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 investigative 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
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]

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.

ADDRESS: 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:


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, Room 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.

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, Room 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:
Akillah 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: akillah.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. 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.