

Meeting Registration: Registration is open through April 12, 2016; registration will close earlier if space capacity is reached. Registration to view the workshop via webcast is required.

**ADDRESSES:** Meeting Location: Lister Hill Auditorium, National Library of Medicine, 8600 Rockville Pike, NIH Building 38A, Bethesda, MD 20894

Meeting Web page: The preliminary agenda and registration are at ([http://ntp.niehs.nih.gov/go/workshop\\_botanicals](http://ntp.niehs.nih.gov/go/workshop_botanicals)).

Webcast: The meeting will be webcast; the URL will be provided to those who register to view.

**FOR FURTHER INFORMATION CONTACT:** Dr. Cynthia Rider, NTP Toxicologist, NIEHS, P.O. Box 12233, MD K2-12, Research Triangle Park, NC 27709. Telephone: (919) 541-7638, email: [cynthia.rider@nih.gov](mailto:cynthia.rider@nih.gov).

#### **SUPPLEMENTARY INFORMATION:**

#### **Background**

The safety of botanical dietary supplements, hereafter referred to as botanicals, is an important public health issue. According to the 2012 National Health Interview Survey, 17.7 percent of Americans reported having used nonvitamin, nonmineral dietary supplements (including botanicals) in the past 12 months (Clarke et al., 2015). Botanicals pose several unique challenges to efficacy and safety evaluation because of their inherent complexity and potential for wide variability in nominally related products. The interrelated challenges associated with the evaluation of botanicals include: (1) Developing methods and criteria for assessing phytoequivalence (*i.e.*, similarity in chemical composition and biological activity) of botanicals, (2) identifying the active constituent(s) or patterns of biological response of botanicals, and (3) assessing absorption, distribution, metabolism, and elimination (ADME) of botanicals. This workshop will engage experts from multiple disciplines to focus on practical approaches for addressing these challenges.

Multiple factors contribute to the variability in botanicals including complex and inconsistent source material, manufacturing processes, formulation, and storage. Botanicals in commerce often display a wide range in the concentration of known constituents. Robust procedures for comparing constituent profiles across multiple botanicals are needed to determine how broadly safety or efficacy evaluations with a specific product can be applied to related products. Topics for discussion at the

workshop include definition of important chemical and biological activity features, statistical methods for comparing across complex mixtures, and how to define "similarity" across botanicals (*i.e.*, how similar do botanicals have to be in order to apply safety data from a reference botanical to nominally-related botanicals).

Botanicals are often perceived to have significant health benefits with low risk of harm. Since botanicals are complex natural products, the particular constituent(s) responsible for biological activity, as related to efficacy or toxicity, is often unknown. Participants at the workshop will discuss the relative merits of dedicating scientific attention to identifying the active constituent(s) in botanicals and identifying biological signatures that are predictive of adverse events (biomarkers of effect). Furthermore, presentations will address promising approaches (*e.g.*, high throughput screening, computational tools) and accompanying challenges for using these approaches to advance our understanding of the risks associated with botanical use.

Understanding the ADME of botanicals is critical to evaluating their safety. However, evaluating ADME in humans and animal models is complicated in the case of botanicals by the large number of constituents, the wide range of concentrations, potential interactions (botanical-botanical and botanical-drug interactions), as well as interindividual and animal-to-human differences in pharmacokinetics. The workshop will include discussion of knowledge gaps and available options for assessing ADME of botanicals to inform future safety evaluations.

#### **Meeting and Registration**

This meeting is open to the public, free of charge, with attendance limited only by the space available. Individuals who plan to attend in person should register at ([http://ntp.niehs.nih.gov/go/workshop\\_botanicals](http://ntp.niehs.nih.gov/go/workshop_botanicals)) by April 12, 2016, to facilitate meeting planning. Registration will close earlier if space capacity is reached. Registration is required to view the Webcast; the URL for the Webcast will be provided in the email confirming registration. A preliminary agenda and additional information are available at ([http://ntp.niehs.nih.gov/go/workshop\\_botanicals](http://ntp.niehs.nih.gov/go/workshop_botanicals)). Interested individuals are encouraged to access the Web site to stay abreast of the most current information regarding the workshop.

Visitor and security information for those attending in person is available at <https://www.nih.gov/about-nih/visitor-information/campus-access-security>.

Individuals with disabilities who need accommodation to participate in this event should contact Dr. Rider at telephone: (919) 541-7638 or email: [cynthia.rider@nih.gov](mailto:cynthia.rider@nih.gov). TTY users should contact the Federal TTY Relay Service at 800-877-8339. Requests should be made at least five business days in advance of the event.

#### **Background Information on the NTP**

NTP is an interagency program established in 1978 (43 FR 53060) to strengthen the Department of Health and Human Services' activities in toxicology research and testing, and develop and validate new and better testing methods. Other activities of the program focus on strengthening the science base in toxicology and providing information about potentially toxic chemicals to health regulatory and research agencies, scientific and medical communities, and the public. NTP is located administratively at the National Institute of Environmental Health Sciences (NIEHS). Information about NTP and NIEHS is found at <http://ntp.niehs.nih.gov> and <http://www.niehs.nih.gov>, respectively.

#### **Reference**

Clarke, T.C. et al. Trends in the use of complementary health approaches among adults: United States, 2002-2012, in National health statistics reports. 2015. National Center for Health Statistics: Hyattsville, MD.

Dated: December 15, 2015.

**John R. Bucher,**

*Associate Director, National Toxicology Program.*

[FR Doc. 2015-31833 Filed 12-17-15; 8:45 am]

**BILLING CODE 4140-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **National Institute of Neurological Disorders and Stroke; 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:* National Institute of Neurological Disorders and Stroke Initial Review Group; Neurological Sciences and Disorders A.

*Date:* February 22–23, 2016.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Best Western Tuscan Inn, 425 North Point Street, San Francisco, CA 94133.

*Contact Person:* Natalia Strunnikova, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Boulevard, Suite 3208, MSC 9529, Bethesda, MD 20892–9529, 301–402–0288, [Natalia.strunnikova@nih.gov](mailto:Natalia.strunnikova@nih.gov).

*Name of Committee:* National Institute of Neurological Disorders and Stroke Initial Review Group; Neurological Sciences and Disorders C.

*Date:* February 23–24, 2016.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* JW Marriott New Orleans, 614 Canal Street, New Orleans, LA 70130.

*Contact Person:* William C. Benzing, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Boulevard, Suite 3204, MSC 9529, Bethesda, MD 20892–9529, 301–496–0660, [benzingw@mail.nih.gov](mailto:benzingw@mail.nih.gov).

*Name of Committee:* National Institute of Neurological Disorders and Stroke Initial Review Group; Neurological Sciences and Disorders B.

*Date:* February 25, 2016.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* JW Marriott New Orleans, 614 Canal Street, New Orleans, LA 70130.

*Contact Person:* Birgit Neuhuber, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Boulevard, Suite 3208, MSC 9529, Bethesda, MD 20892–9529, [neuhuber@ninds.nih.gov](mailto:neuhuber@ninds.nih.gov).

*Name of Committee:* Neurological Sciences Training Initial Review Group; NST–1 Subcommittee.

*Date:* March 7–8, 2016.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Arlington, 1325 Wilson Boulevard, Arlington, VA 22209.

*Contact Person:* William C. Benzing, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Boulevard, Suite 3204, MSC 9529, Bethesda, MD 20892–9529, 301–496–0660, [benzingw@mail.nih.gov](mailto:benzingw@mail.nih.gov).

*Name of Committee:* Neurological Sciences Training Initial Review Group; NST–2 Subcommittee.

*Date:* March 14–15, 2016.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Pier 2620 Hotel, 2620 Jones Street, San Francisco, CA 94133.

*Contact Person:* Elizabeth A Webber, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Boulevard, Suite 3208, MSC 9529, Bethesda, MD 20892–9529, 301–496–1917, [webbere@mail.nih.gov](mailto:webbere@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: December 14, 2015.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015–31769 Filed 12–17–15; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG–2015–1050]

#### Cooperative Research and Development Agreement: Diesel Outboard Engine Development

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of intent; request for comments.

**SUMMARY:** The Coast Guard announces its intent to enter into a Cooperative Research and Development Agreement (CRADA) with Mercury Marine (Mercury) to evaluate and test the advantages, disadvantages, required technology enhancements, performance, costs, and other issues associated with diesel outboard engine technology. A test schedule has been proposed in which Mercury will provide and install two of their diesel outboard engines onto a selected Coast Guard boat platform; the Coast Guard Research and Development Center (R&D Center) will outfit the platform with the necessary instrumentation to monitor power, speed, and fuel consumption; and a Coast Guard field unit will operate the boat for performance testing over a six-month period to collect information on reliability, maintenance requirements, and availability data. While the Coast Guard is currently considering partnering with Mercury, the agency is soliciting public comment on the possible nature of and participation of other parties in the proposed CRADA. In addition, the Coast Guard also invites other potential non-Federal participants to propose similar CRADAs.

**DATES:** Comments must be submitted to the online docket via <http://www.regulations.gov>, or reach the Docket Management Facility, on or before January 19, 2016.

Synopses of proposals regarding future CRADAs must reach the Coast Guard (see **FOR FURTHER INFORMATION CONTACT**) on or before January 19, 2016.

**ADDRESSES:** Submit comments online at <http://www.regulations.gov> following Web site instructions.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this notice or wish to submit proposals for future CRADAs, contact LT Keely Higbie, Project Official, Surface Branch, U.S. Coast Guard Research and Development Center, 1 Chelsea Street, New London, CT 06320, telephone 860–271–2815, email [Keely.J.Higbie@uscg.mil](mailto:Keely.J.Higbie@uscg.mil).

#### SUPPLEMENTARY INFORMATION:

#### Public Participation and Request for Comments

We request public comments on this notice. Although we do not plan to respond to comments in the **Federal Register**, we will respond directly to commenters and may modify our proposal in light of comments.

Comments should be marked with docket number USCG–2015–1050 and should provide a reason for each suggestion or recommendation. You should provide personal contact information so that we can contact you if we have questions regarding your comments; but please note that all comments will be posted to the online docket without change and that any personal information you include can be searchable online (see the **Federal Register** Privacy Act notice regarding our public dockets, 73 FR 3316, Jan. 17, 2008). We also accept anonymous comments.

We encourage you to submit comments through the Federal eRulemaking Portal at <http://www.regulations.gov>. If your material cannot be submitted using <http://www.regulations.gov>, contact the Coast Guard (see **FOR FURTHER INFORMATION CONTACT**). Documents mentioned in this notice, and all public comments, are in our online docket at <http://www.regulations.gov> and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

Do not submit detailed proposals for future CRADAs to the Docket Management Facility. Instead, submit