Let me ask you another question. You are much stricter then, under the requirements of the New Drug Application. Do I understand correctly that if company A makes a New Drug Application for a drug that is not patentable, is on the market for 4 or 5 years, is a good drug, and then another company wants to put it on to the market, you require company B to go through the same clinical testing that you required of company A; is that correct?

Mr. GOODRICH. We may or may not.

Dr. GODDARD. We may if the scientific literature does not provide a sufficient amount of information with respect to clinical studies. In that case, company B may be required to repeat, in effect, those studies carried out along the same lines by company A.

Senator NELSON. How often do you permit a company to submit a New Drug Application on the same chemical formula as one that is on file without requiring any clinical tests at all?

Mr. GOODRICH. It is very infrequently that we say no tests are necessary.