automated methods. All products of 25 drug entities, that is 25 chemicals that are used in an estimated 1,025 products, can be analyzed in 1971. It is planned to analyze the balance of the top 80 drug entities during 1972, and to finish analysis of the top 200 drug entities in 1973. After 1973, it is proposed to analyze all brands of 80 to 100 drug entities each year, with others in the top 200 as required. The analyses will be conducted in sufficient detail to provide information on inter-lot variability, a measure of a manufacturer's capability to produce uniform products. When the program is fully operational, nearly 90,000 separate analyses a year will be achieved. This systematic monitoring program will be carried out in addition to our present surveillance activities.

Drugs selected for analysis and for the other aspects of the quality-assurance program will be chosen on the basis of sales volume, their medical use, the precision of dosage required, and the known risk of contaminants in the product. The cost of the analytical portion of the program will amount to $800,000 a year.

INSPECTION OF FACILITIES

Currently, each of the 104 firms manufacturing and distributing drugs in Canada is inspected by FDD staff on the average of once every three years. By 1973, the inspection rate will be increased to once every year. In addition, an intensive review will be initiated of other indicators of manufacturing capability, including documents relating to master formulae, manufacturing and packaging orders and stability data. From these data, plus information on drug recalls, warnings, prosecutions, seizures and complaints, a guide will be provided to prospective purchasers of drugs. The additional cost of the inspection component of the program is estimated at $330,000 a year.

ASSESSMENT OF EFFICACY

Some of the claims made for some drug products on the Canadian market, particularly those which have been on the market for a considerable length of time, should be reviewed. By 1975, acceptable claims will be established for 80 selected drug entities, that is, 80 chemicals which are used in an estimated 1,600 drug products. This project will utilize FDD staff physicians and scientists in conjunction with panels of expert consultants. Where possible, the results of the United States drug efficacy studies will be utilized. The major study in the United States was carried out by expert panels established by the National Academy of Sciences-National Research Council in Washington.

Clinical equivalency of competing brands of the same drug entity is a matter of great practical significance to the practising physician. It is usually not possible to compare clinical equivalency directly, but an indirect measure is provided by measurements of the drug in blood, urine and other body fluids after dosing human volunteers. These so-called bio-availability studies are difficult, costly and time-consuming, and priorities must be set to determine those drugs which should be studied. These include: the medical use for the drug, precision of dosage required, availability of acceptable analytical methodology to detect the drug in body fluids, and solubility of the drug. The bio-availability studies are more difficult since they require human volunteers who are given the drug and then samples of body fluids are taken at regular intervals over a period of many hours. It is not possible to speed up this type of testing by introducing automated methods, as it is with the chemical procedures. Current investigations will be expanded to permit assessment of the bio-availability of 225 drug products (approximately 12 drug entities) each year. It will be necessary to continue work in this area for several years, because of the necessarily slow rate of progress expected. Substantial gains in the area of assessment of acceptable claims for drug entities should be achieved by 1975, and it is expected this portion of the program can then be terminated. The annual cost of the efficacy part of the program is considered to be an additional $775,000 ($425,000 for assessment of claims and $350,000 for assessment of clinical equivalency).

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The need to continually review and up-date price data will be the responsibility of the Department of Consumer and Corporate Affairs. Resources are required to develop an efficient data storage and retrieval program. It is estimated that the program of price data collection will cost approximately $100,000 annually. The FDD component in the publication program is estimated to cost $350,000 the first full year.

It is anticipated that approximately 130 additional employees, including physicians, chemists, technicians and other support staff across Canada will be required to carry out the new program....

CZECHOSLOVAK VISITORS

A Czechoslovak technological delegation, headed by Ing. Jan Gabel, First Vice-Minister of the Czechoslovak Federal Ministry of Technology and Investments, arrived in Canada on May 24 for a 17-day visit at the invitation of Mr. Jean-Luc Pepin, Minister of Industry, Trade and Commerce. The delegation's broad interests covered a number of diverse fields. The visit reflected the desire of both countries to exchange information on the application of advanced technology and modern management techniques in government and industry.

The guests had discussions with federal officials as well as those from the provinces of Ontario and Quebec. The delegation also visited a number of public and private companies in those two provinces.