

registration file, or via regular mail if email is not an option. The invoice will contain information regarding the obligation incurred, the amount owed, and payment procedures. A facility will not be registered as an outsourcing facility until it has paid the annual establishment fee under section 744K of the FD&C Act. Accordingly, it is important that facilities seeking to operate as outsourcing facilities pay all fees immediately upon receiving an invoice. If an entity does not pay the full invoiced amount within 15 calendar days after FDA issues the invoice, FDA will consider the submission of registration information to have been withdrawn and adjust the invoice to reflect that no fee is due.

Outsourcing facilities that registered in FY 2016 and wish to maintain their status as an outsourcing facility in FY 2017 must register during the annual registration period that lasts from October 1, 2016, to December 31, 2016. Failure to register and complete payment by December 31, 2016, will result in a loss of status as an outsourcing facility on January 1, 2017. Entities should submit their registration information no later than December 10, 2016, to allow enough time for review of the registration information, invoicing, and payment of fees before the end of the registration period.

#### B. Re-Inspection Fee

FDA will issue invoices for each re-inspection after the conclusion of the re-inspection, via email to the email address indicated in the registration file or via regular mail if email is not an option. Invoices must be paid within 30 days.

#### C. Fee Payment Procedures

1. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at <https://userfees.fda.gov/pay>. Once you search for your invoice, click "Pay Now" to be redirected to *Pay.gov*. Note that electronic payment options are based on the balance due. Payment by credit card is available for balances less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be drawn on U.S. bank accounts as well as U.S. credit cards.

2. *If paying with a paper check:* Checks must be in U.S. currency from a U.S. bank and made payable to the Food and Drug Administration.

Payments can be mailed to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197-9000. If a check is sent by a courier that requests a street address, the courier can deliver the check to: U.S. Bank, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery contact the U.S. Bank at 314-418-4013).

3. *If paying with a wire transfer:* Use the following account information when sending a wire transfer: New York Federal Reserve Bank, U.S. Dept of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., 14th Floor, Silver Spring, MD 20993-0002. The originating financial institution may charge a wire transfer fee. An outsourcing facility should ask its financial institution about the fee and add it to the payment to ensure that the order is fully paid. The tax identification number of FDA is 53-0196965.

Dated: July 27, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-1984]

#### Request for Nominations on the Tobacco Products Scientific Advisory Committee

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of a nonvoting member to represent the interests of tobacco growers to serve on the Tobacco Products Scientific Advisory Committee for the Center for Tobacco Products (CTP), notify FDA in writing. FDA is also requesting nominations for a nonvoting member to represent the interests of tobacco growers to serve on the Tobacco Products Scientific Advisory Committee, and an alternate to this representative. A nominee may either be self-nominated or nominated by an

organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

**DATES:** Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent the interests of tobacco growers must send a letter stating that interest to the FDA by *August 31, 2016* (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by August 31, 2016.

**ADDRESSES:** All statements of interest from industry organizations interested in participating in the selection process should be sent to Caryn Cohen (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives should be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal at: <https://www.accessdata.fda.gov/scripts/FACTRSportal/FACTRS/index.cfm> or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993-0002. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's Web site at: <http://www.fda.gov/AdvisoryCommittees/default.htm>.

**FOR FURTHER INFORMATION CONTACT:** Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, Center for Tobacco Products, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 1-877-287-1373 (choose Option 5), email: [TPSAC@fda.hhs.gov](mailto:TPSAC@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The Agency intends to add nonvoting industry representatives to the following advisory committee:

#### I. CTP Advisory Committee

*Tobacco Products Scientific Advisory Committee*

The Tobacco Products Scientific Advisory Committee (the Committee) advises the Commissioner of Food and Drugs (the Commissioner) or designee in discharging responsibilities related to the regulation of tobacco products. The Committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information, and recommendations to the Commissioner.

## II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent the interests of tobacco growers should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent the interests of tobacco growers for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent the interests of tobacco growers.

## III. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting member to represent the interests of tobacco growers. Contact information, current curriculum vitae, and the name of the committee of interest should be sent to the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.)

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: July 27, 2016.

**Janice M. Soreth,**

*Acting Associate Commissioner, Special Medical Programs.*

[FR Doc. 2016-18085 Filed 7-29-16; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Opportunity to Co-sponsor an Office on Women's Health Awards Ceremony and Event for its 25th Anniversary

**AGENCY:** Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, Office on Women's Health.

**ACTION:** Notice.

**SUMMARY:** Pursuant to 42 U.S.C. 300u, 42 U.S.C. 300u-2, and 42 U.S.C. 237a (3509 of the Patient Protection and Affordable Care Act), notice is given that the Office on Women's Health (OWH) is soliciting proposals from non-federal public and private sector entities to co-sponsor the OWH Anniversary Celebration event in the Washington, DC area in late September, 2016.

**DATES:** Representatives of eligible organizations should submit expressions of interest no later than 6:00 p.m. EST on August 16, 2016.

**ADDRESSES:** Expressions of interest should be directed electronically to [Valerie.Borden@hhs.gov](mailto:Valerie.Borden@hhs.gov) or mailed to the Office on Women's Health, Office of the Assistant Secretary for Health, Department of Health and Human Services, 200 Independence Avenue SW., Room 730F.3, Washington, DC 20201. Attention: Valerie Borden.

**FOR FURTHER INFORMATION CONTACT:** Questions may be directed to Valerie Borden, Office on Women's Health, 200 Independence Avenue SW, Room 730F.3, Washington, DC 20201. Email: [Valerie.Borden@hhs.gov](mailto:Valerie.Borden@hhs.gov).

**SUPPLEMENTARY INFORMATION:** The OWH was established in 1991 to improve the health of American women by advancing and coordinating a comprehensive women's health agenda throughout the Department of Health and Human Service (HHS). The OWH provides national leadership and coordination to improve the health of women and girls through policy, education, and model programs. The office fulfills its mission by advancing policy and issuing competitive contracts and grants to an array of community, academic, and other organizations at the national and community levels. This year marks the office's 25th anniversary.

The event will feature a panel discussion focusing on the future of women's health. It will also feature an award ceremony for organizations and partners who helped improve the health and well-being of women and girls in the U.S. over the past 25 years.

The co-sponsor will assist with the development of the substantive content

of the event and other event planning, coordination, and logistics in partnership with the OWH staff. In addition the co-sponsor will be responsible for the event venue and any food and beverages.

#### *Eligibility for Co-Sponsorship*

To be eligible, a potential co-sponsor shall:

1. Have a demonstrated understanding, commitment, and experience in improving the health of women and girls;
2. Participate substantively in the co-sponsored activity, not just provide funding or logistical support; and
3. Have an organizational or corporate mission that is consistent with OWH and HHS.

Each co-sponsorship proposal shall contain a description of: (1) The entity or organization's background and history, (2) its ability to satisfy the co-sponsorship criteria detailed above, and (3) its proposed involvement in the co-sponsored activity. The selected co-sponsoring organization(s) shall furnish the necessary personnel, materials, services, and facilities to administer its responsibility for the event. These duties will be outlined in a co-sponsorship agreement with OWH that will set forth the details of the co-sponsored activity, including the requirements that any fees collected by the co-sponsor shall be limited to the amount necessary to cover the co-sponsor's related meeting expenses.

**Evaluation Criteria:** After engaging in exploratory discussions with potential co-sponsors that respond to this notice, the OWH will select the co-sponsor or co-sponsors using the following evaluation criteria:

- (1) Qualifications and capability to fulfill co-sponsorship responsibilities;
- (2) Creativity related to enhancing the event;
- (3) Potential for reaching and generating attendees from among key stakeholders, including federal, state and local policymakers, other health officials, non-profits interested in women's health, and underserved/ special populations;
- (4) Experience with events;
- (5) Past or current work specific to women's health;
- (6) Personnel names, professional qualifications, and specific expertise with event planning;
- (7) Availability and description of facilities to support the event, including office space, information technology, and telecommunication resources; and,
- (9) Proposed plan for managing an event with the OWH.

Expressions of interest should outline eligibility in response to the