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.