The regional and district offices are advised by a monthly sheet of the new drug submissions received and of those pending or cleared. They receive as well, a card summarizing the new drug submissions cleared which is intended to be filed under proper (non-proprietary) name, brand name and manufacturer's name.

Processing of Supplementary Information

After a new drug submission has been accepted, any deviation in the use, composition, pharmaceutical forms, etc. from information and data given in the original submission, may be the subject of a supplemental submission. A supplement may involve a change in (1) the trade name, (2) the method of manufacture, (3) the dosage or dosage forms, (4) the method of analysis, (5) the labelling, (6) additional active ingredients, (7) additional inactive ingredients (colour, flavour, excipients, etc.), (8) additional claims. If there is a significant change in the active ingredients, method of manufacture, route of administration or dosage forms so that the safety is questionable, the so-called supplement may be classified as a new drug submission and entered and handled accordingly. If it is a relatively simple change in the formulation, labelling, method of analysis, manufacturing process or a small extension of the claims, it is considered as a supplement and handled as soon as possible. If a reply can reasonably be expected to be given within two weeks, the information is not acknowledged. If it appears that a longer time will be required for review, the receipt of the supplement is acknowledged. Supplements are not numbered but a record is kept of all correspondence in the correspondence record book. If the supplement involves the use of a new trade name, a revised card is issued. If it involves a new dosage unit, a new card is usually issued, but not always.

Since supplements may range all the way from one paragraph in a letter (e.g. notification of change of address or a change in a trade name) to a number of volumes (if they are trying to justify an extension of claims), it has been difficult to work out a standard method of handling them. We have been forced to do the best we could with the staff available.

Mr. NICHOLSON: Mr. Chairman, I would like Dr. Morrell to indicate how many new drug submissions they may have in the course of a month or so?

Dr. MORRELL: I have a table here which indicates the number for the last four or five years. This is a list of bona fide new drug submissions received, not including supplementaries. During 1958 there were 162; during 1959, 197; during 1960, 197; during 1961, 150 and during 1962, 177. Someone has made the addition and it is 883 for those years.

Mr. NICHOLSON: If a drug has been accepted in the United States, Great Britain or some other country of the world, it would still be a new drug submission in Canada, is that right?

Dr. MORRELL: Yes, sir.

Mr. NICHOLSON: Thank you.

Mr. HARLEY: I should like to ask Dr. Morrell whether he would go through the steps that take place before it becomes a new drug submission? In other words, how does the drug company inform you that they are going to put a new drug up for experimental purposes? What is the procedure followed before it reaches this stage?

Dr. MORRELL: Mr. Chairman, they notify us by a letter that usually gives some information. If I may say so, at this stage, and perhaps it is a little early, I think we need some strengthening of section C.01.307, which is the section I am referring to and which covers the restrictions on the