Senator NELSON. So his statement that these were preliminary is incorrect?

Dr. GODDARD. Their statement is incorrect.

Senator NELSON. Now, as to item 2:

2. Present FDA regulations expressly provide that after this preliminary review and upon completion of the application, it will then be accepted for filing by FDA and for formal consideration in accordance with the time schedule provided by statute. Requests by FDA for additional information from a company during this "review" process does not constitute a rejection by FDA of a New Drug Application.

Would you comment on that?

Dr. GODDARD. Yes. Again I do not understand their use of the word "rejection." It does constitute the filing of an "incomplete." We send an "incomplete" letter which spells out in detail where all the faults are with this particular NDA. It is not a rejection. It is an "incomplete" and the company receives written notice of the faults that I cited in this morning's testimony. So, again, it is——

Senator NELSON. So you did not assert that it is anything other than an incomplete in this particular case, is that right?

Dr. GODDARD. That is correct.

Senator NELSON (reading).

Commissioner Goddard stated before the Committee today that he planned to adopt a new procedure whereby each application submitted would be immediately "filed" within the technical meaning of the statute. We think his comment on this point would have given a "fairer balance" if he had noted that the Pharmaceutical Manufacturers Association in March 1963, and again in December 1966, expressly recommended to FDA in writing, on behalf of its member companies, the filing procedure which Commissioner Goddard now says he will adopt.

Dr. GODDARD. I do not think that is quite accurate, either, Senator. The PMA wanted us to start the clock running, the 180 days the Congress says we will have on these technical applications, on any kind of application. This is not what we contemplate. We said in our statement and this is how we intend to implement this. If we perceive immediately that an application is grossly inefficient, we are not going to waste our time, we are just going to box it up and send it back to them.

On the other hand, if after a preliminary review, the NDA seems to contain the required elements, we will notify the applicants and the clock will start running. So, again, this is what we said before.

I do not disagree that in general terms, they have suggested that the normal filing mechanism be adopted, but there was that nice little technicality in there that I wanted to bring to your attention.

Senator NELSON. At this point, we will formally give them credit for whatever they did get.

Dr. GODDARD. Thank you.

Senator NELSON (reading).

4. It would have been appropriate, accurate and scientifically supportable if Commissioner Goddard had said, in commenting upon the statistics of the review procedure, that there are often honest and justifiable differences of scientific opinion between FDA staff and industry scientific personnel.

Commissioner Goddard also made other observations on which PMA and member companies will undoubtedly have some pertinent comment when we have the opportunity of testifying before Senator Nelson's subcommittee.

Dr. GODDARD. I think I covered that. I am perfectly willing to subject our judgment to the review of the scientific community and I only hope they will be willing to do so as well.