There are no capital costs or operating and maintenance costs associated with this collection.

Dated: March 15, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–6737 Filed 3–18–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96D–0022]

Computer Assisted Product License Application (CAPLA) Guidance Manual (March 1996); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance manual entitled ''Computer Assisted Product License Application (CAPLA) Guidance Manual (March 1996).'' This guidance manual was developed by FDA's Center for Biologics Evaluation and Research (CBER). The manual provides guidance for the submission of computer assisted license applications. The guidance manual is intended to increase the efficiency and quality of the review process for applicants and FDA. The manual also supersedes a previous Points to Consider guidance made available in November 1990.

DATES: Written comments by June 19, 1996.

ADDRESSES: Submit written requests for single copies of the guidance manual entitled ''Computer Assisted Product License Application (CAPLA) Guidance Manual (March 1996)'' to the Division of Congressional and Public Affairs (HFM–11), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send two self-addressed adhesive labels to assist that office in processing your requests. The guidance manual may also be obtained by mail or FAX by calling the Center for Biologics Evaluation and Research Voice Information System at 1–800–835–4709.

Additionally, persons with access to the INTERNET may obtain the guidance manual in several ways. Users of ''Web Browser'' software, such as Mosaic, Netscape, or Microsoft Internet Explorer may obtain this document via the World Wide Web by using the following Uniform Resource Locators:
http://www.fda.gov/cber/cberftp.html
ftp://ftp.fda.gov/CBER/

The document may also be obtained via File Transfer Protocol (FTP). Requesters should connect to FDA's FTP Server, FTP.FDA.GOV (192.73.61.21). CBER's documents are maintained in a subdirectory called ''CBER'' on the server. Logins with the user name of anonymous are permitted, and the user's e-mail address should be sent as the password. The ''READ.ME'' file in that subdirectory describes the available documents which may be available as an ASCII text file (*.TXT), or a WordPerfect 5.1 or 6.x document (*.w51,wp6), or both. Finally, the document can be obtained by ''bounce-back e-mail''. A message should be sent to: ''CAPLA@a1.cber.fda.gov''.

Submit written comments on the guidance manual to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance manual and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Timothy W. Beth, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: One of FDA's continuing objectives is to improve the speed and quality of its biologics licensing review and approval program. In order to reach a decision to approve a license application the agency must evaluate all information and data provided by applicants that support the safety, purity, potency, and efficacy of the proposed product. To make the review process more efficient for industry and FDA, CBER is utilizing electronic information systems technology. FDA believes the increased use of CAPLA's and computerization will enhance the timeliness, effectiveness, and efficiency of the biologics review process and reduce burdensome, nonessential hard-copy handling and storage.

In the Federal Register of November 20, 1990 (55 FR 48291), FDA announced the availability of a document entitled ''Points to Consider (PTC): Computer Assisted Submissions for License Applications.'' Since the publication of that document, CBER has gained considerable experience and expertise in the area of electronic information transfer. FDA is announcing in this Federal Register notice a document entitled ''Computer Assisted Product License Application (CAPLA) Guidance Manual (March 1996).'' This new manual supersedes the 1990 PTC document, and should be used as guidance by applicants for electronically submitting license applications or new drug applications (NDA's) to CBER.

A CAPLA is any electronic submission, ranging from a single diskette containing data files to a complete system including custom software and sponsor-owned hardware. Over time, CBER expects CAPLA's will evolve from stand-alone systems to submissions containing just electronic information files, with no applicant provided hardware or software. Applicants should confer with the CBER CAPLA coordinator early in the development of a CAPLA to assess whether it is necessary to include ''commercial off the shelf'' (COTS) software products or custom developed tools to support the CAPLA submission. The manual contains a listings of preferred COTS software and CBER contacts.

The guidance manual provides general information to applicants on the design, development, and submission of CAPLA's. The guidance manual is intended to address the special circumstances to be considered when an applicant electronically submits information in support of a license application; however, the guidance manual does not explain the scientific, clinical, or regulatory aspects of preparing a license application.

The manual is divided into four main sections: (1) Introduction; (2) CAPLA design and development; (3) CAPLA delivery and operations; and (4) CBER's computing environment. The manual also provides information regarding the following topics: Joint planning between the applicant and CBER, cross-platform tools, clinical review, CAPLA guidance for biostatistical review, data presentation formats, communication with CBER, CBER contacts, and license application forms.

The CAPLA guidance manual provides information regarding milestones that the applicant should consider when planning for CAPLA submissions. The following milestones are outlined in the guidance manual: (1) 12 to 18 months before submission: confer on network system requirements; (2) 6 months before submission: confer on CAPLA structure and content; (3) 1 to 3 months before submission: provide demonstration or prototype CAPLA; (4) 30 days before submission: submit

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.