authorities and processes, its initiatives and programs, etc.; and,

- Provide a venue for advocacy for patient stakeholders within FDA and be transparent to patients about Agency actions.

In addition to an annual meeting, the FDA Patient Network consists of other activities, including the:

- FDA Patient Network Web site—A new, patient-centered Web site that contains educational modules, centralized Agency information, and multidirectional communication tools;
- Biweekly *FDA Patient Network News* email newsletter; and hosting of periodic meetings, briefings, and listening session between patient advocates and FDA staff.

II. Patient Perspectives in Regulatory Decisionmaking

Establishing a means for obtaining input from patients and patient advocate groups will allow FDA to further enhance its benefit-risk assessment in regulatory decisionmaking. Patients who live with a disease have a direct stake in the outcomes of the review process and are in a unique position to contribute to the weighing of benefit-risk considerations that can occur throughout the medical product development process. Though several programs exist that facilitate patient representation on Advisory Committees or participation in selected review meetings, there are currently few venues in which the patient perspective is discussed outside of a specific product's marketing application review. The medical product review process could benefit from a more scientific, systematic, and expansive approach to obtaining input from patients who are experiencing a particular disease condition.

As part of the proposed agreements for Prescription Drug User Fee Act (PDUFA) V, FDA plans to conduct meetings with patients and patient advocacy groups to gather broader patient input. This meeting kicks off these efforts and provides an opportunity to gain feedback on how FDA can best structure these upcoming meetings.

FDA seeks public discussion based on the following questions. These questions are intended to frame patient input at the May 18, 2012, meeting and there will be time at the meeting to discuss the following issues.

(1) How can FDA ensure gathering a broad range of representative patient input that is relevant to a specific disease area during its meetings with patients? For example, who should serve as representatives of patients?

(2) What methodological and practical issues should FDA consider as it develops its strategy for eliciting the patient perspective? For instance, FDA is interested in addressing topics including, but not limited to, the following:

(a) Are there particular advantages or disadvantages to utilizing face-to-face meetings versus web-based or other methods in obtaining the patient perspective on a particular disease condition and its treatment?

(b) How can FDA ensure that certain subpopulations, such as patients with the most severe form of the disease, are represented?

III. Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research Efforts

Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research plan to conduct a series of patient-focused drug development meetings to gather patient input on the clinical context of a disease and its impact on a patient's daily life. These considerations, which would include an analysis of the severity of the disease condition and the current state of the available treatment options, can be critical in regulatory decisionmaking. FDA is interested in obtaining patient input on the context of specific disease areas through the patient-focused drug development meetings. The following questions are examples of topics for which FDA believes the patient perspective could add valuable insight. They are presented in this document for general discussion at the Patient Network Conference.

A. Understanding the Disease Condition

(1) What are the clinical manifestations of the disease that have the greatest impact on patients?

(2) Are there other aspects of the disease that have a significant impact on a patient's daily life? (e.g., impaired mobility, sleep problems, etc.)

(3) How do the clinical manifestations change with disease progression?

(4) How do the other aspects of the disease change with disease progression?

B. Assessment of Treatment Options

(1) How effective are approved therapies at treating the clinical manifestations of the disease?

(2) How well do approved therapies mitigate the other aspects of the disease?

(3) How does the effectiveness of approved therapies change with progression of the disease?

(4) Does therapy effectiveness vary by patient subpopulation?

FDA is continuing to make plans for its efforts and will be able to provide more detail on the patient-focused drug development meetings at the Patient Network Conference.

IV. Center for Devices and Radiologic Health Efforts

Center for Devices and Radiologic Health is interested in a public discussion on issues related to risk associated with medical products, and on avenues for patients to provide input into regulatory decisionmaking related to the amount of risk patients may be willing to accept in exchange for a potential treatment benefit. The following questions are presented in this document for general discussion at the Patient Network Conference.

(1) How do patients perceive and weigh risks associated with medical treatment in light of the risk associated with the underlying condition being treated and the potential benefit from the treatment?

(2) Under what circumstances and in which populations would various levels of risk be appropriate/acceptable?

(3) How can medical device companies, government, academia, community physicians and patients collaborate to account for the level of risk acceptable to patients affected by serious or life threatening illnesses?

(4) What mechanisms would be appropriate for patients to provide input into regulatory decisionmaking for new therapeutic and diagnostic products—e.g., web-based survey instruments? Patient representation at advisory committee meetings? Patient input to medical device companies during clinical trial design? Who (FDA, patient advocate groups, medical device companies, etc.) could sponsor such surveys?

(5) Are patients willing to accept responsibility for the level of risk to which they may be exposed if patient input increases risk tolerance?

Dated: April 13, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–9418 Filed 4–18–12; 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 Diseases; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as

amended (5 U.S.C. App.), notice is hereby given of meetings of the National Diabetes and Digestive and Kidney Diseases Advisory Council.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings 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 Diabetes and Digestive and Kidney Diseases Advisory Council.

Date: May 16, 2012.

Open: 8:30 a.m. to 12 p.m.

Agenda: To present the Director's Report and other scientific presentations.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Conference Room E1/E2, Bethesda, MD 20892.

Closed: 1:45 p.m. to 3:45 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Conference Room E1/E2, Bethesda, MD 20892.

Contact Person: Brent B. Stanfield, Ph.D., Director, Division of Extramural Activities, National Institute of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd., Room 715, MSC 5452, Bethesda, MD 20892, (301) 594–8843, *stanfibr@niddk.nih.gov.*

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council Kidney, Urologic and Hematologic Diseases Subcommittee.

Date: May 16, 2012.

Open: 1 p.m. to 2:30 p.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Conference Room F1/F2, Bethesda, MD 20892.

Closed: 2:30 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Conference Room F1/F2, Bethesda, MD 20892.

Contact Person: Brent B. Stanfield, Ph.D., Director, Division of Extramural Activities, National Institute of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd., Room 715, MSC 5452, Bethesda, MD 20892, (301) 594–8843, *stanfibr@niddk.nih.gov.*

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council Diabetes, Endocrinology and Metabolic Diseases Subcommittee.

Date: May 16, 2012.

Open: 3 p.m. to 4 p.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Conference Room E1/E2, Bethesda, MD 20892.

Closed: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Conference Room E1/E2, Bethesda, MD 20892.

Contact Person: Brent B. Stanfield, Ph.D., Director, Division of Extramural Activities, National Institute of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd., Room 715, MSC 5452, Bethesda, MD 20892, (301) 594–8843, *stanfibr@niddk.nih.gov.*

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council Digestive Diseases and Nutrition Subcommittee.

Date: May 16, 2012.

Open: 1 p.m. to 2:15 p.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Conference Room D, Bethesda, MD 20892.

Closed: 2:30 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Conference Room D, Bethesda, MD 20892.

Contact Person: Brent B. Stanfield, Ph.D., Director, Division of Extramural Activities, National Institute of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd., Room 715, MSC 5452, Bethesda, MD 20892, (301) 594–8843, *stanfibr@niddk.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *www.niddk.nih.gov/fund/divisions/DEA/Council/coundesc.htm.,* where an agenda and any additional information for the meeting will be posted when available.

(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: April 13, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–9458 Filed 4–18–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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 Child Health and Human Development Special Emphasis Panel; Neuroplasticity and the Maternal Brain.

Date: April 30, 2012.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Sherry L. Dupere, Ph.D., Director, Division of Scientific Review, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, 301–451–3415, *duperes@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)