

accommodate persons with disabilities. If you require accommodations due to a disability, please contact Yinghua Wang (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 13, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-05386 Filed 3-15-18; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-N-0757]

#### Pathways to Global Unity; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA), in collaboration with the Association of Food and Drug Officials (AFDO), is announcing the following public workshop entitled "Pathways to Global Unity." This 2½-day public workshop is intended to provide information about FDA drug and device regulation to the regulated industries.

**DATES:** The public workshop will be held on June 11–12, 2018, from 8 a.m. to 5:30 p.m., and on June 13, 2018, from 8 a.m. to 12 p.m.

**ADDRESSES:** The public workshop will be held at the Doubletree by Hilton Hotel Burlington Vermont, 870 Williston Rd., Burlington, VT 05403, 802-865-6626. For directions to the hotel and information on lodging, visit <http://burlington.afdo.org/hotel.html>. Attendees are responsible for their own accommodations.

**FOR FURTHER INFORMATION CONTACT:** Krystal Reed, Association of Food and Drug Officials, 155 West Market St., 3rd Floor, York, PA 17401, 717-757-2888, Fax: 717-650-3650, email: [kreed@afdo.org](mailto:kreed@afdo.org).

**SUPPLEMENTARY INFORMATION:**

### I. Background

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The workshop helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), as outreach activities by government agencies to small businesses.

### II. Topics for Discussion at the Public Workshop

The public workshop helps fulfill the Department of Health and Human Services and FDA's mission to protect the public health. The workshop will provide FDA-regulated drug and device entities with information on a number of topics concerning FDA requirements related to the production and marketing of drugs and/or devices. The public workshop's agenda is available at <http://www.afdo.org/conference>. Topics for discussion include the following:

- FDA Associate Commissioner for Regulatory Affairs Update
- Health Canada: Single Audit Program
- Enforcement Trends in Drug, Devices, and Compounding Pharmacy Inspections
- FDA Compliance Questions Panel
- International Compliance—Industry Perspective
- Puerto Rico Emergency Response Update
- Artificial Intelligence
- Supply Chain Control
- Dermal Abyss: Tattoos as Medical Condition Monitors
- Design Controls for Combination Products
- Benefit Risk—Using Benefit Risk in Making Post-Market Decisions

### III. Participating in the Public Workshop

**Registration:** You are encouraged to register by May 1, 2018. Registration fees cover the cost of facilities, materials, and breaks. Seats are limited; therefore, please submit your registration as soon as possible. Course space will be filled in order of receipt of registration. Those accepted into the course will receive confirmation. Registration will close after the course is filled. Registration at the site is not guaranteed but may be possible on a space-available basis on the day of the

public workshop beginning at 7:30 a.m. The cost of registration is as follows:

| Category   | Cost of registration |
|--|----------------------|
| AFDO Members .....   | \$550                |
| AFDO Non-Members .....   | 650                  |
| Additional Fee for Registration Postmarked After May 1, 2018 ..... | 100                  |

To register online, please visit <http://www.afdo.org/conference> (FDA has verified the website address, but is not responsible for subsequent changes to the website after this document publishes in the **Federal Register**.) For alternative registration, please complete and submit an AFDO Conference Registration Form, available at <http://burlington.afdo.org/registration.html>, along with a check or money order payable to AFDO. Please mail your completed registration form and payment to: AFDO, 155 West Market St., 3rd Floor, York, PA 17401. The registrar will also accept payment through Visa, MasterCard, and American Express credit cards. For more information on the public workshop, or for questions about registration, please contact AFDO at 717-757-2888, [afdo@afdo.org](mailto:afdo@afdo.org), or <http://www.afdo.org/conference>.

If you need special accommodations due to a disability, please contact Krystal Reed (see **FOR FURTHER INFORMATION CONTACT**) at least 21 days in advance of the workshop.

Dated: March 13, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-05389 Filed 3-15-18; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Advisory Council on Alzheimer's Research, Care, and Services; Meeting

**AGENCY:** Assistant Secretary for Planning and Evaluation, HHS.

**ACTION:** Notice of meeting.

**SUMMARY:** This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council on Alzheimer's Research, Care, and Services provides advice on how to prevent or reduce the burden of Alzheimer's disease and related dementias on people with the disease and their caregivers. During the April meeting, the Clinical Care Subcommittee will be taking charge of the theme, focusing on advancing consensus on dementia care elements to

guide new outcomes measurement. The Council will hear speakers in two sessions, one focuses on developing consensus about dementia care elements, and the second on models that are informing outcomes measurement. The meeting will also include updates on work from the previous meetings, a presentation on the final report from the October 2017 Care Summit, and federal workgroup updates.

**DATES:** The meeting will be held on April 27, 2018 from 9:00 a.m. to 5:00 p.m. EDT.

**ADDRESSES:** The meeting will be held in Room 800 in the Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201.

*Comments:* Time is allocated in the afternoon on the agenda to hear public comments. The time for oral comments will be limited to two (2) minutes per individual. In lieu of oral comments, formal written comments may be submitted for the record to Rohini Khillan, OASPE, 200 Independence Avenue SW, Room 424E, Washington, DC 20201. Comments may also be sent to [napa@hhs.gov](mailto:napa@hhs.gov). Those submitting written comments should identify themselves and any relevant organizational affiliations.

**FOR FURTHER INFORMATION CONTACT:** Rohini Khillan (202) 690-5932, [rohini.khillan@hhs.gov](mailto:rohini.khillan@hhs.gov). Note: Seating may be limited. Those wishing to attend the meeting must send an email to [napa@hhs.gov](mailto:napa@hhs.gov) and put "April 27 Meeting Attendance" in the Subject line by Tuesday, April 17, so that their names may be put on a list of expected attendees and forwarded to the security officers at the Department of Health and Human Services. Any interested member of the public who is a non-U.S. citizen should include this information at the time of registration to ensure that the appropriate security procedure to gain entry to the building is carried out. Although the meeting is open to the public, procedures governing security and the entrance to Federal buildings may change without notice. If you wish to make a public comment, you must note that within your email.

**SUPPLEMENTARY INFORMATION:** Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). Topics of the Meeting: During the April meeting, the Clinical Care Subcommittee will be taking charge of the theme, focusing on advancing consensus on dementia care elements to guide new outcomes measurement. The Council will hear speakers in two sessions, one focuses on developing

consensus about dementia care elements, and the second on models that are informing outcomes measurement. The meeting will also include updates on work from the previous meetings, a presentation on the final report from the October 2017 Care Summit, and federal workgroup updates.

*Procedure and Agenda:* This meeting is open to the public. Please allow 30 minutes to go through security and walk to the meeting room. The meeting will also be webcast at [www.hhs.gov/live](http://www.hhs.gov/live).

*Authority:* 42 U.S.C. 11225; Section 2(e)(3) of the National Alzheimer's Project Act. The panel is governed by provisions of Public Law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: March 12, 2018.

**John R. Graham,**

*Acting Assistant Secretary for Planning and Evaluation.*

[FR Doc. 2018-05368 Filed 3-15-18; 8:45 am]

**BILLING CODE 4150-05-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of an Exclusive Patent License: Anti-Marinobufagenin Antibodies and Methods for Diagnosis and Treatment of Cardiovascular Disease and Fibrotic Disease

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The National Institute on Aging, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the U.S. and International Patents and Patent Applications listed in the **SUPPLEMENTARY INFORMATION** section of this notice to CTS Biopharma LLC, located in Sunnyvale, CA.

**DATES:** Only written comments and/or complete applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before April 2, 2018 will be considered.

**ADDRESSES:** Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Richard T. Girards, Jr., Esq., MBA, Senior Technology Transfer Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM

1E508 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702 (for overnight courier services); Telephone: (240)-276-6825; Facsimile: (240)-276-5504; Email: [richard.girards@nih.gov](mailto:richard.girards@nih.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **Intellectual Property**

United States Provisional Patent Application No. 60/694,733 [HHS Ref No. E-092-2004/0-US-01], filed on June 27, 2005 and entitled "Anti-marinobufagenin antibodies and methods for their use;" Patent Cooperation Treaty Patent Application No. PCT/US2006/024918 [HHS Ref No. E-092-2004/0-PCT-02], filed on June 26, 2006 and entitled "Anti-marinobufagenin antibodies and methods for their use;" and U.S. and foreign patents and/or patent applications claiming priority to the aforementioned applications, including but not limited to United States Patent No. 8,038,997 [HHS Ref No. E-092-2004/0-US-03] entitled "Anti-marinobufagenin antibodies and methods for their use."

Certain rights in the patent and these applications have been assigned to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of the Licensed Patent Rights for the following: (1) The use of anti-marinobufagenin antibodies for one or both of (a) the treatment of fibrotic disease and (b) the treatment of cardiovascular disease, including but not limited to preeclampsia and (2) companion diagnostics associated with the aforementioned treatments.

The patents and applications potentially to be licensed disclose antibodies (mAbs) that specifically bind marinobufagenin. They also disclose use of these mAbs in the diagnosis and treatment of cardiovascular disease such as hypertension. Further, they disclose use of these mAbs in the diagnosis and treatment of fibrotic diseases. The patents and applications potentially to be licensed also disclose technologies useful with respect to companion diagnostics for both fibrotic and cardiovascular diseases. The public substantially will benefit from the clinical and commercial development of these mAbs for the treatment and of cardiovascular as well as fibrotic disorders. The public also will benefit from the clinical and commercial development of companion diagnostics relative to these conditions.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404.