Mr. MARTIN: You did, but I thought that was the wrong procedure in view of the impression that Mr. Orlikow had left. Now, the minister has said that to the best of his knowledge he did not countermand any suggestion made by Dr. Morrell.

Mr. ORLIKOW: I did not make that suggestion. I just thought this should be in the record of the future. I have no knowledge and I made no suggestion at all that the minister countermanded any recommendations made by Dr. Morrell.

The CHAIRMAN: Could we now have Dr. Morrell's statement? It is agreed.

Dr. MORRELL: Mr. Chairman, I have prepared a statement on the procedures used by the food and drug directorate in handling new drug submissions. I think this has been distributed to each member. It may be rather dull reading but I am prepared to read it.

The CHAIRMAN: I think we should have it read.

Dr. MORRELL: Although the regulations imply that the new drug submissions should be sent to the minister, they are usually addressed to the director. If they are sent to the minister, they are sent from there to the director's office. The director's secretary sends them at once to the medical section.

In the medical section they are examined, first of all, to determine whether or not the drug in question is a new drug as defined by section C.01.301. In the great majority of cases the drug is found to be a new drug. In either case the manufacturer is notified of the receipt of the submission (usually on the same day) and if it is a new drug, pertinent information relating to it is entered on a file card and in a ledger. There are some cases where it takes a good deal longer to make a decision, but usually on the same day the manufacturer gets a receipt of the submission.

Mr. NICHOLSON: Most of us know what a drug submission is but it would facilitate matters if Dr. Morrell could explain what it is at this point.

Dr. MORRELL: I am afraid it is going to be dull. Section C.01.302 of the present regulations requires every manufacturer to submit to the minister what we call a new drug submission in respect of any drug that is new as defined in the regulations. There is a definition of the new drug in the regulations.

In the present regulations, section C.01.301, this definition appears. This submission has to be made in the form, manner and contents satisfactory to the minister. It should include all the information that the manufacturer has in respect of that drug. It should include the chemical structure, composition; the methods of control; the methods of manufacture; the labelling; the claim the manufacturer is going to make; the pharmacology and toxicology of the drug; the clinical results of the tests to discover what hazards are encountered in the use of the drug; the dosage in which the drug should be given in the usual course of treatment; the pharmaceutical form in which the drug is put up for use, and so on. All of this infromation on these subjects must be included in the new drug submission. It is then required that this information be filed in duplicate with the minister before the drug is put on the market in the usual commercial way. Prior to this, of course, the manufacturer must have used the drug both in the laboratory and in the clinic in order to collect the information.

Provision is now made under section C.01.307 of the regulations to allow him to do this. He must, before sending out a new drug for clinical trial, notify the minister that he is going to do so, supply the minister with a name or a distinguishing mark by which the drug is known, he must label it—there is a special statement required on the label which says "for use by qualified investigators only"—and he must send it only to a qualified investigator. He must also keep records of the reports of these investigators on the results of that clinical