activities including updates on CDC scientific and programmatic activities.

Agenda items are subject to change as priorities dictate.

FOR FURTHER INFORMATION CONTACT: Robert Delaney,Executive Secretary, Advisory Committee to the Director,CDC, 1600 Clifton Road, NE., M/S D–14, Atlanta, Georgia 30333. Telephone 404/639–7000.

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: February 10, 2005.

Alvin Hall,

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

[FR Doc. 05–2961 Filed 2–15–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panels: Occupational Health and Safety Research, Program Announcement (PA) 04038, and NIOSH Support for Conferences and Scientific Meetings, Program Announcement Request (PAR) 05005

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 Panels (SEP): Occupational Health and Safety Research, Program Announcement 04038, and NIOSH Support for Conferences and Scientific Meetings, Program Announcement Request 05005.

Times and Dates: 5 p.m.–5:30 p.m., March 9, 2005 (Open); 5:30 p.m.–7:30 p.m., March 9, 2005 (Closed); 8:30 a.m.–6:30 p.m., March 10, 2005 (Closed).

Place: Royal Sonesta Hotel New Orleans, 300 Bourbon Street, New Orleans, LA 70140–1014 telephone 504–586–0300.

Status: Portions of 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 Program Announcement 04038 and Program Announcement Request 05005.

Contact Person for More Information: Pamela J. Wilkerson, MPA, Scientific Review Administrator, Office of Extramural Programs, National Institute for Occupational Safety and Health, CDC, 1600 Clifton Road, NE., MS–E74, Atlanta, GA 30333, Telephone 404–498–2556.

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 the CDC and the Agency for Toxic Substances and Disease Registry.

Dated: February 8, 2005.

Alvin Hall,

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

[FR Doc. 05–2963 Filed 2–15–05; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cellular, Tissue and Gene Therapies Advisory Committee (formerly the Biological Response Modifiers Advisory Committee); Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Cellular, Tissue and Gene Therapies Advisory Committee (formerly the Biological Response Modifiers Advisory Committee). This meeting was announced in the **Federal Register** of January 27, 2005 (70 FR 3934). The amendment is being made to reflect the cancellation of the closed portion of the meeting and the following portions of the document: *Date and Time*, *Agenda*, *Procedure*, and *Closed Committee Deliberations*. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Gail Dapolito or Rosanna L. Harvey, 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 3014512389. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 27, 2005, FDA announced that a meeting of the Cellular, Tissue and Gene Therapies Advisory Committee (formerly the Biological Response Modifiers Advisory Committee) would be held on March 3 and 4, 2005. On page 3935, in the first column, the introductory paragraph, *Date and Time*, *Agenda*, and *Procedure* portions of the document are amended to read as follows:

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.

Date and Time: The meeting will be held on March 3, 2005, from 8 a.m. to approximately 6 p.m. and on March 4, 2005, from 8 a.m. to approximately 5 p.m.

Agenda: On March 3, 2005, all day and on March 4, 2005, in the morning, the committee will discuss cellular therapies for repair and regeneration of joint surfaces. Additionally, on March 4, 2005, the committee will discuss safety issues related to retroviral vector-mediated tumorigenesis in gene transfer clinical trials.

Procedure: On March 3, 2005, from 8 a.m. to approximately 6 p.m. and on March 4, 2005, from 8 a.m. to approximately 5 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 February 23, 2005. Oral presentations from the public will be scheduled on March 3, 2005, between approximately 11 a.m. and 11:30 a.m. and on March 4, 2005, between approximately 12 noon and 12:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 23, 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.

On page 3935, in the second column, the *Closed Committee Deliberations* portion of the document is deleted to reflect the cancellation of the closed portion of the meeting on March 3, 2005.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: February 8, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–2920 Filed 2–15–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Industry Exchange Workshop on Food and Drug Administration Clinical Trial Requirements; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Philadelphia District, in cooperation with the Society of Clinical Research Associates (SoCRA), is announcing a workshop on FDA Clinical trial statutory and regulatory requirements. This 2-day workshop for the clinical research community targets sponsors, monitors, clinical investigators, institutional review boards, and those who interact with them for the purpose of conducting FDA regulated clinical research. The workshop will include both industry and FDA perspectives on proper conduct of clinical trials regulated by FDA.

Date and Time: The public workshop is scheduled for Wednesday, April 13, 2005, from 8:15 a.m. to 5 p.m. and Thursday, April 14, 2005, from 8:15 a.m. to 4 p.m.

Location: The public workshop will be held at the Sheraton University City Hotel Philadelphia, 3549 Chestnut St., Philadelphia, PA 19104, 215–387–8000, FAX: 215–387–7920.

Contact: Marie Falcone, Food and Drug Administration, U.S. Customhouse, 200 Chestnut St., rm. 900, Philadelphia, PA 19106, 215–597–2120 ext. 4003, FAX: 215–597–5798, e-mail: *mfalcone@ora.fda.gov*.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) and the registration fee of $485 (member), $560 (nonmember), or $460 (government employee nonmember). (Registration fee for nonmemebers includes a 1 year membership.) The registration fee for FDA employees is waived. Make the registration fee payable to SoCRA, P.O. Box 101, Furlong, PA 18925. To register via the Internet go to *http://www.socra.org/FDA_Conference.htm*. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

The registrar will also accept payment by major credit cards. For more information on the meeting, or for questions on registration, contact 800–SoCRA92 (800–762–7292), or 215–345–7369, or via e-mail: *socramail@aol.com*. Attendees are responsible for their own accommodations. To make reservations at the Sheraton University City Hotel at the reduced conference rate, contact the Sheraton University City Hotel (see *Location*) before March 13, 2005.

The registration fee will be used to offset the expenses of hosting the conference, including meals, refreshments, meeting rooms, and materials. Space is limited, therefore interested parties are encouraged to register early. Limited onsite registration may be available. Please arrive early to ensure prompt registration.

If you need special accommodations due to a disability, please contact Marie Falcone (see *Contact*) at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: The workshop on FDA Clinical Trials Statutory and Regulatory Requirements, helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health by educating researchers on proper conduct of clinical trials. Topics for discussion include the following: (1) FDA and confidence in the conduct of clinical research; (2) medical device, drug, and biological product aspects of clinical research; (3) investigator initiated research; (4) Pre-investigational new drug (IND) application meetings and FDA meeting process; (5) informed consent requirements; (6) ethics in subject enrollment; (7) FDA regulation of Institutional Review Boards; (8) electronic records requirements; (9) adverse event reporting; (10) how FDA conducts bioresearch inspections, and (11) what happens after the FDA inspection. FDA has made education of the research community a high priority to assure the quality of clinical data and protect research subjects.

The workshop helps to implement the objectives of section 406 of the FDA Modernization Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The workshop also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) by providing outreach activities by Government agencies directed to small businesses.

Dated: February 4, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–2922 Filed 2–15–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food and Drug Administration Drug Educational Forum; Public Workshop; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of February 3, 2005 (70 FR 5686). The document announced a public workshop. The document was published with a typographical error in the **SUPPLEMENTARY INFORMATION** section. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 05–2098, appearing on page 5686, in the **Federal Register** of Thursday, February 3, 2005, the following correction is made:

1. On page 5687, in the second column, the fifth line from the bottom should read ''abbreviated new drug applications (ANDAs)''.

Dated: February 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–2921 Filed 2–15–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0355]

Scientific Considerations Related to Developing Follow-On Protein Products; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until