Topic 2: Patients' Perspectives on Current Approaches To Treating CFS and ME

1. What treatments are you currently using to help treat your condition or its symptoms? (Examples may include FDA-approved medicines, over-the-counter products, and other therapies, including non-drug therapies such as activity limitations.)

a. What specific symptoms do your treatments address?

b. How has your treatment regimen changed over time and why?

2. How well does your current treatment regimen treat the most significant symptoms of your disease?

a. Have these treatments improved your daily life (for example, improving your ability to do specific activities)? Please explain.

b. How well have these treatments worked for you as your condition has changed over time?

c. What are the most significant downsides of these treatments (for example, specific side effects)?

For each of these topics, a brief initial patient panel discussion will begin the dialogue, followed by a facilitated discussion inviting comments from other patient participants. FDA has not yet identified the panel participants. As part of the meeting registration, patients who are interested in presenting comments as part of the initial panel discussions may indicate which topic(s) they wish to address and will be asked to provide a brief summary of responses to the questions listed below. FDA will confirm with patients who have been identified to provide comments as part of the opening panel discussion in advance of the workshop.

FDA will try to accommodate all participants who wish to speak on Day 1, either through the panel discussions, audience participation, or the open public comment period; however, the duration of comments may be limited by time constraints. Those who are unable to attend the meeting in person, but who would like to provide their perspective on the discussion questions for topics 1 and 2 are invited to submit electronic or written comments to the Division of Docket Management (see *Comments*).

Day 2 of the workshop (April 26, 2013), will include a scientific discussion on how best to facilitate and expedite the development of safe and effective drug therapies for signs and symptoms related to CFS and ME. Presentations and panel discussions will include the following:

- Lessons learned from previous studies;
- The role of drug repurposing;
- Pathways to expediting drug therapies;
- Appropriate clinical trial design in CFS and ME;
- Outcome measures to assess efficacy; and
- Potential valid endpoint measurements of symptom improvement.

III. Transcripts

Please be advised that a transcript of the workshop will be available for review at the Division of Dockets Management (see *Comments*) and on the Internet at *http://www.regulations.gov.* The transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: March 6, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–05562 Filed 3–8–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; ODCS Small Business.

Date: March 13–14, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Yi-Hsin Liu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301–435–1781, *liuyh@csr.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. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: March 5, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–05511 Filed 3–8–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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 meetings.

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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Hematology and Vascular Pathobiology.

Date: April 1–2, 2013.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ai-Ping Zou, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301–408–9497, *zouai@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and AIDS Related Research.

Date: April 1, 2013.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Eduardo A Montalvo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7852, Bethesda, MD 20892, (301) 435–1168, *montalve@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: March 5, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–05510 Filed 3–8–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5447–C–01]

Notice of Formula Allocations and Program Requirements for Neighborhood Stabilization Program Formula Grants; Correction

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of Formula Allocations and Program Requirements for Neighborhood Stabilization Program Formula Grants; Correction.

SUMMARY: On October 19, 2010, HUD published the ''Notice of Formula Allocations and Program Requirements for Neighborhood Stabilization Program Formula Grants'' (Unified NSP Notice) in the **Federal Register**, at 75 FR 64322. That notice provided unified program requirements for the NSP1 grantees and NSP3 grantees. The allocation formula, application process and program requirements for NSP1 grantees were originally published in an October 6, 2008 **Federal Register** Notice at 73 FR 58330 and amended by a June 19, 2009, April 9, 2010, and an August 27, 2010 **Federal Register** Notice at 74 FR 29223, 75 FR 18228 and 75 FR 52772, respectively. This notice is revising the Unified NSP Notice to include the provision of corrective action(s) or sanctions among HUD's remedial actions for failure of NSP1 grantees to meet the four year expenditure requirement.

FOR FURTHER INFORMATION CONTACT: Stanley Gimont, Director, Office of Block Grant Assistance, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7286, Washington, DC 20410, telephone number 202–708–3587 (this is not a toll-free number). Persons with hearing or speech impairments may access this number via TTY by calling the Federal Relay Service at 800–877–8339. FAX inquiries may be sent to Mr. Gimont at 202–401–2044.

SUPPLEMENTARY INFORMATION:

Program Background and Purpose

The Neighborhood Stabilization Program (or NSP) was established by the Housing and Economic Recovery Act of 2008 (HERA) (Pub. L. 110–289, approved July 30, 2008), specifically Division B, Title III of HERA, for the purpose of stabilizing communities that have suffered from foreclosures and abandonment. HERA appropriated $3.92 billion to be made available to all states and selected local governments on a formula basis, commonly referred to as NSP1.

The purpose of the funds awarded under NSP is to target the stabilization of neighborhoods negatively affected by properties that have been foreclosed upon and abandoned. The Unified NSP Notice provides further background for the program, the program principles, and the objectives and outcomes of the NSP program.

NSP is a component of the CDBG program, authorized under Housing and Community Development Act of 1974 (HCD Act) (42 U.S.C. 5301 et seq.).

Summary of Corrections

M. Timeliness of Use and Expenditure of NSP Funds

Background

This notice is revising section II.M of the Unified NSP Notice to include providing for corrective action(s) or sanctions among HUD's remedial actions for failure of NSP1 grantees to meet the 4 year expenditure requirement. As provided in the ''Background'' of section M of the Unified NSP Notice, HUD intended that recapture, corrective actions or sanctions be among the available remedies for all NSP grantees. However, two of these remedies were inadvertently omitted from the requirement. This revision adds the omitted language.

Revised Requirement

Section II.M.2 of the Unified NSP Notice is revised to read:

Timely expenditure of NSP1 funds. The timely distribution or expenditure requirements of sections 24 CFR 570.494 and 570.902 are waived to the extent necessary to allow the following alternative requirement: All NSP1 grantees must expend on eligible NSP activities an amount equal to or greater than the initial allocation of NSP1 funds within 4 years of receipt of those funds or HUD will recapture and reallocate the amount of funds not expended or provide for other corrective action(s) or sanction.

Dated: March 1, 2013.

Mark Johnston,

Deputy Assistant Secretary for Special Needs.

[FR Doc. 2013–05526 Filed 3–8–13; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–ES–2013–N051; FXES11130300000–134–FF03E00000]

Notice of Availability of Draft Habitat Conservation Plan; Receipt of Application for Incidental Take Permit; Enbridge Pipelines (Lakehead), L.L.C.

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service, USFWS), have received an application from Enbridge Pipelines (Lakehead) L.L.C. (applicant), for an incidental take permit (ITP) under the Endangered Species Act of 1973 (ESA). If approved, the ITP would authorize incidental take of the federally endangered Hine's Emerald Dragonfly (hereafter ''HED''). The applicant has prepared a low-effect habitat conservation plan (HCP) to cover activities associated with pipeline maintenance work in Garfield Township, Mackinac County, Michigan. We invite comments from the public on the application, which includes the low-effect HCP, which has been determined to be eligible for a Categorical Exclusion under the National Environmental Policy Act of 1969, as amended (NEPA).

DATES: To ensure consideration, please send your written comments on or before April 10, 2013.

ADDRESSES: Send written comments via U.S. mail to the Field Supervisor, Attn: Barbara Hosler, U.S. Fish and Wildlife Service, 2651 Coolidge Road East, Ste. 101, Lansing, MI 48823. Phone: 517–351–2555. Fax: 517–351–1443. TTY: 1–800–877–8339, or by electronic mail to *Barbara_Hosler@fws.gov*.

FOR FURTHER INFORMATION CONTACT: Barb Hosler, (517) 351–6326

SUPPLEMENTARY INFORMATION: We have received an application from Enbridge