DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Workshop on Addressing Challenges in the Assessment of Botanical Dietary Supplement Safety; Notice of Public Meeting; Registration Information

SUMMARY: The National Toxicology Program (NTP) announces the public workshop, "Addressing Challenges in the Assessment of Botanical Dietary Supplement Safety." Presenters from academia, government, and industry will introduce the challenges in assessing botanical dietary supplement safety and present various approaches that could facilitate progress in three focus areas. The workshop will consist of plenary presentations and panel discussions. Information about the meeting and registration is available at (http://ntp.niehs.nih.gov/go/workshop_botanicals).

DATES: Meeting: April 26-27, 2016, from 9 a.m. to approximately 5 p.m. Eastern Daylight Time (EDT).

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 Webpage: The preliminary agenda and registration are at (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.

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) 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). Interested individuals are encouraged to access the website 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. 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.

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BILLING CODE 4140-01-P

[FR Doc. 2015-31833 Filed: 12/17/2015 8:45 am; Publication Date: 12/18/2015]