the requirement of the Regulations on Drug Notification. Of this total, 2215 products were produced by 168 firms located in the United States, 238 products originated in France, 146 in England, 83 in Germany and 46 in Switzerland. Of the remainder, 8 were produced in Denmark, 7 in Austria, 4 in Holland, 4 in Ireland, 4 in Hong Kong and 1 in each of Italy, Finland, Scotland, Sweden, Japan and South Africa. I should emphasize that this data relates to the importation of the final dosage form of the drug only and does not include bulk chemicals or partially processed pharmaceuticals.

We anticipate that most of the increase in drug imports resulting from the passage of Bill C-102 probably will be in the form of bulk drugs, which will then be formulated into final dosage form in Canada. Under these circumstances both the Canadian manufacturer and the Food and Drug Directorate—through its inspection and analytical programs—can exercise adequate surveillance.

The Food and Drug Directorate has taken a number of steps to assist foreign manufacturers to meet Canadian standards for imported drugs. A comprehensive Drug Manufacturers Guide has been prepared explaining the manufacturing facilities and control requirements of the Food and Drug Regulations in considerable detail. This Guide covers such items as Premises and Equipment, Sanitation, Personnel, Records and Samples, Quality Control, Product Information Records and Recall Systems.

The contents have already been discussed with pharmaceutical manufacturers and the Guide will be available shortly for distribution to the trade.

In addition, a draft has been prepared of a Guide on the Manufacturing Facilities and Controls of Imported Drugs. This document deals particularly with the interpretation of the Food and Drug Regulations as they apply to the information and evidence a drug importer must maintain about the manufacturing facilities and controls of his foreign drug supplier. This Guide will be ready shortly for distribution to the pharmaceutical industry. I am sure it will be apparent to hon. members that these two Guides—the preparation of which has been a task of considerable magnitude for officers of the Food and Drug Directorate—will be of considerable assistance to manufacturers.

They will also be of great value in obtaining voluntary compliance with the Food and Drug Regulations.

[Mr. Gendron.]

Regulations under the Food and Drugs Act have been amended to increase the control over imported drugs. It now is an offence for a person to import a drug in dosage form unless he has information available in Canada to show that the manufacturing facilities and control regulations have been met. Moreover, it is an offence for a person to import a drug in dosage form unless each lot or batch has been tested in Canada by an acceptable method to ensure identity, potency and purity for its recommended use, or failing that, satisfactory evidence is available to the Directorate that each lot or batch has been adequately tested in the country of origin.

Because a considerable number of drugs imported into Canada originate in Europe, the Directorate has taken an additional step to keep European manufacturers informed of the requirements which must be met before drugs can be imported into this country. A senior officer of the Directorate, who holds a Doctorate in organic chemistry as well as a degree in pharmacy, will be stationed permanently in Europe. As the Directorate's representative there, he will be able to provide valuable advice to European drug manufacturers who wish to export drugs to Canada, and will be in a position to evaluate their capabilities of meeting Canadian requirements. This arrangement will not only assist the Directorate in assessing the information and evidence supplied by European manufacturers but also alert the Directorate as to the standards of manufacturers in Europe.

For many years all foreign manufacturers of biological products such as vaccines, sera, toxoids and antibiotics for parenteral use, have been inspected at regular intervals by a senior officer of the department.

We look forward to the day when effective mechanisms have been established for the international standardization of requirements for manufacturing facilities and controls in drug plants. Until then, we are continuing to cooperate with the World Health Organization in its laudable efforts in this field.

A draft document on this important subject has been received from the World Health Organization and officers of the department have provided extensive comments on it. In addition, we are expanding our exchange of information with other governments regarding the quality of drug manufacturers in their country. For example, within the last two weeks an officer of our Food and Drug Directorate obtained extensive information on this matter at briefing sessions held with his