This brings up for mention another important duty of the Food and Drug Directorate. No one may sell a *new* drug in Canada unless he first provides the Minister of National Health and Welfare with a description of the drug, a list of all ingredients, route of administration, dosage, a description of the pharmaceutical form, claims to be made, method of manufacture and control, the pharmacological properties, and results of clinical tests to demonstrate safety and effects. A *new* drug is not limited to new chemical substances; a product may be considered to be new because of its method of manufacture, its composition, its dosage and route of administration or because of the claims made for it. (When all factors are taken into account there were 180 *new* drugs for which manufacturers submitted the required information during 1959.)

The information submitted to the Minister is reviewed by a team of scientists and medical men in the Food and Drug Directorate. They carefully and critically review all data and information on which the manufacturer is basing his claim that he has an effective product that is safe when properly used. In addition, the manufacturers' processing methods and controls are carefully studied.

At the time a new drug is released for sale a decision has to be made as to whether it should be sold only on prescription. The Department is assisted in this action by the advice of a committee consisting of a representative of the Canadian Pharmaceutical Association and of the Canadian Medical Association together with the Director of Food and Drugs. In general, any drug that can be classed as a sedative, hypnotic or tranquillizer, goes automatically on the prescription list. This course has been followed because experience with these drugs indicates that they are frequently misused by the public. Amphetamine and its salts are also on the prescription list for the same reasons. In fact, misuse and abuse are main reasons for adding drugs to the list but other factors are considered: (*a*) the drug is new and has been shown experimentally to have undesirable side reactions; (*b*) the drug is designed exclusively for treatment of a serious disease for which self-medication is not advisable; (*c*) the drug is habit forming; and (*d*) injury from the drug is insidious and not easily recognized until far advanced. Members of the medical profession and pharmacists are advised of the prescription list so that there will be no misunderstanding on their part.

The Food and Drug Directorate also has a responsibility with respect to the quality of drugs. The qualities of drugs that are demanded by law may be listed as follows: (*a*) the drug must have the quantitative composition claimed for it in terms of active ingredients; (*b*) the medication must be contained in the pharmaceutical form in such a way that it is wholly available to the person taking it, and if special claims are made as to the rate or time of release of the medication they must be true claims; (*c*) the drug and excipient, vehicle or container in which it is held must be free from harmful extraneous substances; and (*d*) the drug must have the stability required of it. There are specific regulations covering each of these points and every year many hundreds of drugs are sampled and tested in the Food and Drug laboratories to ensure that they meet the quality requirements set forth.

The Food and Drugs Act is a part of criminal law and it lays down standards and other requirements that will minimize health hazards and fraud in the sale and use of these products. It outlines areas of responsibilities for the manufacturers and distributors but it does not guarantee that drugs will meet the quality standards expected of them. Violations of the law can be and are uncovered and remedial or punitive action taken. It is not, however, a proper function of the Food and Drug laboratories to act as a control laboratory for the pharmaceutical industry. The first responsibility for safety and potency is put squarely on the manufacturer. The ability, facilities and conscience of the manufacturer is the 'priceless' ingredient in a drug which the drug plant inspection program of the FDD attempts to measure. An experienced inspector will know a good deal about these aspects of quality in a plant after having examined procedures, records and facilities and talked to supervisory staff.