Evaluation and Research (HFD–150), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2473.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 21, 1997 (62 FR 13650), FDA published a draft guidance for industry entitled ''Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products'' as part of efforts to encourage the submission of supplemental applications for drug and biological products. The intent of that draft guidance was to clarify what clinical evidence of effectiveness should be provided in new drug applications and supplemental applications. On that same date, the agency published a draft guidance for industry entitled ''FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products,'' which considered the quality and quantity of data that may be adequate to add a new use to the prescribing information for a product used in the treatment of cancer. These guidances were published as part of agency efforts to expedite the development of new and supplemental uses for drug and biological products.

In November 1997, the Modernization Act (Pub. L. 105–111) was signed into law by the President. Section 403 of the Modernization Act specifies that FDA will continue its efforts to encourage sponsors to submit supplemental applications for new uses for their products. Consistent with section 403 of the Modernization Act, the agency has finalized the draft guidances it issued in March 1997. After considering comments submitted by the public, FDA announced the availability, in final form, of the guidance entitled ''Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products'' in the **Federal Register** of May 15, 1998 (63 FR 27093).

This notice announces the availability of the final version of the guidance entitled ''FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products.'' This guidance focuses on the particular information to be provided when submitting an application for the approval of a supplemental new cancer treatment use for a marketed drug or therapeutic biological product. Cancer research often reveals potential new uses for already marketed drugs, and it is important to have new uses approved for inclusion in the product labeling as soon as adequate evidence of product safety and effectiveness for the new use becomes available.

Consistent with section 403(c) of the Modernization Act, CDER and CBER have designated key persons who will: (1) Encourage the prompt review of supplemental applications for approved products, and (2) work with sponsors to facilitate the development and submission of data to support supplemental applications.

Within CDER, the Associate Director for Medical Policy is fulfilling the requirements of section 403(c) of the Modernization Act by working with sponsors to facilitate the development of supplemental applications. Within the Division of Oncology Drug Products, the Special Assistant to the Division Director is working with sponsors to facilitate the development and submission of data to support supplemental applications for drug products used in cancer treatment. Efforts include: (1) Managing initiatives to seek the views of major groups and of individuals in the cancer research and treatment community, (2) managing and monitoring actions regarding possible labeling revisions, and (3) preparing regular progress reports.

Within CBER, supplemental applications are being facilitated by the Deputy Director, Medical, in accordance with section 403(c) of the Modernization Act. Review activities for most oncologic product applications are managed by the Office of Therapeutics Research and Review. The Oncology Branch of the Division of Clinical Trials Design and Analysis will work with sponsors to facilitate the development and submission of data to support supplemental applications for biologics used in cancer treatment.

This guidance represents the agency's current thinking on new cancer treatment uses for marketed drug and biological products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public in any way. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Dated: January 27, 1999.

Jane E. Henney,

Commissioner of Food and Drugs.

[FR Doc. 99–2562 Filed 2–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0375]

Guidance for Staff, Industry and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Guidance for Staff, Industry and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA).'' Under the Sectoral Annex on Medical Devices (Annex), FDA has agreed to designate conformity assessment bodies (CAB's) as third parties (i.e., organizations outside of FDA) authorized to perform premarket and quality system evaluations consistent with the Annex. This guidance will assist those who are interested in participating in this program as CAB's or as applicants pursuing premarket and quality system evaluations consistent with the Annex.

DATES: Written comments may be submitted at any time.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. If you do not have access to the World Wide Web, submit written requests for single copies of the guidance entitled ''Guidance for Staff, Industry and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA)'' on 3.5″ diskette to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Written comments concerning this guidance may be submitted at any time to the contact person listed below.

FOR FURTHER INFORMATION CONTACT: John F. Stigi, Division of Small Manufacturers Assistance (HFZ–220),

Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597 or FAX 301–443–8818.

SUPPLEMENTARY INFORMATION:

I. Background

The United States and the European Community (EC) exchanged letters on October 30, 1998, which brought the MRA into force on December 7, 1998. FDA published a final rule on the MRA on November 6, 1998 (63 FR 60122).

In the MRA negotiations, FDA led the negotiations on the Annex to the MRA between the United States and the EC. These negotiations resulted in the drafting of the MRA, which includes a special section pertaining to medical devices that is referred to as the Annex. The Annex provides for a 3-year transition period. After the transition period FDA and the EC may normally endorse premarket and quality system evaluation reports provided by equivalent third parties, the CAB's.

In order to establish confidence in the conformity assessment process, CAB's will be required to participate in rigorous joint exercises to demonstrate their proficiency to conduct evaluations. Upon implementation of this program, CAB evaluations will be exchanged and normally endorsed by both FDA and the EC for the marketing of medical devices.

FDA is using the National Voluntary Conformity Assessment System Evaluation (NVCASE) administered by the National Institute of Standards and Technology (NIST) of the U.S. Department of Commerce to recognize one or more accreditation bodies that, in turn, will accredit potential U.S. CAB's seeking to be designated under the Annex to evaluate medical devices produced for the EC market. FDA has considered the recommendations made by the NIST under NVCASE and has designated the U.S. CAB's that meet criteria for technical competence established in the Annex, for possible participation in transition activities.

In the **Federal Register** of July 2, 1998 (63 FR 36247), FDA published information regarding the process for CAB's to become eligible for designation under the Annex. On the same date, the agency announced the availability of a draft guidance on the third party program (63 FR 3621). The agency received three comments on the draft guidance. FDA has reviewed these comments and has made no significant revisions in the guidance in response to these comments. The agency has, however, included additional information regarding conflicts of interest, including additional examples of situations that would indicate a potential conflict of interest.

II. Significance of Guidance

This guidance represents the agency's current thinking on ''Guidance for Staff, Industry, and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so using the World Wide Web. CDRH maintains an entry on the World Wide Web for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH Home Page includes the ''Guidance for Staff, Industry and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA),'' device safety alerts, access to **Federal Register** reprints, information on premarket submissions including lists of approved applications and manufacturers' addresses, small manufacturers assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH Home Page may be accessed at ''http://www.fda.gov/cdrh''.

IV. Comments

Interested persons may, at any time, submit written comments regarding this guidance to the contact person listed above. Such comments will be considered when determining whether to amend the current guidance.

Dated: January 19, 1999.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 99–2509 Filed 2–2–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel.

Date: February 3, 1999.

Time: 1:00 PM to 3:00 PM.

Agenda: To review and evaluate grant applications.

Place: Double Tree Hotel, 2055 Harbor Boulevard, Ventura, CA 93001, (Telephone Conference Call).

Contact Person: Paul K. Strudler, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4100, MSC 7804, Bethesda, MD 20892, (301) 435–1716.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Endocrinology and Reproductive Sciences Initial Review Group Reproductive Biology Study Section.

Date: February 8–9, 1999.

Time: 8:30 AM to 5:00 PM.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Dennis Leszczynski, PHD, Scientific Review Administrator, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 6170, MSC 7892, Bethesda, MD 20892, (301) 435–1044.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel ZRG1–SSS–W(17).

Date: February 8–10, 1999.

Time: 6:00 PM to 1:00 PM.

Agenda: To review and evaluate grant applications.