SUBJECT:

Exchange of Inspectional Information

(FDA Agreement Number 225-75-4057)

(Previously CPG 7156c.01)

Notes:

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

Tel. No. 301-59406740

This MOA is in effect indefinitely.

Dept. of Health, Education, and Welfare is now Dept. of Health and Human Resources.

MEMORANDUM OF AGREEMENT

Between The

SWEDISH NATIONAL BOARD OF HEALTH

And The

FOOD AND DRUG ADMINISTRATION

Preamble:

1. The Food and Drug Administration, a constituent of the Department of Health, Education, and Welfare, and the Swedish National Board of Health and Welfare, fully recognize that cooperation and collaboration will serve to advance, to their mutual benefit, the state of science and technology in the interest of public health; that such cooperation and collaboration will serve to upgrade the quality of drugs in international commerce; and that such cooperation and collaboration will strengthen the bonds of friendship between the United States and Sweden; and

2. In the interest of the benefits accruing to their countries, the two agencies have agreed as follows:

Article 1

The principal objective of this agreement is to enhance opportunities for the exchange of information, ideas, skills, techniques, and methods through cooperation and collaboration in areas of mutual concern and interest to the two agencies participating in this agreement.

Article 2

To the extent that the two participating agencies agree this cooperation and collaboration shall initially include specifically the mutual recognition of inspections of drug manufacturing plants, as programmed and conducted by the respective agencies.

Article 3

This agreement shall include provisions for the expeditious exchange of written inspection reports prepared by the inspecting officials for each inspection and such reports shall be endorsed by the proper authorities of the respective agencies. Such reports shall be in English.

Article 4

All such inspections conducted by the participating agencies shall be

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based on the Food and Drug Administration's regulations on good manufacturing procedures, the European Free Trade Association's good manufacturing practices, or the World Health Organization's document on the Good Practices in the Manufacture and Quality Control of Drugs.

Article 5

In selected instances either of the two participating agencies may request in writing certain procedures to be followed for a particular drug inspection, certain areas of manufacturing operation which should be given special coverage and other points of particular concern to the respective agency requiring such information.

Article 6

In appropriate cases, drug officials of the two signatory agencies shall be encouraged to participate in drug quality control workshops, seminars, and conferences, sponsored by either of the two agencies. Such participation will serve to further the cooperation and collaboration between the two agencies and permit a better understanding of each other's programs, objectives, and responsibilities.

Article 7

This agreement also provides for the two participating agencies to conduct joint inspections of drug manufacturing plants in either the United States or Sweden as occasion and opportunity permit. This in effect, will provide an excellent means of exchanging inspection techniques, procedures, and philosophy of the drug authorities of the two agencies. Funding for such joint inspections will be the obligation of the respective agencies unless other provisions are made in specific instances.

Article 8

Annually, or as needed, the two participating agencies will review the progress and benefits derived under this agreement.

Article 9

At any time, the two agencies shall consider any amendment or additional Articles to this Agreement or other matter relating thereto, or any implementation required under this agreement. The terms of this agreement shall apply to all Articles and any implementation thereof, unless the agencies otherwise agree.

Article 10*

The two participating agencies shall consider that the word "drug," as

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used in this Agreement, will include veterinary pharmaceutical products, as well as pharmaceutical products intended for use in humans.

This agreement shall enter into force upon signature by the heads of the respective participating agencies and shall remain in force until mutually agreed- that the agreement shall be amended, and/or implemented, or terminated.

*Article 10 added as an addendum February, 1980

/s/
Bror Rexed, M.D.
Director General
National Board of Health and Welfare
Stockholm, Sweden
October 17, 1972

/s/
Charles C. Edwards, M.D.
Commissioner of Food and Drugs
Department of Health, Education, and Welfare
Washington, D.C.
October 3, 1972

FDA Commissioner is currently: David A. Kessler, M.D.

Dept. of Health, Educ., & Welfare is now Dept. Of Health and Human Resources