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