written or electronic comments on the draft guidance entitled ''Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling'' by September 16, 2002. You must submit two copies of any comments. Individuals may submit one copy. You must identify comments with the docket number found in brackets in the heading of this document. Comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 5, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–17961 Filed 7–16–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1458]

Medical Devices: Class II Special Controls Guidance Document: Apnea Monitors; Guidance for Industry and FDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Apnea Monitors; Guidance for Industry and FDA.'' This document describes a means by which apnea monitors may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying apnea monitors into class II (special controls).

DATES: Submit written or electronic comments on the guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance entitled ''Class II Special Controls Document: Apnea Monitors; Guidance for Industry and FDA'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed labels to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: William Noe, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 22, 2000 (65 FR 57355), FDA announced the availability of this draft guidance document and invited interested persons to comment on it by December 21, 2000. FDA also announced in that notice its intention to modify the guidance so that it would apply to apnea monitors for patients of all ages. In that same issue of the **Federal Register** (65 FR 57301), FDA proposed to classify the apnea monitor into class II with this guidance document as the special control. This guidance supersedes the draft guidance entitled ''Guidance for Infant/Child Apnea Monitor 510(k) Submissions.''

FDA received comments on the draft guidance from one manufacturer. We considered this manufacturer's comments and included some of its suggestions in our revised guidance. We revised the guidance to make it applicable to devices intended for adults as well as infants and children, added information concerning industry's option to submit an abbreviated 510(k) when relying on a class II special controls guidance document, and retitled the guidance to reflect these changes.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on ''Class II Special Controls Guidance Document: Apnea Monitors; Guidance for Industry and FDA.'' 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 and regulations.

III. Electronic Access

In order to receive the guidance entitled ''Class II Special Controls Guidance Document: Apnea Monitors; Guidance for Industry and FDA'' via your fax machine, call the Center for Devices and Radiological Health (CDRH) Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1178) 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 Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes 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. A search capability for all CDRH guidance documents is available at http://www.fda.gov/cdrh/guidance.html. Guidance documents are also available at http://www.fda.gov/ohrms/dockets.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in the labeling section of this guidance discussing labeling under 21 CFR 807.87(e) was approved under OMB control number 0910–0120. The collection of information in the labeling section of this guidance discussing labeling under 21 CFR 801.109 was approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this guidance at any time. 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. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 5, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–17958 Filed 7–16–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Science and Regulation of Biological Products: From a Rich History to a Challenging Future; Public Symposium

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public symposium.

The Food and Drug Administration (FDA) is announcing a public symposium entitled ''Science and Regulation of Biological Products: From a Rich History to a Challenging Future.'' The purpose of the symposium is to commemorate the 100th anniversary of the enactment of the Biologics Control Act, the first Federal law regulating biological products. The symposium is dedicated to the memory and achievements of Dr. Harry Meyer, Jr., who, together with Dr. Paul Parkman, developed the first licensed rubella virus vaccine. The Center for Biologics Evaluation and Research (CBER) staff and invited guests will present scientific lectures describing the achievements of the past and the challenges of the future in the areas regulated by CBER (blood, vaccines, and therapeutic biological products).

Date and Time: The public symposium will be held on Monday, September 23, 2002, from 8:30 a.m. to 5 p.m., and Tuesday, September 24, 2002, from 8:30 a.m. to 12 noon.

Location: The public symposium will be held at the National Institutes of Health (NIH), Natcher Conference Center, Bldg. 45, 45 Center Dr., Bethesda, MD.

Contact:

For information about this notice: Michael D. Anderson, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6210, FAX 301–594–1944.

For information about the public symposium: Gail Sherman, Center for Biologics Evaluation and Research (HFM–42), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–2000, FAX 301–827–3079, e-mail: Sherman@cber.fda.gov.

Registration: Mail, fax, or e-mail your registration information (including name, professional degree, title, e-mail address, firm name, address, telephone, and fax number) to Gail Sherman by September 1, 2002. There is no registration fee for the public symposium. Space is limited, therefore, interested parties are encouraged to register early. There will be no onsite registration.

Travel Information: The NIH campus is accessible via the Washington, DC metro system, Red Line, at the Medical Center stop. The Natcher Conference Center is a short walk from the metro station, or you may take one of the many shuttle buses that run from the metro station to the various buildings on the campus. Due to newly imposed security measures, visitors parking is limited and use of private vehicles may cause significant delays in entering the campus.

If you need special accommodations due to a disability, please contact Gail Sherman at least 7 days in advance.

Dated: July 11, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–18039 Filed 7–16–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission of Childhood Vaccines; Request for Nominations for Voting Members

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations to fill three vacancies on the Advisory Commission on Childhood Vaccines (ACCV). The ACCV was established by Title XXI of the Public Health Service Act (the Act), as enacted by Public Law (Pub. L.) 99–660 and as subsequently amended, and advises the Secretary of Health and Human Services (the Secretary) on issues related to implementation of the National Vaccine Injury Compensation Program (VICP).

DATES: The agency must receive nominations on or before August 16, 2002.

ADDRESSES: All nominations are to be submitted to the Director, Division of Vaccine Injury Compensation, Office of Special Programs, HRSA, Parklawn Building, Room 8A–46, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Ms. Cheryl A. Lee, Principal Staff Liaison, Policy Analysis Branch, Division of Vaccine Injury Compensation, at (301) 443–2124.

SUPPLEMENTARY INFORMATION: Under the authorities that established the ACCV, viz. the Federal Advisory Committee Act of October 6, 1972 (Public Law 92–463) and section 2119 of the Act, 42 U.S.C. 300aa–19, as added by Public Law 99–660 and amended, HRSA is requesting nominations for three voting members of the ACCV.

The ACCV advises the Secretary on the implementation of the VICP. The activities of the ACCV include: Recommending changes in the Vaccine Injury Table at its own initiative or as the result of the filing of a petition; advising the Secretary in implementing section 2127 regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions; surveying Federal, State, and local programs and activities related to gathering information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b); advising the Secretary on the methods of obtaining, compiling, publishing, and using credible data related to the frequency and severity of adverse reactions associated with childhood vaccines; and recommending to the Director of the National Vaccine Program that vaccine safety research be conducted on various vaccine injuries.

The ACCV consists of nine voting members appointed by the Secretary as follows: Three health professionals, who are not employees of the United States Government and have expertise in the health care of children, the epidemiology, etiology and prevention of childhood diseases, and the adverse reactions associated with vaccines, at least two shall be pediatricians; three members from the general public, at least two shall be legal representatives (parents or guardians) of children who have suffered a vaccine-related injury or death; and three attorneys, at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death, and one shall be an attorney