Thus, the Act and regulations provide a working document of specifications, which is used by the enforcement agency and which should be familiar to the trades and industries governed by them. Years of experience have established that there are very few occasions for which it does not provide adequate powers to protect the public interest in a satisfactory manner. On the other hand regulations are frequently changed. Numerous new foods and drugs are introduced to the market each year and new processing methods and packages must be considered, often requiring prompt amendments to existing standards or the establishment of new standards. Such changes can be made without much delay by Order in Council, which is a great advantage in the public interest.

**Drugs**

The Food and Drugs Act requires that drugs be manufactured under sanitary conditions. This requirement is applied to different classes of drugs in different ways. For example, it is to be expected that a drug made for injection into the human body should be made with somewhat greater precautions with respect to bacterial contamination than an ointment. The Act sets out in detail what is expected of biological products such as living vaccines for oral or parenteral use, parenteral antibiotics, sera, toxoids, insulin and corticotrophin.

None of this group of drugs may be made for sale in Canada unless licensed under the Food and Drugs Act and the regulations give, in detail, the requirements that must be met before a licence is granted. These include an inspection of the premises and facilities that are to be used in manufacture and an assessment of the qualifications and experience of the personnel in charge of their production. Furthermore, no new licenced product may be sold unless the first several lots are completely tested by the Department of National Health and Welfare in its laboratories. Afterwards 'spot checks' are made of the product to determine that safety and quality are being maintained.

Standards for all drugs are provided for in one or another of the following ways. (1) By regulation under the Act itself, in which case no other standard for that drug is permitted. Examples are thyroid tablets and digitalis preparations. (2) The standard is set forth in a pharmacopoeia or other standard work that is named in a schedule to the Food and Drugs Act. These compendia are the International Pharmacopoeia, the British Pharmacopoeia, the U.S. Pharmacopoeia, the French Codex, the Canadian Formulary, the British Pharmaceutical Codex and the National Formulary. (3) When a standard has not been provided for a drug in either (1) or (2) the manufacturer must set a standard of his own. This he does in fact when he labels the drug with a quantitative list of the active ingredients. In doing so he must not sell a drug that can be confused in any way with a drug which is standardized under (1) or (2).

Actually the greater number of newer drugs and products are included in the third group. The situation at present is that manufacturers find it more profitable to sell a product that is exclusively their own than to compete with one another for the market in official drugs (pharmacopoeial drugs) on a generic name basis. In all fairness, however, it should be pointed out that a manufacturer can properly believe that his pharmacopoeial drug is superior to that of a competitor, even though they are both made to meet the same official standard, and deserves to be advertised and marketed as an individual product.

Under Canada's free enterprise, capitalistic system of economy, no prohibitions prevent the drug manufacturer from adding, at will, to the number of products he offers for sale—provided they meet a known standard, are safe under conditions of use that will be employed and are properly labelled and advertised. As a result, there are estimated to be about 25,000 drug products offered for sale in Canada. This is in contrast to the limited numbers that are sold in some other countries where the government actually limits the number of brands of any one kind of product that may be sold.