Biological Products 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 November 16, 2016, from 8:30 a.m. to 2:30 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD, 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.* For those unable to attend in person, the meeting will also be Webcast and will be available at the following link: *https://collaboration.fda.gov/vrbac1116/.*

FOR FURTHER INFORMATION CONTACT: Sujata Vijh or Rosanna Harvey, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6128, Silver Spring, MD 20993–0002, at 240–402–7107, *sujata.vijh@fda.hhs.gov* and 240–402–8072, *rosanna.harvey@fda.hhs.gov,* 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 Web site at *http://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:

Agenda: On November 16, 2016, the committee will meet in open session to discuss and make recommendations on the safety and efficacy of a Hepatitis B Vaccine manufactured by Dynavax.

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 Web site 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 Web site after the meeting. Background material is 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 November 1, 2016. Oral presentations from the public will be scheduled between approximately 12:15 p.m. to 1:15 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 October 24, 2016. 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 October 25, 2016.

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 Sujata Vijh 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: August 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–20763 Filed 8–29–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

FDA Small Business and Industry Assistance Regulatory Education for Industry Fall Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of conference.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) and the Center for Devices and Radiological Health (CDRH) are sponsoring a 2 day conference entitled ''FDA Small Business and Industry Assistance Regulatory Education for Industry (REdI) Fall Conference.'' The goal of this conference is to provide direct, relevant, and helpful information on the key aspects of drug and device regulations. Our primary audience is that of small manufacturers of drug and/or device medical products who want to learn about how FDA approaches the regulation of drugs and devices. However, anyone involved in the pharmaceutical and/device industry may attend.

DATES: The public conference will be held on September 27 and 28, 2016, from 8:15 a.m. to 4:15 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration information.

ADDRESSES: The public conference will be held at the Sheraton Silver Spring Hotel, 8777 Georgia Ave., Cypress and Magnolia Ballrooms (4th floor), Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Brenda Stodart, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–6707, *cdersbia@fda.hhs.gov;* or Elias Mallis, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–7100, *DICE@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public conference entitled ''FDA Small Business and Industry Assistance Regulatory Education for Industry (REdI) Fall Conference.'' This conference is intended to increase the drug and device industry's awareness of applicable FDA regulations. There will be an opportunity for questions and answers following each presentation.

II. Topics for Discussion at the Conference

• *CDER:* Manufacturing Process Validation; Interactions with FDA; Emerging Technology and Inspection for New Drug Applications and Biologic License Applications.

• *CDRH:* 510(k); De Novo; Design Controls; and Complaints.

Registration: There is no fee to attend the public conference. Space is limited, and registration will be on a first-come, first-served basis. To register, please complete registration at: *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm514324.htm.*

If you need special accommodations due to disability, please contact *info@sbiaevents.com* at least 7 days in advance.

Streaming Webcast of the Conference: This public conference will also be Webcast. Persons interested in viewing the Webcast must register to receive a confirmation email with the Webcast link.

Transcripts: Transcripts will not be available.

Dated: August 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–20764 Filed 8–29–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1427]

Agency Information Collection Activities; Proposed Collection; Comment Request; Hazard Analysis and Critical Control Point Procedures for the Safe and Sanitary Processing and Importing of Juice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of our regulations mandating the application of hazard analysis and critical control point (HACCP) principles to the processing of fruit and vegetable juices.

DATES: Submit either electronic or written comments on the collection of information by October 31, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–N–1427 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Hazard Analysis and Critical Control Point Procedures for the Safe and Sanitary Processing and Importing of Juice.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined