including standards for premises in which drugs are manufactured, qualifications of supervisory staff; requirements for testing raw and finished products, systems for recall of drug, records of tests and information on adverse reactions that may be reported. There requirements cover imported drugs as well as those produced in Canada.

(b) Regulations setting forth the limitations on the distribution of drug samples to the professions named in the act were passed in July, 1963. They are given in sections C.01.048 and C.01.049 and require that a manufacturer distribute samples of drugs only to physicians, dentists, veterinary surgeons and pharmacists. Furthermore, the manufacturer must first receive a written order signed by the physician, dentist, veterinary surgeon or pharmacist specifying the name and amount of the sample requested if the drug is a prescription drug, or a maximum single and daily dose of it is prescribed by regulation or if it is a preparation that must be labelled "for therapeutic use only" or if it is a new drug (see Schedule I to the regulations).

I call your attention to Schedule I of the regulations. This is a new schedule which has been added.

Regulations permitting a very restricted sale of Schedule H drugs were passed in July, 1963, and are contained in sections C.07.001 to C.07.006 inclusive. Lysergic acid (diethylamide), commonly known as LSD may only be sold to an institution approved by the minister for clinical use by qualified investigators in those institutions.

The use of the drug is limited to the determination of its hazards and efficacy or for laboratory research in such institutions. The minister must be informed of every sale before it is made and must approve the sale in respect to quantity and dosage form. An adequate accounting of the use of the drug by each institution must be made at the request of the minister.

The control of the sale of thalidomide is the same except that it may be sold only as the bulk chemical in powdered form for animal or chemical experiments.

The new drug regulations were completely rewritten and were passed in October, 1963. They are now included in sections C.08.001 to C.08.009. Although rewritten, they maintain many of the requirements previously in force to which are now added a number of additional sections. The revised regulations include the recommendations made by the special committee of the Royal College of Physicians and Surgeons. The new sections include a revised definition of a new drug which definitely covers significant changes in excipients as ones that will result in a drug being considered as a new drug. It also states that a new drug is one that is "new" in Canada.

A new feature of the new drug regulations is the requirement of a "preclinical submission" from the manufacturer before he may distribute a new drug for clinical trial (section C.08.005). In that respect I call your attention to section C.08.005 of the food and drug regulations in the blue pages. In such a submission the manufacturer must include prescribed information about its chemistry, the manufacturing procedures and controls used in producing and testing its purity and safety and information to justify its clinical trial. In effect, this is information to support its clinical use. The manufacturer must also provide the names and qualifications of all clinical investigators who are to use the new drug and he must ensure that such investigators have the facilities necessary and that the investigator has information about the new drug that will enable him to use it on humans with the minimum of hazard to the patient.

Following the filing of a satisfactory preclinical submission, the manufacturer may distribute his new drug for clinical trial in order to gather data and information to file a new drug submission, much as he has done in the past.