SUMMARY: The Centers for Disease Control and Prevention (CDC) announces the following meeting and Tribal Consultation Session. The meetings are being hosted by CDC/ATSDR in-person only and are open to the public. Attendees must pre-register for the event by March 2, 2018, at the following link: www.cdc.gov/tribal/meetings.html.

DATES:
March 13, 2018
• 8:00 a.m.–5:00 p.m., EDT—Tribal Caucus (Open only to elected tribal leaders and by invitation)
March 14, 2018
• 8:00 a.m.–5:00 p.m., EDT—TAC Meeting (Open to the public)

ADDITIONAL INFORMATION: This meeting is being held in accordance with Presidental Executive Order No. 13175, November 6, 2000, and the Presidential Memorandum of November 5, 2009, and September 23, 2004, Consultation and Coordination with Indian Tribal Governments.

Purpose: The purpose of the TAC and consultation meetings is to advance CDC/ATSDR support for and collaboration with American Indian and Alaska Native (AI/AN) tribes and to improve the health of AI/AN tribes by pursuing goals that include assisting in eliminating the health disparities faced by AI/AN tribes; ensuring that access to critical health and human services and public health services is maximized to advance or enhance the social, physical, and economic status of AI/ANs; and promoting health equity for all Indian people and communities. To advance these goals, CDC/ATSDR conducts government-to-government consultations with elected tribal officials or their authorized representatives. Consultation is an enhanced form of communication that emphasizes trust, respect, and shared responsibility. It is an open and free exchange of information and opinion among parties that leads to mutual understanding.

Matters To Be Considered: The agenda will include discussions on tribal priorities for the CDC and ATSDR, public health capacity in Indian Country, AI/AN public health concerns, budget and funding opportunities, and programmatic highlights. Agenda items are subject to change as priorities dictate.

Tribal nations also will have an opportunity to present testimony about tribal health issues. All tribal leaders are encouraged to submit written testimony by 5:00 p.m. (EST) Friday, February 16, 2018, to CDC’s Tribal Support Unit via mail to 4770 Buford Highway NE, MS E–70, Atlanta, GA 30341–3717, or email to TribalSupport@cdc.gov. Tribal leaders can find guidance to assist in developing tribal testimony for CDC and ATSDR at www.cdc.gov/tribal/consultation/index.html.

Based on the number of tribal leaders giving testimony and the time available, it may be necessary to limit the time for each.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Claudette Grant,
Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

FOR FURTHER INFORMATION CONTACT:
Carmen Clelland, PharmD, MPA, MPH, Associate Director for Tribal Support, Office for State, Tribal, Local and Territorial Support, CDC, 4770 Buford Highway, Mailstop E–70, Atlanta, GA 30341–3717; (404) 498–2205; cclelland@cdc.gov.

PROFESSIONAL CONSIDERATIONS: This meeting is being held in accordance with Presidental Executive Order No. 13175, November 6, 2000, and the Presidential Memorandum of November 5, 2009, and September 23, 2004, Consultation and Coordination with Indian Tribal Governments.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6888]

Neurological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Neurological Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA’s regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on March 1, 2018, from 8 a.m. to 6 p.m.

ADDRESSES: Hilton Washington, DC North/Gaithersburg, 620 Perry Pkwy., Salons A, B, C, and D, Gaithersburg, MD 20877. The hotel’s telephone number is 301–977–8900. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.

FOR FURTHER INFORMATION CONTACT: Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G642, Silver Spring, MD 20993–0002, Aden.Asefa@fda.hhs.gov, 301–796–0400, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency’s website at https://www.fda.gov/AdvisoryCommittees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agency: On March 1, 2018, the committee will discuss, make recommendations, and advise FDA regarding the evaluation of clinical study data to support the safety and effectiveness of intracranial aneurysm treatment devices and factors that can affect clinical outcomes such as aneurysm morphology, size, and location in the neurovasculature. FDA is also convening this committee to seek expert opinion on the scientific and clinical considerations relating to the clinical trial design that may be relevant to the determination of safety and effectiveness for these devices.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s website after the meeting. Background material is available at https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 19, 2018. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 12, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 16, 2018.

Persons attending FDA’s advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets. FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at Annmarie.Williams@fda.hhs.gov or 301–796–5966 at least 7 days in advance of the meeting.