Head Start Program and the expansion of services by other agencies providing child care and early childhood education, it is estimated that approximately 8,000 CDA candidates will require assessment and a credential award during each of the next four years.

In the face of these challenges, the Department seeks to ensure the continuity of the administration of this unique national credentialing program, which provides affordable credentialing award services which are nationally recognized, cost effective, represent quality standards for staff working with children ages birth to five years, and enjoy the confidence of the States, institutions of higher learning, and the field of early childhood.

(Catalog of Federal Domestic Assistance Program Number 93.600, Project Head Start)

Dated: December 11, 1997.

James A. Harrell,

Deputy Commissioner, Administration on Children, Youth and Families.

[FR Doc. 97–32954 Filed 12–16–97; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0430]

Medical Devices; Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications, [510(k)], to FDA; 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 Document for the Submission of Tumor Associated Antigen Premarket Notifications, [510(k)], to FDA.'' The guidance document provides suggestions for the nonclinical laboratory studies and the design, conduct, and analysis of appropriate clinical studies that the Center for Devices and Radiological Health (CDRH), FDA, believes will provide reasonable assurance of the safety and effectiveness of these devices. The guidance document also sets forth the review criteria and describes the data to support a 510(k) submission. The guidance accompanies a final rule, which appears elsewhere in this issue of the **Federal Register**, announcing the reclassification of tumor associated antigen immunological test systems from class III (premarket approval) to class II (special controls).

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written comments concerning this guidance document to the contact person listed below. Submit written requests for single copies of ''Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications, [510(k)], to FDA'' to the Division of Small Manufacturers Assistance (DSMA), Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist the office in processing your request, or fax your request to 301–443–8818. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Peter E. Maxim, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293.

SUPPLEMENTARY INFORMATION:

I. Background

FDA issued an order (September 19, 1996) in the form of a letter reclassifying tumor associated antigen immunological test systems from class III to class II. The order identified the premarket notification guidance document for tumor associated antigens as one of the designated special controls. The guidance document contains general information on the definition of qualifying devices and the administrative requirements for submitting a 510(k) to FDA. The document also lists the types of nonclinical (analytical) studies to be included in the submission. These studies include reagent characterization, assay specificity, and device performance characteristics to include precision, linearity, interfering substances, analytical sensitivity and methods of comparison to another device. Finally, the document provides guidance on the design of clinical studies to support a submission for a new tumor marker intended to monitor previously treated patients.

This guidance document represents the agency's current thinking on the design of clinical studies expected to support a 510(k) submission for new tumor markers intended to monitor previously treated patients. 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 requirements of the applicable statute, regulation, or both.

II. Requests for Comments

Interested persons may, at any time, submit to the contact person listed above written comments regarding this guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

III. Electronic Access

In order to receive the ''Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications, [510(k)], to FDA'' via your fax machine, call the CDRH Facts-On-Demand system at 1–800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (957) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). The CDRH maintains an entry on the WWW for easy access to the Web. Updated on a regular basis, the CDRH home page includes ''Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications, [510(k)], to FDA,'' device safety alerts, **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. ''Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications, [510(k)], to FDA'' will be available at http://www.fda.gov/cdrh/ode/ed—cl.html.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 1–800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES

AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

Dated: October 7, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–32875 Filed 12–16–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Cardiovascular and Renal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on January 27, 1998, 8:30 a.m. to 5:30 p.m.; and January 28, 1998, 9 a.m. to 4 p.m.

Location: National Institutes of Health, Natcher Conference Center, 45 Center Dr., Bethesda, MD 20892.

Contact Person: Joan C. Standaert, Center for Drug Evaluation and Research (HFD–110), 419–259–6211, or Danyiel A. D'Antonio (HFD–21), 301–443–5455, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12533. Please call the Information Line for up-to-date information on this meeting.

Agenda: On January 27, 1998, the committee will review and discuss: (1) New drug application (NDA) 20–736, Verdia™ (tasosartan, Wyeth-Ayerst Research), as a therapy for hypertension; and (2) the unapproved outpatient use of intermittent intravenous positive inotropic agents. On January 28, 1998, the committee will review and discuss NDA 20–718, Integrilin™ (eptifibatide, Cor Therapeutics, Inc.), for use in the settings of percutaneous transluminal angioplasty and acute coronary syndrome.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 20, 1998. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. on January 27, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 20, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 11, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–32874 Filed 12–16–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0188]

International Conference on Harmonisation; Guidance on General Considerations for Clinical Trials

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a guidance entitled ''E8 General Considerations for Clinical Trials.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance sets forth general scientific principles for the conduct, performance, and control of clinical trials.

DATES: Effective December 17, 1997. Submit written comments at any time.

ADDRESSES: Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Copies of the guidance are available from the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573. Single copies of the guidance may be obtained by mail from the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, or by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. Copies may be obtained from CBER's FAX Information System at 1–888–CBER–FAX or 301–827–3844.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: G. Alexander Fleming, Center for Drug Evaluation and Research (HFD–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6391.

Regarding ICH: Janet J. Showalter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research (CDER) and CBER, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).