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]

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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.