Dated: October 17, 2005.

Robert E. Polson,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 05–21356 Filed 10–25–05; 8:45 am]

BILLING CODE 4168–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel; Meeting

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Enhancing Utilization of Childhood Immunization Client Recall Practices by Private Providers, RFA; IP 05–088; Improving Vaccination Coverage in the Greater than 65 Years of Age Population, RFA IP 05–091; Influenza Vaccination of Children and Accompanying Adults: Mass Vaccination versus Vaccination in Routine Care, RFA IP 05–094; Effectiveness of a Hospital Based Program for Vaccination of Birth Mothers and Household Contacts with Inactivated Influenza Vaccine, RFA; IP 05–095; and Developing Methods and Strategies to Increase Use of Immunization Registries by Private Providers, RFA IP 05–096.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Enhancing Utilization of Childhood Immunization Client Recall Practices by Private Providers, RFA IP 05–088; Improving Vaccination Coverage in the Greater than 65 Years of Age Population, RFA IP 05–091; Influenza Vaccination of Children and Accompanying Adults: Mass Vaccination versus Vaccination in Routine Care, RFA IP 05–094; Effectiveness of a Hospital Based Program for Vaccination of Birth Mothers and Household Contacts with Inactivated Influenza Vaccine, RFA IP 05–095; and Developing Methods and Strategies to Increase Use of Immunization Registries by Private Providers, RFA IP 05–096.

Times and Dates: 8 a.m.–5 p.m., November 21, 2005 (Closed).

Place: Renaissance Hotel, 1 Hartsfield Center Parkway, Atlanta, GA 30354, Telephone 404.209.9999.

Status: The meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Enhancing Utilization of Childhood Immunization Client Recall Practices by Private Providers, RFA IP 05–088; Improving Vaccination Coverage in the Greater than 65 Years of Age Population, RFA IP 05–091; Influenza Vaccination of Children and Accompanying Adults: Mass Vaccination versus Vaccination in Routine Care, RFA IP 05–094; Effectiveness of a Hospital Based Program for Vaccination of Birth Mothers and Household Contacts with Inactivated Influenza Vaccine, RFA IP 05–095; and Developing Methods and Strategies to Increase Use of Immunization Registries by Private Providers, RFA IP 05–096.

FOR FURTHER INFORMATION CONTACT: Horace M. Stiles, PHD MPH DDS, Scientific Review Administrator, National Institute for Occupational Safety and Health, CDC, 1600 Clifton Road, NE., MS E–74, Atlanta, GA 30333, Telephone 404–498–2584.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: October 19, 2005.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 05–21341 Filed 10–25–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

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

Date and Time: The meeting will be held on November 16, 2005, from 8:30 a.m. to 5:15 p.m. and on November 17, 2005, from 8:30 a.m. to 5:30 p.m.

Location: Holiday Inn Select, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Christine Walsh or Denise Royster, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512391. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 16, 2005, the committee will hear presentations and discuss the use of Madin-Darby Canine Kidney Cells for manufacture of Inactivated Influenza Vaccines. On November 17, 2005, the committee will discuss developing new Pneumococcal Vaccines for U.S. licensure for adults.

Procedure: On November 16, 2005, from 8:30 a.m. to 5:15 p.m. and on November 17, 2005, from 10 a.m. to 5:30 p.m., the meeting is open to the public. 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 November 9, 2005. Oral presentations from the public will be scheduled on November 16, 2005, between approximately 1:45 p.m. and 2:15 p.m. and on November 17, 2005, between approximately 1 p.m. and 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 9, 2005, 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.

Closed Committee Deliberations: On November 17, 2005, from 8:30 a.m. to 9:55 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

Persons attending FDA's advisory committee meetings are advised that the

agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Christine Walsh or Denise Royster at least 7 days in advance of the meeting.

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

Dated: October 18, 2005.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. 05–21350 Filed 10–25–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0392]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Cystic Fibrosis Transmembrane Conductance Regulator Gene Mutation Detection Systems; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled ''Class II Special Controls Guidance Document: CFTR Gene Mutation Detection Systems.'' This guidance document describes a means by which cystic fibrosis transmembrane conductance regulator (CFTR) gene mutation detection systems may comply with the requirements of special controls for class II devices. It includes recommendations for validation of performance characteristics and recommendations for product labeling. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify CFTR gene mutation detection systems into class II (special controls). This guidance document is immediately in effect as the special control for CFTR gene mutation detection systems, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on this guidance at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Class II Special Controls Guidance Document: CFTR Gene Mutation Detection Systems'' 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 one self-addressed adhesive label to assist that office in processing your request or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Zivana Tezak, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0597.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying CFTR gene mutation detection systems into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for CFTR gene mutation detection systems. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs regulation (§ 10.115). The guidance represents the agency's current thinking on CFTR gene mutation detection systems. 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

To receive ''Class II Special Controls Guidance Document: CFTR Gene Mutation Detection Systems'' by fax machine, call the 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 (1564) 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 by using the Internet. The Center for Devices and Radiological Health (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 manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site 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 on the Division of Dockets Management Internet site 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