available at *http://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 September 22, 2014. Oral presentations from the public will be scheduled between approximately 11 a.m. to 12 p.m. on September 30, 2014. 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 September 12, 2014. 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 September 15, 2014.

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 physical disabilities or special needs. If you require special accommodations due to a disability, please contact Karen Strambler at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://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: July 10, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–16777 Filed 7–16–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0889]

Site Tours Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Tobacco Products (CTP), Office of Science is announcing an invitation for participation in its Site Tours Program. This program is intended to give CTP staff an opportunity to visit facilities involved in the growing, processing, or manufacturing of tobacco or currently regulated tobacco products (i.e., cigarettes, roll-your-own, and smokeless tobacco). These visits are intended to provide CTP staff with the opportunity to gain a better understanding of the tobacco industry and its operations and are not intended as regulatory inspections or facility visits for the purposes of developing Tobacco Product Manufacturing Practice regulations. The purpose of this notice is to alert parties interested in participating in the Site Tours Program to submit requests to CTP.

DATES: Interested parties should submit either an electronic or written request for participation by September 15, 2014. The request should include a description of your facility, including as applicable, a list of all tobacco products processed and/or manufactured there. Please specify the physical address(es) of the site(s) for which you are submitting a request along with a proposed 1-day tour agenda.

ADDRESSES: If your facility is interested in offering a site visit, you should submit a request to participate in the program either electronically to *http://www.regulations.gov* or in writing to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Carolyn Dresler, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 240–402–4067, *carolyn.dresler@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) was signed into law, amending the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and giving FDA authority to regulate tobacco product manufacturing, distribution, and marketing.

CTP's Office of Science is continuing the Site Tours Program to provide its scientific and regulatory staff the opportunity to gain a better understanding of the tobacco industry and its operations, including tobacco product manufacturing and aspects of tobacco growing, processing, and storage that may affect the physical and chemical properties of tobacco. Although FDA generally does not regulate tobacco farms and tobacco warehouses, the Agency believes that gaining a better understanding of the operations performed at these facilities may be helpful. The goals of the Site Tours Program are to: (1) Provide CTP firsthand exposure to industry's manufacturing processes; (2) learn about control measures used by tobacco product manufacturers to ensure product consistency; (3) understand the processing of different forms of tobacco and the manufacturing processes used for various types of tobacco products and their influences on product constituents; and (4) understand how growing conditions, curing, storage, and manufacturing processes might influence the levels of tobacco or tobacco smoke constituents.

II. Description of Site Tours Program

In the Site Tours Program, small groups of CTP staff plan to observe the operations of tobacco growers, tobacco warehouses, and tobacco product manufacturing facilities of cigarettes, roll-your-own, and smokeless tobacco companies, including the manufacturing of paper, filters, and pouch materials. Please note that the Site Tours Program is not intended to include official FDA inspections of facilities to determine compliance with the FD&C Act or for the purposes of developing Tobacco Product Manufacturing Practice regulations; rather, the program is meant to educate CTP staff and improve their understanding of the tobacco industry and its operations.

III. Site Selection

CTP plans to select one or more of each of the following types of facilities: A large cigarette manufacturing facility, a small cigarette manufacturing facility, a smokeless manufacturing facility, a burley tobacco farm, a flue-cured tobacco farm, a tobacco rolling paper facility, a tobacco warehouse and a tobacco processing facility. All travel expenses associated with the site tours

will be the responsibility of CTP. Final site selections will be based on the availability of CTP funds and resources for the relevant fiscal year, as well as the following factors: (1) Compliance status of the requesting facility and affiliated firm, if applicable; (2) whether the requesting facility is in arrears for user fees; (3) whether the requesting facility or affiliated firm, if applicable, has a significant request or marketing application or submission pending with FDA; and (4) whether the requesting facility will be engaged in active manufacturing or processing during the proposed time of the visit.

IV. Requests for Participation

Requests are to be identified with the docket number found in brackets in the heading of this document. Requests received by the Agency are available for public examination in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 14, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–16794 Filed 7–16–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0021]

AbbVie Inc., et al.; Withdrawal of Approval of Abbreviated New Drug Applications for Prescription Pain Medications Containing More Than 325 Milligrams of Acetaminophen

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 7 abbreviated new drug applications (ANDAs) for prescription drug products containing more than 325 milligrams (mg) of acetaminophen. The holders of these ANDAs have waived their opportunity for a hearing.

DATES: Effective July 17, 2014.

FOR FURTHER INFORMATION CONTACT: Rachel Turow, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–5094.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 14, 2011 (76 FR 2691), FDA announced its plans to reduce the maximum dosage unit strength of acetaminophen in prescription drug products. The notice announced FDA's conclusion that, based on a reevaluation of the relative risks and benefits of prescription acetaminophen products, fixed-combination prescription drugs containing more than 325 mg of acetaminophen per dosage unit (tablet, capsule, or liquid) do not provide a sufficient margin of safety to protect the public against the serious risk of acetaminophen-induced liver injury. Accordingly, we asked product sponsors to limit the maximum amount of acetaminophen per dosage unit to 325 mg and, for those products containing more than 325 mg of acetaminophen per dosage unit, to submit requests that FDA withdraw approval of their applications under § 314.150(d) (21 CFR 314.150(d)). FDA asked that all such requests be made before January 14, 2014, after which date the Agency planned to initiate proceedings under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(e)) to withdraw approval of any prescription drug products containing more than 325 mg of acetaminophen per dosage unit that remained on the market.

FDA did not receive a request for withdrawal of approval of an application containing more than 325 mg of acetaminophen per dosage unit from one sponsor. In addition, FDA received requests for withdrawal of approval of five applications for products containing more than 325 mg of acetaminophen per dosage unit for which sponsors either submitted requests under § 314.150(c) or failed to cite a relevant regulatory provision. FDA contacted all of these sponsors on multiple occasions to ask that they submit a request that FDA withdraw approval of their applications under § 314.150(d), but they failed to respond.

With respect to the application for which FDA received no request for withdrawal, FDA initiated proceedings under § 314.150(a) and (b) to withdraw approval. With respect to the requests for withdrawal of approval submitted under § 314.150(c), the Agency notes that because FDA has made a determination under § 314.150(a) that approval of these applications should be withdrawn for reasons of safety, application holders may not withdraw their applications under § 314.150(c). The text of § 314.150(c) expressly precludes withdrawal of an application under the subsection if FDA has made a safety determination under § 314.150(a). Similarly, when a request for withdrawal is made without a citation to any regulation, FDA does not consider it to be appropriately notified that an application holder has voluntarily waived the opportunity for a hearing. Accordingly, FDA decided to proceed with withdrawal of approval of applications for which sponsors either submitted requests under § 314.150(c) or failed to cite a relevant regulatory provision under the withdrawal procedures outlined in § 314.150 (a) and (b).

Thus, in a notice published in the **Federal Register** on March 27, 2014 (79 FR 17156), the Director of CDER offered an opportunity for a hearing on a proposal to issue an order, under section 505(e) of the FD&C Act and 21 CFR 314.150(a), withdrawing approval of 6 ANDAs for products containing more than 325 mg of acetaminophen for which the ANDA holders did not voluntarily request to withdraw their applications under § 314.150(d). The ANDA holders were provided an opportunity to request a hearing to show why approval of their ANDAs should not be withdrawn. None of the ANDA holders requested a hearing in response to the notice.

The ANDAs listed in table 1, other than ANDA 040148, were the subject of the March 27, 2014, **Federal Register** notice. Because the holders of these ANDAs failed to request a hearing by April 28, 2014, they are considered to have waived their opportunity for a hearing under § 314.200(a)(2) and FDA is now withdrawing approval of their applications.

In addition, table 1 includes ANDA 040148 for which the ANDA holder submitted a timely voluntary request for withdrawal under 314.150(d) and waived its opportunity for a hearing. However, ANDA 040148 was erroneously omitted from the March 27, 2014, **Federal Register** notice (79 FR 17163) announcing withdrawal of approval of 108 ANDAs. FDA is now withdrawing approval of ANDA 040148 as well.