confirmation; and (5) day of submission: provide certifications.

Please note that an accompanying paper submission of the application remains a requirement at this time (21 CFR 601.2 and 601.3). The information in the electronic submission should not differ from the information provided in the paper submission.

As with other guidance documents, FDA does not intend this guidance manual to be all-inclusive. The manual is intended to provide information, not to set forth requirements. Applicants may follow the guidance or may choose to use alternative methods even though they are not provided in the manual. If an applicant chooses to use alternative methods, that applicant is encouraged to discuss the matter further with CBER.

This guidance document is not binding on either FDA or persons submitting biological license applications or NDA's to CBER, and does not create or confer any rights, privileges, or benefits for or on any person.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the guidance manual by June 19, 1996. Received comments will be considered in determining whether further revisions to the guidance manual are warranted. If the CAPLA guidance manual is revised or updated, a notice will be published in the Federal Register announcing its availability.

Dated: March 13, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–6742 Filed 3–20–96; 8:45 am]

BILLING CODE 4160–01–F

Request for Nominations for Members on Public Advisory Committees; Science Advisory Board to the National Center for Toxicological Research

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Science Advisory Board (the Board) to the National Center for Toxicological Research (NCTR). Nominations will be accepted for two vacancies that will occur on June 30, 1996.

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations for appropriately qualified female, minority, and physically disabled candidates. Final selections from among qualified candidates for each vacancy will be determined by the expertise required to meet specific agency needs and in a manner to ensure appropriate balance of membership.

DATES: Nominations should be received by April 22, 1996.

ADDRESSES: All nominations for membership, except for general public representatives (consumer-nominated members), should be sent to Barbara J. Jewell (address below). All nominations for general public representatives (consumer-nominated members) shall be submitted in writing to Annette J. Funn (address below).

FOR FURTHER INFORMATION CONTACT:

Regarding all nominations for membership, except for general public representatives (consumer-nominated members): Barbara J. Jewell, National Center for Toxicological Research (HFT–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3155.

Regarding all nominations for general public representatives (consumer-nominated members): Annette J. Funn, Office of Consumer Affairs (HFE–88), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5006.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for members to serve on the Board to NCTR. The function of the Board is to advise the Director, NCTR, on establishment and implementation of a research program that will assist in fulfilling the regulatory responsibilities of the Commissioner of Food and Drugs. The Board provides an extra-agency review to ensure that the research programs at NCTR are scientifically sound and pertinent.

Criteria for Members

Persons nominated for membership on the Board shall have adequately diversified experience that is appropriate to the work of the Board in the fields related to toxicological research.

The specialized training and experience necessary to qualify the nominees as experts suitable for appointment are subject to review, but may include experience in medical practice, teaching, and/or research relevant to the field of activity of the Board. The term of office is up to 4 years, depending on the appointment date.

General Public Representatives (Consumer-Nominated Members)

FDA currently attempts to place on committees members who are nominated by consumer organizations. These members are recommended by a consortium of 12 consumer organizations that has the responsibility for screening, interviewing, and recommending consumer-nominated candidates with appropriate scientific credentials. Candidates are sought who are aware of the consumer impact of committee issues, but who also possess enough technical background to understand and contribute to the committee's work. For some advisory committees the agency notes, however, it may require such nominees to meet the same technical qualifications and specialized training required of other expert members of the committee. The term of office for these members is up to 4 years, depending on the appointment date. Nominations are invited for consideration for membership as openings become available.

Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on the Board. Nominations shall state that the nominee is aware of the nomination, is willing to serve as a member of the Board, and appears to have no conflict of interest that would preclude board membership. A current copy of nominee's curriculum vitae should be included. Potential candidates will be asked by FDA to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts in order to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: March 15, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–6739 Filed 3–20–96; 8:45 am]

BILLING CODE 4160–01–F

[FDA–225–96–4001]

Memorandum of Cooperation Between the Food and Drug Administration, Mexico, and Canada

AGENCY: Food and Drug Administration, HHS.

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