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Agency determine whether CHLOR–TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate) extended release tablets, 8 mg, were withdrawn from sale for reasons of safety or effectiveness.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 On our own initiative, we have also determined whether that strength was withdrawn for safety or effectiveness reasons.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that CHLOR–TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate) extended release tablets, 8 mg and 12 mg, were not withdrawn for reasons of safety or effectiveness.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that CHLOR–TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate), extended release tablets, 8 mg and 12 mg, were withdrawn for reasons of safety or effectiveness.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 We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.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