SUBJECT:

Radiation Emission and Human Exposure from Electronic Products

(FDA Agreement Number 225-75-6001)

(Previously CPG 7156a.02)

Notes:

The FDA contact for this MOU is Paul Leggett, Jr., HFZ-342

Tel. No. 301-594-4654

This MOU is in effect indefinitely.

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

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

MEMORANDUM OF UNDERSTANDING

Between The

CANADIAN DEPARTMENT OF NATIONAL HEALTH AND WELFARE
HEALTH PROTECTION BRANCH

And The

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
FOOD AND DRUG ADMINISTRATION

The Health Protection Branch of the Canada Department of National Health and Welfare (hereinafter referred to as HPB) and the Food and Drug Administration of the U.S. Department of Health, Education, and Welfare (hereinafter referred to as FDA) do hereby jointly agree to the following terms and conditions as stated herein.

I. Purpose

To establish a formal mechanism by which the Canadian Health Protection Branch and the U.S. Food and Drug Administration may develop a procedure to exchange information on compliance program efforts which are of mutual concern to both agencies.

This understanding is restricted to those activities which involve controlling radiation emission and human exposure from electronic products.

II. Items of Agreement

A. FDA agrees that:

1. Prior to the issuance of standards by FDA under the Radiation Control for Health and Safety Act to control the emissions of radiation from electronic products, HPB will be consulted during the development stage of the standards, for advice on the latest available scientific and medical data in the field of electronic product radiation, the reasonableness and technical feasibility of such standards, and the standards currently in existence or being developed by HPB dealing with same subject.

2. Copies of all regulations; standards, policy statements, and other similar documents pertaining to electronic product radiation will be provided to HPB.

3. Upon request from HPB, FDA will promptly furnish copies of decisions arising from inspections of manufacturers of electronic products prepared by FDA personnel.

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4. Joint inspections of electronic product manufacturing plants may be conducted in the United States and 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. FDA shall endeavor to provide prompt notification to HPB with respect to electronic product defects and noncompliance with FDA performance standards. This will include the name of the firm, the model number and other identification, the reason for the compliance action and a description of the manufacturer's corrective action program.

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

7. Information shall be provided to the extent that United States law permits. Information furnished to FDA by HPB will be treated as confidential for interagency use only insofar as United States law permits. The provision of information shall not extend to the disclosures of financial data or trade secrets.

B. HPB agrees that:

1. Prior to the establishment of standards or regulations under the Radiation Emitting Devices Act or the Food and Drugs Act relative to radiation emitting devices, FDA will be consulted during the development stage for advice on the latest available scientific and medical data in the field of radiation emitting devices, and reasonableness and technical feasibility of such standards, and the standards currently in existence or being developed by FDA dealing with the same subject.

2. Copies of all regulations, standards, policy statements, and other similar documents pertaining to radiation emitting devices will be provided to FDA.

3. Upon request from FDA, HPB will promptly furnish copies of decisions arising from inspections of manufacturers of radiation emitting devices prepared by HPB personnel.

4. Joint inspections of radiation emitting devices' manufacturing 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

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developing common administrative practices, and for early mutual recognition of the inspectional findings of our respective inspectors and investigators.

5. HPB shall endeavor to provide prompt notification to FDA with respect to radiation emitting device defects or noncompliance with Canadian performance standards.

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

7. Information shall be provided to the extent national legislation permits. The provision of information will not extend to the disclosure of financial data or trade secrets.

III. Name and Address of Participating Agencies

A. Health Protection Branch
Health and Welfare of Canada
Brookfield Road
Ottawa, KLA 1C1

B. Food and Drug Administration
Department of Health, Education and Welfare
5600 Fishers Lane
Rockville, MD 20857

IV. Liaison Officers

A. Mr. G.E. MacDonald
Chief, Compliance Services
Environmental Health Directorate
Health Protection Branch
Telephone: 613-995-7059

B. Mr. Robert G. Britain
Director, Division of Compliance
Bureau of Radiological Health
Food and Drug Administration
Telephone: 301-443-4016

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A. Health Protection Branch, Health Canada Room 203, EH Bldg., Tunney's Pasture, Ottawa, Ontario, Canada K1A OL2

B. Dept. of Health, Education, and Welfare is now Dept. of Health and Human Services

A. Director General, Environmental Health Directorate is currently: Mr. Roy Hickman Tel. No. 613-957-1804

B. Chief of Non-Medical Radiological Device Branch, HFZ-342 (Currently: Paul Leggett, Jr.) Center for Devices and Radiological Health Tel. No. 301-594-4654

Notes:

V. Period of Agreement

This Memorandum of Understanding shall continue in effect unless modified by mutual consent of both parties or terminated by either party upon thirty (30) days advance written notice to the other.

This Memorandum of Understanding does not modify existing agreements nor does it preclude entering into separate agreements setting forth procedures for special programs which can be handled more efficiently and expeditiously by special agreement.

Nothing in this agreement is intended to diminish or otherwise affect the authority of either agency to carry out its respective statutory functions.

/s/

Currently: David A. Kessler, M.D.

ALEXANDER M. SCHMIDT, MD
COMMISSIONER
FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

DATE: 12/16/74

/s/

Currently: Joseph Losos, M.D.

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

A.B. MORRISON, Ph.D.
ASSISTANT DEPUTY MINISTER
HEALTH PROTECTION BRANCH
CANADA DEPARTMENT OF NATIONAL HEALTH AND WELFARE

DATE: 12/16/74