approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*. (Select this public workshop from the posted events list).

I. Background

Biofilms play a key role in the development of device-related and other healthcare associated infections. Published literature indicates that biofilms are a major culprit in the development of resistant infections. However, the biochemical and physiochemical characteristics of biofilms are not widely understood.

With the increasing use of implanted and indwelling devices, understanding biofilm development on these devices and factors that impact biofilm formation is critical. Research on the basic science of biofilms may provide insight on device-associated biofilms, ultimately advancing research on technologies that are intended to prevent biofilm formation.

This public workshop seeks to share scientific information between academia, industries interested in developing products to address biofilm contamination, and U.S. Government scientists.

II. Topics for Discussion at the Public Workshop

FDA seeks to address and receive comments on the following topics:

1. Research on biofilms and their public health impact.

2. Challenges faced by the scientific community, government, and industry on addressing biofilm contamination of medical devices.

3. Critical areas of research that will address the scientific and clinical challenges faced by the stakeholders when developing technologies that are intended to prevent biofilm formation.

This public workshop may also form the basis for future discussions related to novel biofilm prevention technologies that could benefit U.S. public health.

Dated: January 17, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–01412 Filed 1–23–14; 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 the Public Health Service Act; Availability of Summary Report and Requested Labeling Changes

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a summary report of the pediatric studies of sodium nitroprusside conducted in accordance with the Public Health Service Act (the PHS Act) and is making available requested labeling changes for sodium nitroprusside. The Agency is making this information available consistent with the PHS Act.

FOR FURTHER INFORMATION CONTACT: Lori Gorski, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6415, Silver Spring, MD 20993–0002, 301–796–2200, Fax: 301–796–9855, email: *lori.gorski@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Sodium Nitroprusside Summary Review

In the **Federal Register** of January 21, 2003 (68 FR 2789), sodium nitroprusside (SNP) was identified as a drug that needed further study in pediatrics. The approved labeling lacked adequate information on dosing, pharmacokinetics, tolerability, and safety information in pediatric patients from birth to 18 years of age who receive SNP for controlled reduction of blood pressure.

A written request (WR) for pediatric studies of sodium nitroprusside was issued on July 8, 2002, to Abbott Laboratories, the holder of the new drug application for sodium nitroprusside. FDA did not receive a response to the written request. Accordingly, the National Institutes of Health (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.

The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) submitted clinical study reports for SNP. The two studies are:

- NICHD–2003–09–DR–SNP1: A randomized double-blind, parallel group, dose-ranging, effect-controlled, multicenter study of intravenous infusions of SNP in pediatric patients who require deliberate, controlled relative-induced hypotension for at least 2 hours.
- NICHD–2003–09–LT–SNP2: A multicenter, randomized, double-blind, placebo-controlled, parallel group study to determine the pharmacodynamics of sodium nitroprusside during the prolonged infusion in pediatric subjects. This study was a withdrawal to placebo study.

Upon completion of these pediatric studies, a report of the pediatric studies of sodium nitroprusside was submitted to NIH and FDA. In the **Federal Register** of October 3, 2012 (77 FR 60441), FDA announced the opening on August 31, 2012, of docket FDA–2012–N–0284 for submission of data from pediatric studies of sodium nitroprusside. The data submitted to the docket were submitted in accordance with section 409I of the PHS Act (42 U.S.C. 284m) and were the same data submitted to investigational new drug application 71,979, with the exception that personal privacy information had been redacted from the data submitted to the docket.

The sodium nitroprusside docket remained opened for public comment from October 3, 2012, through November 2, 2012. There were no comments submitted to the docket during that time, and a memorandum for the record stating such was posted to the docket on November 5, 2012.

During the review of the submission, the Division of Cardiovascular and Renal Products identified inconsistencies in subject numbers between the pharmacokinetic/pharmacodynamic (PK/PD) analysis set and the ITT–E (intent to treat-efficacy) population in the study report NICHD–2003–09–DR–SNP1 and notified NIH. In a meeting with FDA on November 29, 2012, NIH indicated that that they identified treatment assignment inconsistencies between the two datasets and provided a strategy for addressing the concern and performing reanalysis. The need for reanalysis resulted in suspension of the review as of November 29, 2012. The corrected datasets and reanalysis were provided to the Agency and submitted to the docket on September 26, 2013.

The key findings of this submission are:

- The blood pressure lowering effect of SNP was demonstrated in both of the trials.

• A higher proportion of patients in the high-dose group achieved target mean arterial pressure (MAP) compared to the lowest dose of 0.3 microgram/kilogram/minute (μg/kg/min). The time-to-target MAP was also significantly shorter for the high-dose groups.

• With a starting dose of 0.3 μg/kg/min, ~25 percent of patients achieved target MAP in 5 minutes. Maintaining on a stable dose of 0.3 μg/kg/min for 10 minutes resulted in ~50 percent of patients reaching target MAP. Hence, a starting dose of 0.3 μg/kg/min is reasonable. It should also be noted that it may be prudent to maintain the infusion rate for an additional 5 to 10 minutes before titrating.

• The proportion of patients with MAP reductions of >20 percent below target increased in a dose-dependent manner.

• The safety profile of SNP in both the trials was largely consistent with the expected events as a result of the underlying disease and preoperative setting. Only blood pressure reduction events were clearly drug- and dose-related.

• Even though only four neonates were studied in the trial, there is no expectation that the PK/PD relationship and the safety profile would be any different in this age group.

• The FDA Adverse Event Reporting System (FAERS) search (up to October 25, 2012) retrieved only 26 pediatric cases with SNP use. Of these, four cases of elevated carboxyhemoglobin associated with SNP treatment were reported. The Office of Surveillance and Epidemiology review outlines several reasons why these data cannot be used to calculate incidence of adverse events in the population.

• For this submission, one large site (N = 36 enrolled in Protocol NICHD–2003–09–LT–SNP2; Investigator: Dr. David Rosen) was inspected. The Office of Scientific Investigations recommends the data be accepted.

• As a part of the WR, long-term safety data and a 1-year followup period for patients enrolled in the trial were sought. Information from followup was not available in the submission. However, the value of such information is limited and is not expected to have an impact on the ability to overcome the labeling gap. The complete report can be found at docket number FDA–2012–N–0284.

II. Recommendation

The submission provides a reasonable algorithm for administration of sodium nitroprusside to allow its use in perioperative settings to achieve controlled hypotension for pediatric patients from birth to 18 years. FDA's requested labeling changes are available on the FDA Web site at *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm379088.htm* and in the docket (Ref. 1).

III. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested person between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov.*

1. FDA Requested Labeling Changes.

Dated: January 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–01390 Filed 1–23–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney and Diseases; Notice of Closed Meeting

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

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 Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel PAR12–265: NIDDK Ancillary Studies to Major Ongoing Clinical Research: Epidemiology of Gut Microbiome in Diabetes.

Date: February 28, 2014.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 749, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8894, *begumn@niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: January 17, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–01386 Filed 1–23–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0099]

Agency Information Collection Activities: Application for T Nonimmigrant Status; Application for Immediate Family Member of T–1 Recipient; and Declaration of Law Enforcement Officer for Victim of Trafficking in Persons, Form I–914 and Supplements A and B. Extension, Without Change, of a Currently Approved Collection

ACTION: 60-day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment upon this proposed extension of a currently approved collection of information or new collection of information]. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (i.e. the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until March 25, 2014.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0099 in the subject box, the agency name and Docket ID USCIS USCIS–2006–0059. To avoid duplicate submissions, please use only one of the following methods to submit comments: