ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of cooperation (MOC) between the FDA, the Subsecretaría de Regulación y Fomento Sanitario, Mexico, and the Health Protection Branch, Canada. The purpose of the MOC is to expand and strengthen communications among the three governments in the scientific and regulatory fields of health.

DATES: The agreement became effective October 30, 1995.

FOR FURTHER INFORMATION CONTACT: Marilyn E. Veek, Office of International Affairs (HFY–50), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4480.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and memoranda of cooperation between FDA and others shall be published in the Federal Register, the agency is publishing notice of this memorandum of cooperation.

Dated: March 11, 1996.

Gary J. Dykstra,

Acting Associate Commissioner for Regulatory Affairs.

Memorandum of Cooperation Between the Subsecretaría de Regulación y Fomento Sanitario Secretaría de Salud (SSA) of the United Mexican States and the Food and Drug Administration (FDA), Department of Health and Human Services of the United States of America and the Health Protection Branch (HPB), Health Canada of Canada Regarding Cooperation in the Scientific and Regulatory Fields of Health

Preamble

The Subsecretaría de Regulación y Fomento Sanitario, the Food and Drug Administration and the Health Protection Branch seek to expand and strengthen communications among the three governments in the scientific and regulatory fields of health.

I. Purpose

The Subsecretaría de Regulación y Fomento Sanitario of the Secretaría de Salud (SSA) of the United Mexican States, the Food and Drug Administration (FDA) of the Department of Health and Human Services of the United States of America, and the Health Protection Branch (HPB) of the Department of Health of Canada affirm by this document their intention to strengthen existing mutual cooperation in the scientific and regulatory areas of regulated products, specifically foods (including dietary supplements), drugs (including biologics), cosmetics, medical devices, radiation-emitting electronic products, and related products. The parties intend to enhance, expand, and develop joint efforts to exchange information in health and in regulatory areas related to regulated products and prevention of health fraud related to the following areas:

A. The exchange of information at the earliest feasible stages of investigations into the safety of regulated products.

B. The exchange of information (including, for example, legislation, regulations, proposed amendments, guidelines, and technical documents such as evaluations of foreign suppliers of regulated products and enforcement decisions, including recalls or rejected shipments of products, and training material for regulatory officers) with respect to regulated products.

C. Communication on evaluation of the safety and nutritional quality of food, of the safety, effectiveness, and quality of drugs (including biologics) and medical devices, of the chemical and microbiological safety of cosmetics. The activities are intended to include, for example, communications on clinical protocols, new product approvals, and withdrawal of marketing approval due to concerns about safety, lack of proof of effectiveness, bioequivalence problems, etc.

D. The parties also intend to communicate on the evaluation of the chemical and microbiological safety of foods and cosmetics by exchanging information on chemical and microbiological analytical methods and criteria for safety evaluation.

E. Exchange of information on areas where two or more of the countries regulatory requirements are equivalent, with a view to working toward the development of a common approach in determining compliance status. The participants also intend to discuss their standards with a view toward considering whether it would be appropriate to undertake harmonization activities.

F. Strive through increased dialogue to achieve a common position in meetings of international organizations.

G. Communicate concerning the development of research and monitoring protocols and projects (including, for example, such areas as epidemiology, dietary surveys and health hazard related issues) and pre- and post-market surveillance activities.

H. Communicate concerning the development of programs to increase consumer protection related to health fraud.

II. Specific Plans

As the need arises in areas described in Section I, the participants may develop and agree upon specific plans of cooperation which will be incorporated in written agreements or arrangements.

III. Source of Funding

Each party to the Memorandum of Cooperation intends to fund its own activities subject to the availability of appropriated funds, personnel, and other resources. Any exchange of information or other activity under this Memorandum of Cooperation are to be performed in accordance with applicable laws and regulations.

IV. Participating Parties

A. Subsecretaría de Regulación y Fomento Sanitario, Secretaría de Salud, Lieja 7, 1er. Piso, Col. Juarez, 06696 Mexico, D.F.

B. Food and Drug Administration, Department of Health and Human Services, 5600 Fishers Lane, Rockville, Maryland 20857.

C. Health Protection Branch, Health Canada, Tunney's Pasture, Ottawa, Ontario K1A 0L7.

V. Liaison Officers

A. Coordinador de Asesores, Subsecretaría de Regulación and Fomento Sanitario, Lieja 7, 1er. Piso, Col. Juarez, 06696 Mexico, D.F., (525) 553–73–28 and (525) 553–6979; FAX (525) 553–69–96.

B. Director, International Affairs Staff, Office of External Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–4480; FAX (301) 443–0235.

C. Advisor to the Assistant Deputy Minister, Health Protection Branch, Health Canada, Tunney's Pasture, Ottawa, Ontario K1A 0L7, (613) 957–1804; FAX (613) 957–3954.

VI. Duration

Cooperation under this memorandum will commence upon signature of all participants. This memorandum may be revised by mutual written consent of all participants. Cooperation under this memorandum may be terminated upon thirty days advance written notice to the other participants.

For the Food and Drug Administration of the United States of America

Sharon Smith Holston
Title: Deputy Commissioner, External Affairs, FDA
Date: October 30, 1995
Place: Ottawa, Canada

For the Subsecretaría de Regulación y Fomento Sanitario of the United Mexican States

Rafael Camacho Solís
Title: Subsecretario de Regulación y Fomento Sanitario
Date: 30/x/95
Place: Ottawa, Canada

For the Health Protection Branch of Canada

Kent R. Foster
Title: ADM, HPB
Date: 30 October 1995
Place: Ottawa, Canada

[FR Doc. 96–6740 Filed 3–20–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed

collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency—s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements contained in BPD–718: Advance Directives (Medicare and Medicaid); *Form No.:* HCFA-R–10; Use: Certain Medicare and Medicaid organizations are responsible for collecting and documenting, in medical records, whether or not an individual has executed an advance directive, this document indicates the individual—s preference if he/she is incapacitated. Frequency: On occasion; Affected Public: Business or other for-profit, Not-for-profit institutions, Federal government, and State, local or tribal government; *Number of Respondents:* 38,927; *Total Annual Responses:* 38,927; *Total Annual Hours Requested:* 908,250.

To request copies of the proposed paperwork collections referenced above, call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address:

HCFA, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attention: Louis Blank, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850

Dated: March 13, 1996.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources.

[FR Doc. 96–6751 Filed 3–20–96; 8:45 am]

BILLING CODE 4120–03–P

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 et seq.) this notice is publishing the following summaries of proposed collections for public comment. The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Video Display Terminal (VDT) Operators Eye Care Program; *Form No.:* HCFA–81; *Use:* This form is needed to gather information necessary to process employees' request to participate in the VDT Operators' Eye Care Program. Part of the form will be completed by HCFA employees and their supervisors. Another part of the form is completed by personal eye care practitioners and opticians providing services to HCFA employees; *Frequency:* On occasion; *Affected Public*: Business or other for profit, Individuals or households, Federal Government; *Number of Respondents:* 500; *Total Annual Responses:* 500; *Total Annual Hours Requested* 2,000.

2. *Type of Information Collection Request:* Reinstatement, with change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Attending Physicians Statement and Documentation of Medical Emergency; *Form No.:* HCFA–1771; *Use:* This form is used to document the attending physician's statement that the hospitalization was required due to an emergency and give clinical support for the claim; *Frequency:* On occasion; *Affected Public:* Business or other for profit; *Number of Respondents:* 1,700; *Total Annual Responses:* 1,700; *Total Annual Hours Requested* 425.

To request copies of the proposed paperwork collection referenced above, call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attention: Zaneta Davis, 7500 Security Boulevard, Room C2–26–17 Baltimore, Maryland 21244–1850.

Dated: March 14, 1996.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff.

[FR Doc. 96–6757 Filed 3–20–96; 8:45 am]

BILLING CODE 4120–03–P

Public Information Collection Requirements Submitted for Public Comment and Recommendations

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summaries of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Reinstatement, without change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Information Collection Requirements in Final Peer Review Organization Sanction Regulations, 42 CFR 1004.40(b), 1004.50(g), 1004.60(b), and 1004.70 (b) and (c); *Form No.:* HCFA–R–65; *Use:* This rule revises and updates the procedures governing the imposition and adjudication of program sanctions predicated on recommendations of State Utilization and Quality Control Peer Review Organizations (PROs). These changes are being made as a result of