The laboratory people do not make their comments on the form provided but write them as a summary of the data and information given in the submission with comments on their adequacy in relation to the criteria presented in a guide used for this purpose and when they have finished with it, the submission and the comments are returned to the associate director.

The associate director studies the comments made by the laboratory people and checks them with the information given in the submission. He always examines critically the claims and proposed promotional material and frequently discusses with the laboratory people their comments, objections and suggestions on the whole subject matter in the submission. He may also discuss at this point, any questionable features in the submission with the medical section. Finally, the associate director sets down a summary on the form provided, of his own comments, remarks and recommendations in respect to the submission, and returns the submission and the accompanying file of comments to the medical section.

It is the duty of the chief medical officer together with his chemist assistant to then review all the reports and the submission itself. Special attention needs to be paid to the manufacturing controls described and to the clinical data. The nonproprietary (proper) name, if there is one, is recorded or decided upon at this time and in conjunction with the associate director, whether or not the drug should be a prescription drug. If there is any deficiency found in the new drug submission, a letter is written to the manufacturer by the chief medical officer pointing out what is missing or what is wrong with the submission and stating that further information is necessary or that something contained in it is unacceptable. Such a letter to the manufacturer states also that the new drug submission is not acceptable in its present form.

If, however, there is no objection taken up to this point and if everything else is satisfactory, the submission is sent to inspection services for a review of the labels. Labels are examined for compliance with the labelling requirements of the food and drug regulations. Inspection services also review the wording of promotional material and if they find it objectionable the matter is reported to and discussed with, the medical section. Inspection services then return the submission with their comments to the medical section. At this point a new drug card for the product in question is completed and a new drug acceptance form is made out. Very frequently a letter is also written to the manufacturer pointing out some objection to the labelling or other similar matter that must be corrected. Both the new drug acceptance form and this letter are sent to the director who signs them both and they are then mailed to the manufacturer. This is a standard form and the wording is the same for all new drugs.

The Director may be informed, at any time during this whole procedure, that there is some special difficulty arising or that disagreement with the manufacturers has occurred during the processing of the submission. Such information, depending on the seriousness of the difficulty, may lead to a conference of food and drug officers or a conference which includes the manufacturer's representatives as well as food and drug staff, for the purpose of establishing or clarifying a policy or resolving the disagreement in a manner that is proper and in conformity with the requirements of the act and regulations.

In actual practice, the number of conferences on new drugs in which the director is involved is smaller than those in which the associate director, the laboratory staff or the medical section take part. These latter meetings are fairly numerous. There is considerable correspondence and often telephone calls and visits from the manufacturer's medical or technical staff in connection with many new drug submissions.