release tablets, 12 mg, were being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Avanthi, LLC, c/o KVK–TECH, INC., submitted a citizen petition dated September 27, 2018 (Docket No. FDA–2018–P–3691), under 21 CFR 10.30, requesting that the Agency determine whether CHLOR–TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate) extended release tablets, 8 mg, were withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 12 mg strength, that strength has also been discontinued. On our own initiative, we have also determined whether that strength was withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that CHLOR–TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate) extended release tablets, 8 mg and 12 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that CHLOR–TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate), extended release tablets, 8 mg and 12 mg, were withdrawn for reasons of safety or effectiveness.

We have carefully reviewed our files for records concerning the withdrawal of CHLOR–TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate), extended release tablets, 8 mg and 12 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list CHLOR–TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate), extended release tablets, 8 mg and 12 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 27, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–06382 Filed 4–1–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0218]

Pulmonary-Allergy Drugs Advisory Committee; Cancellation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The meeting of the Pulmonary-Allergy Drugs Advisory Committee scheduled for March 27, 2019, has been cancelled. This meeting was announced in the **Federal Register** of January 31, 2019. This meeting has been cancelled due to new information regarding the application. The Agency intends to continue evaluating the application and, as needed, will announce future meeting dates in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Cindy Chee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *PADAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting, which was announced in the **Federal Register** of January 31, 2019 (84 FR 748).

Dated: March 28, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–06389 Filed 4–1–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Pain Management Best Practices Inter-Agency Task Force

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting is scheduled to be held for the Pain Management Best Practices Inter-Agency Task Force (Task Force). The meeting will be open to the public; public comment sessions will be held during the meeting.

DATES: The Task Force meeting will be held on Thursday, May 9, 2019 from 10:00 a.m. to 5:30 p.m. and Friday, May 10, 2019, from 9:00 a.m. to 12:00 p.m. Eastern Time (ET). The agenda will be posted on the Task Force website at *https://www.hhs.gov/ash/advisory-committees/pain/index.html.*

ADDRESSES: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, Great Hall, 200 Independence Avenue SW, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Alicia Richmond Scott, Designated Federal Officer, Pain Management Best Practices Inter-Agency Task Force, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health, 200 Independence Avenue SW, Room 736E, Washington, DC 20201. Phone: 240–453–2816. Email: *paintaskforce@hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 101 of the Comprehensive Addiction and Recovery Act of 2016 (CARA) requires the Secretary of Health and Human Services, in cooperation with the Secretaries of Defense and Veterans Affairs, to convene the Task Force no later than two years after the date of the enactment of CARA and develop a report to Congress with updates on best practices and recommendations on addressing gaps or inconsistencies for pain management, including chronic and acute pain. The Task Force is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. App), which sets forth standards for the formation and use of advisory committees.

In accordance with CARA, the Task Force will review clinical guidelines and identify gaps and/or inconsistencies for best practices for pain management, including chronic and acute pain, developed or adopted by federal agencies; propose updates to best practices and recommendations for identified gaps or inconsistencies; provide a 90 day the public comment period on any proposed updates and

recommendations; and develop a strategy for disseminating such proposed updates and recommendations to relevant federal agencies and the general public.

The Task Force will convene its third public meeting, on May 9–10, to discuss updates to existing best practices and recommendations based on gaps and inconsistencies for pain management, including chronic and acute pain. The Task Force will receive presentations on implementation and dissemination efforts. The Task Force will deliberate and vote the final recommendations for updates to best practices and recommendations for chronic and acute pain management and prescribing pain medication based on the components outlined in Section 101 of the CARA statute. Information about the final meeting agenda will be posted prior to the meeting on the Task Force website: *https://www.hhs.gov/ash/advisorycommittees/pain/index.html.*

Members of the public are invited to participate in person or by webcast. To join the meeting, individuals must pre-register at the Task Force website at *https://www.hhs.gov/ash/advisory-committees/pain/index.html.* Seating will be provided first to those who have pre-registered. Anyone who has not pre-registered will be accommodated on a first come, first served basis if additional seats are available 10 minutes before the meeting starts. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should indicate the special accommodation when registering online or by notifying the Office of the Assistant Secretary for Health via email at *paintaskforce@hhs.gov* by April 29, 2019. The subject line of the email should read, ''Task Force Meeting Accommodations.'' Non-U.S. citizens who plan to attend in person are required to provide additional information and must notify the Task Force staff via email at *paintaskforce@hhs.gov* 10 business days before the meeting, April 29, 2019. For those unable to attend in person, a live webcast will be available. More information on registration and accessing the webcast can be found at *https://www.hhs.gov/ash/advisory-committees/pain/index.html.*

Members of the public can provide oral comments at the Task Force meeting on May 9, 2019, at 11:00 a.m.–11:30 a.m. ET. Please indicate your willingness to provide oral comments on the registration form which can be found at *https://www.hhs.gov/ash/advisory-committees/pain/index.html.* Individuals who pre-register will be given priority to provide oral public comment within the order they are received. The public comment period will not be extended beyond the allotted time on the agenda. Public comments made during the meeting will be limited to three minutes per person to ensure time is allotted for all those wishing to speak. Please note that the public comment period may end before the time indicated, following the last call for comments. Individuals who are not able to provide oral comments are encouraged to submit their written comments. Written comments should not exceed one page in length. Individuals submitting written comments should submit their comments through the Federal eRulemaking Portal at *http://www.regulations.gov*, docket number HHS–OS–2019–0003.

Dated: March 15, 2019.

Vanila M. Singh,

Chief Medical Officer, Chair, Pain Management Task Force, Office of the Assistant Secretary for Health.

[FR Doc. 2019–06328 Filed 4–1–19; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Biodefense Science Board: Call for Nominees

AGENCY: Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Office of the Assistant Secretary for Preparedness and Response (ASPR), in the Department of Health and Human Services (HHS) seeks applications from qualified individuals for membership on the National Biodefense Science Board (NBSB) or (Board). Terms of five members expire December 31, 2019; therefore, the HHS Secretary (Secretary) will appoint five new voting members. Applicants to those positions may be nominated by a relevant organization or may nominate themselves based on their expertise within the following stakeholder groups: Industry, academia, health care consumer organizations, and organizations representing other appropriate stakeholders. Please visit the NBSB website at *https://www.phe.gov/nbsb* for all application submission information, additional information regarding the qualifications expected for applicants, and application instructions.

DATES: *Nomination Period:* The nomination period is from April 15, 2019, to June 15, 2019, at 11:59 p.m. (EST).

FOR FURTHER INFORMATION CONTACT: CDR Christopher Perdue, MD, MPH, Designated Federal Official, NBSB, ASPR, HHS, office: 202–401–5837, email address: *christopher.perdue@hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to section 319M of the Public Health Service Act, HHS has established the NBSB to provide expert advice and guidance to the Secretary on scientific, technical, and other matters of special interest to HHS regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. The Board may also provide advice and guidance to the Secretary and/or the ASPR on other matters related to public health emergency preparedness and response.

Description of Duties: The Board advises the Secretary and/or ASPR on current and future trends, challenges, and opportunities presented by advances in biological and life sciences, biotechnology, and genetic engineering with respect to threats posed by naturally occurring infectious diseases and chemical, biological, radiological, and nuclear agents. At the request of the Secretary and/or ASPR, the Board reviews and considers information and findings received from the working groups established under 42 U.S.C. 247d–7f(b). At the request of the Secretary and/or ASPR, the Board provides recommendations and findings for expanded, intensified, and coordinated biodefense research and development activities. The Secretary and/or ASPR may assign additional advisory duties concerning public health emergency preparedness and response at his/her discretion.

Structure: The Board consists of 13 voting members, including the chairperson; additionally, there may be non-voting ex officio members. Pursuant to 42 U.S.C. 247d–7f(a), the Secretary appoints members and the chairperson from among the nation's preeminent scientific, public health, and medical experts, as follows: (a) Such federal officials as the Secretary determines are necessary to support the functions of the Board; (b) four individuals from the pharmaceutical, biotechnology, and device industries; (c) four individuals representing academia; and, (d) five other members as appointed by the Secretary, one of whom is a practicing health care professional, one of whom is from an organization representing health care consumers, one of whom has pediatric subject matter expertise, and