docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto Friedman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Rm. 1670, Silver Spring, MD 20993, 240–402–7930, *elizabeth.giaquinto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Determining Whether to Submit an ANDA or a 505(b)(2) Application.'' This guidance is intended to serve as a foundational guidance to assist applicants in determining which one of the abbreviated approval pathways under the FD&C Act is appropriate for the submission of a marketing application to FDA. This guidance highlights criteria for submitting applications under the abbreviated approval pathways described in section 505(j) and 505(b)(2) of the FD&C Act (21 U.S.C. 355(j) and 21 U.S.C. 355(b)(2), respectively), identifies considerations to help potential applicants determine whether an application would be more appropriately submitted under section 505(j) or under section 505(b)(2) of the FD&C Act, and provides direction to potential applicants on requesting assistance from FDA in making this determination.

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the Hatch-Waxman Amendments) added section 505(b)(2) and 505(j) of the FD&C Act, which describe abbreviated approval pathways for drug products regulated by the Agency under the FD&C Act. The Hatch-Waxman Amendments reflect Congress's efforts to balance the need to ''make available more low cost generic drugs by establishing a generic drug approval procedure'' with new incentives for drug development in the form of exclusivities and patent term extensions. With the passage of the Hatch-Waxman Amendments, the FD&C Act describes different routes for obtaining approval of two broad categories of drug applications: New drug applications (NDAs) and abbreviated new drug applications (ANDAs).

This guidance focuses on those applications that can be submitted as ANDAs under section 505(j) of the FD&C Act, petitioned ANDAs under section 505(j)(2)(C) of the FD&C Act, or NDAs under section 505(b)(2) of the FD&C Act. This guidance does not discuss stand-alone NDAs.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on factors for applicants to consider when determining whether to submit an ANDA or a 505(b)(2) application. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 314.94 have been approved under OMB control number 0910–0001. The collection of information for controlled correspondence and pre-ANDA meeting requests has been approved under OMB control number 0910–0797.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated October 10, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–22196 Filed 10–12–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5991]

Agricultural Biotechnology Education and Outreach Initiative; Public Meetings; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meetings; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the following public meetings entitled ''Agricultural Biotechnology Education and Outreach Initiative.'' The purpose of the public meetings is to provide the public with an opportunity to share information, experiences, and suggestions to help inform the development of this education and outreach initiative.

DATES: The public meetings will be held on November 7, 2017, in Charlotte, North Carolina, and on November 14, 2017, in San Francisco, California. Submit either electronic or written comments by November 17, 2017. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meetings will be held at:

- The Omni Charlotte, 132 East Trade St., Charlotte, NC 28202 on November 7, 2017, and
- The San Francisco Marriott Marquis, 780 Mission St., San Francisco, CA 94103 on November 14, 2017.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 17, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of November 17, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, 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–2017–N–5991 for ''Agricultural Biotechnology Education and Outreach Initiative; Public Meetings; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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.'' We will review this copy, including the claimed confidential information, in our 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: *For questions regarding registration to attend a meeting:* Simone Katz, Strategic Results, 101 Lakeforest Blvd., Suite 390, Gaithersburg, MD 20877, 240–449–8427, *simone.katz@strategicresults.com. For all other questions:* Juanita Yates, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1731, *Juanita.yates@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Consolidated Appropriations Act, 2017 (Pub. L. 115–31) stipulates that the Commissioner of Food and Drugs, in coordination with the Secretary of Agriculture, will use appropriated funds to provide consumer outreach and education regarding agricultural biotechnology and biotechnology-derived food products and animal feed, including through publication and distribution of science-based educational information on the environmental, nutritional, food safety, economic, and humanitarian impacts of such biotechnology.

FDA is responsible for promoting and protecting the public health, including by ensuring that the nation's food supply is safe and nutritious. FDA provides information and outreach to a variety of audiences along with extensive, hands-on food safety and nutrition education programs for educators, health professionals, and consumers. Educational materials are targeted to consumers in general, as well as to specific groups such as children/youth, older Americans, underserved populations, individuals with weakened immune systems (related to food safety), pregnant women, and other subpopulations.

To further our public health mission, we develop food safety and nutrition outreach initiatives in conjunction with non-Federal organizations and individuals, including teachers, community leaders, health educators, animal owners, and private and public health professionals, to increase awareness of and provide education on food safety and nutrition.

In developing and implementing the Agricultural Biotechnology Education and Outreach Initiative, FDA will coordinate with the U.S. Department of Agriculture (USDA). We also will collaborate with other U.S. Federal Government Agencies, and public and private organizations as needed. These interactions will help us to develop a comprehensive and thorough framework for consumer education and awareness of the environmental, nutritional, food safety, economic, and humanitarian impacts of agricultural biotechnology. We believe public comment will be helpful to inform the development of this education and outreach initiative.

II. Topics for Discussion at the Public Meetings

FDA is holding two public meetings, one in North Carolina and one in California, to provide the public with an opportunity to provide comments related to FDA's Agricultural Biotechnology Education and Outreach Initiative. We invite the public to share information, experiences, and suggestions that can help inform the development of the education and outreach initiative. We invite interested persons, including those participating in the public meetings, to respond to the following questions specifically regarding agricultural biotechnology and biotechnology-derived food products and animal feed:

1. What are the specific topics, questions, or other information that consumers would find most useful, and why?

2. Currently, how and from where do consumers most often receive information on this subject?

3. How can FDA (in coordination with USDA) best reach consumers with science-based educational information on this subject?

The comments received will help FDA identify education goals, messaging, and dissemination strategies

for FDA's Agricultural Biotechnology Education and Outreach Initiative.

III. Participating in the Public Meeting

Registration: To register for a public meeting, please include your name, title, firm name, address, and phone and fax numbers in your registration information and send to: Simone Katz, Strategic Results, 101 Lakeforest Blvd., Suite 390, Gaithersburg, MD 20877, 240–449–8427, Fax: 240–641–9042, email: *simone.katz@strategicresults.com.* You can register for one or both meetings.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by October 30, 2017, for the Charlotte, NC, meeting and must register by November 6, 2017, for the San Francisco, CA, meeting. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Simone Katz, Strategic Results, 101 Lakeforest Blvd., Suite 390, Gaithersburg, MD 20877, 240–449–8427, Fax: 240–641–9042, email: *simone.katz@strategicresults.com* no later than October 20, 2017, for the Charlotte, NC, meeting and no later than October 27, 2017, for the San Francisco, CA, meeting.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by October 24, 2017, for the meeting in Charlotte, NC, and by November 1, 2017, for the meeting in San Francisco, CA. All requests to make oral presentations must be received by October 20, 2017, for the meeting in Charlotte, NC, and by October 27, 2017, for the meeting in San Francisco, CA.

Streaming Webcast of the Public Meeting: Each public meeting will also be webcast. Individuals who wish to participate by webcast are asked to preregister at: *https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm*

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of each public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.*

Other Issues for Consideration: A summary of key information on participating in a meeting follows:

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING

Date	Address	Preregister	Electronic address	Request to make an oral presentation	Special accommodations	Submit either electronic or written comments
November 7, 2017, from 8:30 a.m. to 1 p.m. EST.	Omni Charlotte Hotel, 132 E Trade St., Charlotte, NC 28202.	October 30, 2017: Closing date for registration.	Please preregister at *https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.*	October 20, 2017.	October 20, 2017: Closing date to request special accommodations due to a disability.	Submit Comments by November 17, 2017, to: *https://www.regulations.gov,* or Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
November 14, 2017, from 8:30 a.m. to 1 p.m. PST.	San Francisco Marriott Marquis, 780 Mission St., San Francisco, CA 94103.	November 6, 2017: Closing date for registration.	Please preregister at *https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.*	October 27, 2017.	October 27, 2017: closing date to request special accommodations due to a disability.	Same as above.

You may also register via email, mail, or fax. Please include your name, title, firm name, address, and phone and Fax numbers in your registration information and send to: Simone Katz, Strategic Results, 101 Lakeforest Blvd., Suite 390, Gaithersburg, MD 20877, 240–449–8427, Fax: 240–641–9042, email: *simone.katz@strategicresults.com.*

Individuals who wish to participate by webcast are asked to preregister at: *https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.*

Dated: October 6, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–22172 Filed 10–12–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5953]

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.