Organization name	Location	State	Supplement award
The WorkPlace, Inc.	Bridgeport	CT	125,000
Blackfeet Community College	Browning	MT	125,000
Turtle Mountain Community College	Belcourt	ND	125,000
Cook Inlet Tribal Council, Inc.	Anchorage	AK	125,000
College of Menominee Nation	Keshena	WI	125,000
Cankdeska Cikana Community College	Fort Totten	ND	125,000

Statutory Authority: Section 2008(a) of Title XX of the Social Security Act, as amended by Section 5507 of the Affordable Care Act (Pub. L. 111–148).

Earl S. Johnson,

Director, Office of Family Assistance.

[FR Doc. 2012–24310 Filed 10–2–12; 8:45 am]

BILLING CODE 4184–48–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Clinical Investigator Training Course

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research/Office of Medical Policy and the Duke University Office of Continuing Medical Education are cosponsoring a 3-day training course for clinical investigators on scientific, ethical, and regulatory aspects of clinical trials. This training course is intended to provide clinical investigators with expertise in the design, conduct, and analysis of clinical trials; improve the quality of clinical trials; and enhance the safety of trial participants. Senior FDA staff will communicate directly with clinical investigators on issues of greatest importance for successful clinical research.

Date and Time: The training course will be held on November 13 and 14, 2012, from 8 a.m. to 5 p.m., and on November 15, 2012, from 8 a.m. to 4 p.m.

Location: The course will be held at the Holiday Inn College Park, 10000 Baltimore Ave., College Park, MD 20740.

Contact Person: Connie Wisner, Office of Medical Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6360, Silver Spring, MD 20993, 301–796–8509.

Registration: Register by October 22, 2012. The registration fee is $400 per person. The fee includes course materials and onsite lunch. Early registration is recommended because seating is limited. There will be no onsite registration.

Register online for the training course at the registration Web site: *http://evm.auxserv.duke.edu/iebms/reg/reg_p1_form.aspx?oc=10&ct=DCRIINVEST&eventid=46475* or download a full-size copy of the registration form and mail a check and completed form to: Duke University Conference and Event Services, FDA Investigator Course Box 90841, 101 Bryan Center, Durham, NC 27708. You will receive an email that confirms your registration. (FDA has verified the Web site address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Attendees are responsible for their own accommodations. A block of rooms has been reserved under ''FDA Clinical Investigator Course'' at the Holiday Inn College Park at a reduced conference rate. Reservations for these accommodations can be made online using the course registration Web site mentioned previously. Click on ''registration form.'' You will see a direct link to the hotel.

Registration materials, payment procedures, accommodation information, and a detailed description of the course can be found at the registration/information Web site mentioned previously.

If you need special accommodations due to a disability, please contact Connie Wisner at least 7 days in advance. Persons attending the course are advised that FDA is not responsible for providing access to electrical outlets.

I. Background

Clinical trial investigators play a critical role in the development of medical products. They are responsible for ensuring the safe and ethical treatment of study subjects and for collecting adequate and reliable data to support regulatory decisions. This course is intended to assist clinical investigators in understanding what preclinical and clinical information is needed to support the investigational use of medical products, as well as the scientific, regulatory, and ethical considerations involved in the conduct of clinical trials. The course will cover a wide variety of key topics, including material on novel safety concerns, adverse event monitoring, compliance with the legal and ethical obligations of clinical research, and acceptable scientific and analytic standards in the design and conduct of clinical studies. The faculty will include a diverse representation of senior FDA staff, enabling FDA to communicate directly with clinical investigators on issues of greatest importance for successful clinical research.

II. Description of the Training Course

A. Purpose

The training course is designed to provide clinical investigators with an overview of the following information:

- The essential toxicological, pharmacological, and manufacturing data to support investigational drug use in humans;
- Fundamental issues in the design and conduct of clinical trials;
- Statistical and analytic considerations in the interpretation of trial data;
- Appropriate safety evaluation during studies; and
- The ethical considerations and regulatory requirements for clinical trials.

In addition, the course should do the following:

- Foster a cadre of clinical investigators with knowledge, experience, and commitment to investigational medicine;
- Promote communication between clinical investigators and FDA;
- Enhance investigators' understanding of FDA's role in experimental medicine; and
- Improve the quality of data while enhancing subject protection in the performance of clinical trials.

B. Proposed Agenda

The course will be conducted over 3 days and comprised of approximately 26 lectures, each lasting between 30 and

45 minutes. The course will be presented mainly by senior FDA staff, with guest lecturers presenting selected topics.

The course will address FDA's role in clinical studies, regulatory considerations for clinical trials, and review of the material generally appearing in an ''investigator's brochure,'' i.e., the preclinical information (toxicology, animal studies, and chemistry/manufacturing information) that supports initial clinical trials in humans. Presenters will discuss the role of clinical pharmacology in early clinical studies and how this information is used in the design of subsequent studies. The course will also include discussions of scientific, statistical, ethical, and regulatory aspects of clinical studies. On November 15, 2012, participants will choose among three breakout sessions that will explain how to put together an application to FDA for drugs, biologics, or devices.

C. Target Audience

The course is targeted at health care professionals responsible for, or involved in, the conduct and/or design of clinical trials.

Dated: September 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–24214 Filed 10–2–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0284]

Pediatric Studies of Sodium Nitroprusside Conducted in Accordance With Section 409I of the Public Health Service Act; Establishment of Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the opening of a public docket to make available to the public a report of the pediatric studies of sodium nitroprusside that were conducted in accordance with the Public Health Service Act (the PHS Act) and submitted to the Director of the National Institutes of Health (NIH) and the Commissioner of Food and Drugs.

DATES: Submit either electronic or written comments by November 2, 2012.

ADDRESSES: You may submit comments, identified by FDA–2012–N–0284, by any of the following methods.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Fax:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Akilah Green, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6475, Silver Spring, MD 20993–0002, email: *akilah.green@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under section 409I of the PHS Act (42 U.S.C. 284m), the Secretary of the Department of Health and Human Services (the Secretary) acting through the Director of NIH, in consultation with FDA and experts in pediatric research, must develop, prioritize, and publish a list of priority needs in pediatric therapeutics, including drugs, biological products, and indications that require study.[1] For drugs and biological products and indications on this list, FDA, acting in consultation with NIH, is authorized to issue a written request to holders of a new drug application (NDA) or abbreviated new drug application (ANDA) for a drug, or holders of a biologics license application (BLA) for a biological product, for which pediatric studies are needed to provide safety and efficacy information for pediatric labeling. If the sponsors receiving the written request decline to conduct the studies or if FDA does not receive a response to the written request within 30 days of the date the written request was issued, the Secretary, acting through the Director of NIH and in consultation with FDA, must publish a request for proposals to conduct the pediatric studies described in the written request and award funds to an entity with appropriate expertise for the conduct of the pediatric studies described in the written request. Upon completion of the pediatric studies, a study report that includes all data generated in connection with the studies must be submitted to FDA and NIH and placed in a public docket assigned by FDA.

Sodium nitroprusside, a hypotensive agent, is labeled for the immediate reduction of blood pressure of patients in hypertensive crises, for producing controlled hypotension in order to reduce bleeding during surgery, and for the treatment of acute congestive heart failure. Off-label use of sodium nitroprusside in pediatric patients is significant, despite the lack of adequate pharmacokinetic, dosing, tolerability, and safety data for this age group.

On January 21, 2003, NIH published a **Federal Register** notice (68 FR 2789) announcing the addition of several drugs, including sodium nitroprusside, to the priority list of drugs most in need of study for use by children to ensure their safety and efficacy. A written request for pediatric studies of sodium nitroprusside was issued on July 8, 2002, to Abbott Laboratories, the holder of the NDA for sodium nitroprusside. FDA did not receive a response to the written request. Accordingly, NIH issued a request for proposals to conduct the pediatric studies described in the written request in July 2004, and awarded funds to Duke University and Stanford University in September 2004, to complete the studies described in the written request. Upon completion of the pediatric studies, a report of the pediatric studies of sodium nitroprusside was submitted to NIH and FDA. As required under section 409I of the PHS act, FDA opened a public docket and NIH placed in the docket the report of pediatric studies of sodium nitroprusside that was submitted to NIH and FDA. The report includes all data generated in connection with the study, including the written request.

We invite interested parties to review the report and submit comments to the docket. The public docket is available

[1] Prior to the 2007 reauthorization of the Best Pharmaceuticals for Children Act (Pub. L. 107–109), the priority list included specific drugs instead of therapeutic areas.