SUBJECT:

Exchange of Drug Plant Inspection Information

(FDA Agreement Number 225-75-2027)

(Previously CPG 7156a.01)

Notes:

The FDA contact for this MOU is Roger Williams, HFD-3

Tel. No. 301-594-6740

This MOU is in effect indefinitely.

Canadian Dept. of National Health and Welfare is now Health Canada

AGREEMENT OF COOPERATION

Between The

CANADIAN DEPARTMENT OF NATIONAL HEALTH AND WELFARE

And The

FOOD AND DRUG ADMINISTRATION

BACKGROUND:

On September 28, 1973, the Commissioner signed an agreement of mutual cooperation, including exchange of drug plant inspection information, between the Food and Drug Administration and the Canadian Department of National Health and Welfare, Health Protection Branch. The Commissioner noted that the two agencies for a number of years have cooperated and coordinated efforts in many ways with respect to the manufacturer and distribution of pharmaceutical products. He stated that it is in no small measure because of this cooperation that drugs marketed in Canada and the United States are as safe and efficacious as modern science and technology will permit. The Commissioner, on behalf of FDA, endorsed the principle of mutual exchange of drug plant establishment inspection information.

AGREEMENT

The agreement is as follows:

1. Upon request from the Health Protection Branch, FDA will promptly furnish copies of establishment inspection reports prepared by FDA's investigators.

2. Inspections of drug plants in the United States (and in the Commonwealth of Puerto Rico) will be conducted under authority of the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Under Section (501)(a)(2)(B) of the Act drugs not manufactured in conformity with current good manufacturing practice are considered adulterated. Good manufacturing practice is interpreted in the Good Manufacturing Practice Regulations published in Part 133 of Title 21, Code of Federal Regulations.

3. In a response to a request from the Health Protection Branch, the FDA will endeavor:

   a. To follow specified procedures during a particular drug plant inspection;
   b. to give specified manufacturing areas special attention; and
   c. to examine more closely specified manufacturing and/or control operations.

Notes:

4. Joint inspection of drug plants may be conducted in the United States and in Canada, provided the manufacturers so consent. This will afford opportunities for comparing inspection and reporting techniques, for exchanging inspection experiences, for developing common administration practices, and for early mutual recognition of the inspectional findings of our respective inspectors and investigators.

5. FDA shall endeavor to provide prompt advice to the Health Protection Branch with respect to manufacturing conditions which are considered, for any particular product, to constitute a potential hazard to health.

6. At appropriate intervals, and by mutual agreement, the Food and Drug Administration will endeavor to arrange for meetings between its inspectors, technical experts and management, and those of the Health Protection Branch for the purpose of reviewing the progress made through implementation of this information exchange.

7. The provision of information shall not extend to the disclosures of financial data or trade secrets.

8. Information shall be provided to the extent that United States law permits. Information furnished FDA by the Health Protection Branch will be treated as confidential for interagency use only insofar as United States law permits.

The following reciprocal agreement was signed by Canada's Assistant Deputy Minister, Health Protection Branch, on October 1, 1973.

1. Inspection reports on drug plants in Canada shall be furnished expeditiously upon request from the Food and Drug Administration.

2. All inspections in Canada shall be based on the Manufacturing Facilities and Control Regulations established under the Canadian Food and Drug Act or the World Health Organization Code of Good Practices in the Manufacture and Quality Control of Drugs.

3. In response to requests from the Food and Drug Administration, the Health Protection Branch will endeavor.

   a. To follow certain specified procedures during a particular drug plant inspection,

   b. to give specified manufacturing areas special attention, or

   c. to examine more closely specified manufacturing and/or control operations.

Notes:

4. Joint inspections of drug plants may be conducted in the United States and in Canada provided the manufacturers so consent. This will afford opportunities for comparing inspection and reporting techniques, for exchanging inspection experiences, for developing common administrative practices and for early mutual recognition of the inspectional findings of our respective inspectors and investigators.

5. The Health Protection Branch will endeavor to up-date inspection reports it has supplied with data demonstrating major changes in company management and/or operations and provide prompt advice when continued exports of a specific product or of any product manufactured by a given company is considered to be a potential hazard to the health of citizens of the United States of America.

6. At appropriate intervals, and by mutual agreement, the Health Protection Branch will endeavor to arrange for meetings between its inspectors, technical experts and management and those of the Food and Drug Administration for the purpose of reviewing the progress made through implementation of this information exchange.

7. The provision of information will not extend to the disclosure of financial data or trade secrets.

8. Information shall be provided to the extent national legislation permits and on the understanding that it will be treated as confidential for intra-agency use only.