• 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: