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

March 16, 2005, the comment period for the notice that appeared in the **Federal Register** of August 16, 2004 (69 FR 50386). In the notice, FDA announced a public workshop on scientific and technical considerations related to the development of follow-on protein pharmaceutical products and plans to develop draft guidance and requested comments related to developing and approving follow-on protein pharmaceutical products. The agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: Submit written and electronic comments by March 16, 2005.

ADDRESSES: Submit written comments on scientific topics related to follow-on protein products 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: Keith Webber, Center for Drug Evaluation and Research (HFD–121), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, 301–443–5089, e-mail: *keith.webber@fda.gov*, or Chris Joneckis, Center for Biologics Evaluation and Research (HFM–1), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20892, 301–827–2000, e-mail: *christopher.joneckis@fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 16, 2004 (69 FR 50386), FDA published a notice with a 90-day comment period to request comments on the scientific and technological perspectives of manufacturers, academia, and other interested persons to determine the state of the science as it relates to protein characterization, production, and assessment of similarity.

The agency has received requests for an extension of the comment period for the notice. In response to these requests, FDA has decided to reopen the comment period for the notice for an additional 30 days, until March 16, 2005.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on this document. Two copies of mailed 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. Received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 11, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–3027 Filed 2–11–05; 4:50 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Health Professions Preparatory, Health Professions Pregraduate and Indian Health Professions Scholarship Programs: Correction

ACTION: Notice; correction.

SUMMARY: The Indian Health Service published a document in the **Federal Register** on January 19, 2005. The document contained two errors.

FOR FURTHER INFORMATION CONTACT: Mr. Jess Brien, Chief, Scholarship Branch, Indian Health Service, 801 Thompson Avenue, Suite 120, Rockville, Maryland 20852; Telephone (301) 443–6197. (This is not a toll-free number.)

Correction

In the **Federal Register** of January 19, 2005, in FR Doc. 05–1030, on page 3046, in the second column, correct the Anticipated Award Start Date to read August 1, 2005; page 3048, in the second column, Application Receipt Date, correct February 28, 2005 to March 28, 2005.

Dated: January 27, 2005.

Charles W. Grim,

Assistant Surgeon General, Director, Indian Health Service.

[FR Doc. 05–2971 Filed 2–15–05; 8:45 am]

BILLING CODE 4160–16–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel Innovations in Cancer Sample Preparation.

Date: April 28, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, EPN–J, 6130 Executive Boulevard, Rockville, MD 20852.

Contact Person: Timothy C. Meeker, MD, Scientific Review Administrator, Special Referral and Resources Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8088, Rockville, MD 20852, (301) 594–1279.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: February 8, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–2957 Filed 2–15–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Heart, Lung, and Blood Institute Special Emphasis Panel, March 2, 2005, 8 a.m. to March 2, 2005, 5 p.m., Sheraton Inner Harbor Hotel, 300 South Charles Street, Baltimore, MD 21201 which was published in the **Federal Register** on January 18, 2005, FR70:2867–2868.

The meeting will be held on March 1 at 8 a.m. instead of March 2, 2005 as previously advertised. The meeting is closed to the public.