summarizes clean area air classifications and recommended microbiological action levels, has been modified to acknowledge that alternate action levels can be justified depending on the method of analysis used. Further clarifications have been made regarding process simulations. In addition, the guidance recommends ''building quality into products'' through science-based facility, equipment, and systems design for sterile drug manufacture. We underscore our encouragement of alternate approaches and innovations to achieve increased sterility assurance.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking. 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 the approach satisfies the requirements of the applicable statute and regulations.

III. 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 (PRA) (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0139, until August 31, 2005.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: September 28, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–22207 Filed 9–29–04; 2:14 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0414]

Guidance for Industry on Food and Drug Administration Review of Vaccine Labeling Requirements for Warnings, Use Instructions, and Precautionary Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: FDA Review of Vaccine Labeling Requirements for Warnings, Use Instructions, and Precautionary Information,'' dated September 2004. The guidance document provides to vaccine manufacturers, medical practitioners, and consumers an overview of the vaccine labeling review process, a description of FDA's review of childhood vaccine labeling, and a discussion of the type of data FDA examines when determining the adequacy of vaccine labeling.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to 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. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the 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*.

FOR FURTHER INFORMATION CONTACT: Astrid Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, suite 200N, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: FDA Review of Vaccine Labeling Requirements for Warnings, Use Instructions, and Precautionary Information,'' dated September 2004. The guidance document provides to vaccine manufacturers, medical practitioners, and consumers an overview of the vaccine labeling review process, a description of FDA's review of childhood vaccine labeling under section 314 of the National Childhood Vaccine Injury Act (NCVIA), and a discussion of the type of data FDA examines when determining the adequacy of vaccine labeling. The processes described represent current FDA practices and do not represent any new interpretation of existing labeling statutes, regulations, or guidances.

The 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 this topic. 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 requirement of the applicable statutes and regulations.

II. Comments

In accordance with 21 CFR 10.115(g)(4)(i), FDA is immediately implementing this guidance. Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: September 20, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–22213 Filed 10–1–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Children's Hospitals Graduate Medical Education Payment Program (CHGME PP)

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Children's Hospitals Graduate Medical Education Payment Program (CHGME PP) conference call.

SUMMARY: This document announces a scheduled CHGME PP conference call for Federal fiscal year (FY) 2005. The

purpose of this conference call is to provide technical assistance related to the CHGME PP.

DATES: The conference call will be held on Wednesday, October 20, 2004 from 1:30 p.m. to 3:30 p.m. EST.

FOR FURTHER INFORMATION CONTACT: Ayah E. Johnson, Ph.D., telephone: (301) 443–1058; Division of Medicine and Dentistry, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, 5600 Fishers Lane, Room 9A–05, Rockville, Maryland 20857; or by e-mail at: *ajohnson@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The CHGME PP, as authorized by section 340E of the Public Health Service (PHS) Act (the Act) (42 U.S.C. 256e), provides funds to children's hospitals to address disparity in the level of Federal funding for children's hospitals that result from Medicare funding for graduate medical education (GME). Pub. L. 106–310 amended the CHGME statute to extend the program through FY 2005.

The statute authorized $280 million for both direct and indirect medical education payments in FY 2000, $285 million in FY 2001, and for each of the FY 2002 through FY 2005 such sums as necessary. Congress appropriated $303 million in FY 2004 for the CHGME PP. These funds have supported over 4,000 residents receiving training in children's teaching hospitals in 31 States.

The agenda for the conference calls will include but not be limited to: (1) Welcome and opening comments; (2) news releases/updates; (3) reminders; and (4) ''on the horizon'' topics of interest. Time will also be available for a question and answer period. Agenda items will be determined as priorities dictate.

Interested parties must register, in advance, but not later than 5 days prior to the scheduled conference call. Conference call registration forms and information about the Program can be found on the CHGME PP Web site. The Web site address is *http://bhpr.hrsa.gov/childrenshospitalgme.*

Dated: September 28, 2004.

Elizabeth M. Duke,

Administrator.

[FR Doc. 04–22282 Filed 10–1–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Infant Mortality; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Infant Mortality (ACIM).

Dates and Times: November 11, 2004, 9 a.m.–5 p.m., November 12, 2004, 8:30 a.m.–3 p.m.

Place: The Latham Hotel, 3000 M Street, NW., Washington, DC 20007 (202) 726–5000.

Status: The meeting is open to the public.

Purpose: The Committee provides advice and recommendations to the Secretary of Health and Human Services on the following: Department programs that are directed at reducing infant mortality and improving the health status of pregnant women and infants; factors affecting the continuum of care with respect to maternal and child health care, including outcomes following childbirth; strategies to coordinate the variety of Federal, State, local and private programs and efforts that are designed to deal with the health and social problems impacting on infant mortality; and the implementation of the Healthy Start program and *Healthy People 2010* infant mortality objectives.

Agenda: Topics that will be discussed include the following: Infant Mortality Differentials; Social Factors and Racial Disparities; and Perinatal Outreach Strategies. Agenda items are subject to change as priorities are further determined.

FOR FURTHER INFORMATION CONTACT: Anyone requiring information regarding the Committee should contact Peter C. Van Dyck, M.D., M.P.H., Executive Secretary, ACIM, Health Resources and Services Administration (HRSA), Room 18–05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, telephone: (301) 443–2170.

Individuals who are interested in attending any portion of the meeting or who have questions regarding the meeting should contact Ann M. Koontz, C.N.M., Dr.P.H., HRSA, Maternal and Child Health Bureau, telephone: (301) 443–6327.

Dated: September 29, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–22283 Filed 10–1–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Training in Primary Care Medicine and Dentistry; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Training in Primary Care Medicine and Dentistry.

Dates and Times: October 21, 2004, 8:15 a.m.–4:30 p.m., October 22, 2004, 8 a.m.–2 p.m.

Place: The Hilton in Gaithersburg, 620 Perry Parkway, Gaithersburg, Maryland 20877.

Status: The meeting will be open to the public.

Purpose: The Advisory Committee provides advice and recommendations on a broad range of issues dealing with programs and activities authorized under section 747 of the Public Health Service Act as amended by The Health Professions Education Partnership Act of 1998, Public Law 105–392. At this meeting the Advisory Committee will work on its draft fifth report which will be submitted to Congress and the Secretary of the Department of Health and Human Services in November 2005 and which focuses on measuring outcomes of Title VII, section 747 grant programs.

Agenda: The meeting on Thursday, October 21, will begin with opening comments from the Chair of the Advisory Committee. A plenary session will follow in which Advisory Committee members will hear speakers address the topic of outcomes measurement from various perspectives. The Advisory Committee will work on its fifth report, both in plenary session and in smaller workgroups. An opportunity will be provided for public comment.

On Friday, October 22, the Advisory Committee will continue work on the report. An opportunity will be provided for public comment.

For Further Information Contact: Anyone interested in obtaining a roster of members or other relevant information should write or contact Jerilyn K. Glass, M.D., Ph.D., Division of Medicine and Dentistry, Bureau of Health Professions, Health Resources and Services Administration, Room 9A–27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–6326. The web address for information on the Advisory Committee is *http://bhpr.hrsa.gov/medicine-dentistry/actpcmd.*