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 committees. All electronic and written submissions submitted to the Docket (see the **ADDRESSES** section) on or before April 19, 2016, will be provided to the committees. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 12:30 p.m. on May 4, 2016. 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 April 11, 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 April 12, 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 Stephanie L. Begansky 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: March 8, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–05573 Filed 3–11–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–4750]

Implementation of the ''Deemed To Be a License'' Provision of the Biologics Price Competition and Innovation Act of 2009; Draft Guidance for Industry; Availability and Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Implementation of the 'Deemed to be a License' Provision of the Biologics Price Competition and Innovation Act of 2009.'' This draft guidance describes FDA's approach to implementation of the statutory provision under which an application for a biological product approved under the Federal Food, Drug, and Cosmetic Act (FD&C Act) on or before March 23, 2020, will be deemed to be a license for the biological product under the Public Health Service Act (PHS Act) on March 23, 2020. Specifically, this draft guidance describes FDA's interpretation of the ''deemed to be a license'' provision of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) for biological products that have been or will be approved under the FD&C Act on or before March 23, 2020. This draft guidance also provides recommendations to sponsors of proposed protein products intended for submission in an application that may not receive final approval under the FD&C Act on or before March 23, 2020, to facilitate alignment of product development plans with FDA's interpretation the transition provisions of the BPCI Act.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 13, 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–2015–D–4750 for ''Implementation of the 'Deemed to be a License' Provision of the Biologics Price Competition and Innovation Act of 2009; Draft Guidance for Industry; Availability and Request for Comments.'' 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.

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; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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: Janice Weiner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6268, Silver Spring, MD 20993–0002, 301–796–3601; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Implementation of the 'Deemed to be a License' Provision of the Biologics Price Competition and Innovation Act of 2009.'' This draft guidance describes FDA's approach to implementation of the provision of the BPCI Act under which an application for a biological product approved under section 505 of the FD&C Act (21 U.S.C. 355) on or before March 23, 2020, will be deemed to be a license for the biological product under section 351 of the PHS Act (42 U.S.C. 262) on March 23, 2020. Specifically, this draft guidance describes FDA's interpretation of the ''deemed to be a license'' provision in section 7002(e) of the BPCI Act for biological products that have been or will be approved under section 505 of the FD&C Act on or before March 23, 2020. This draft guidance also provides recommendations to sponsors of proposed protein products intended for submission in an application that may not receive final approval under section 505 of the FD&C Act on or before March 23, 2020, to facilitate alignment of product development plans with FDA's interpretation of section 7002(e) of the BPCI Act.

Although the majority of therapeutic biological products have been licensed under section 351 of the PHS Act, some protein products historically have been approved under section 505 of the FD&C Act. On March 23, 2010, the BPCI Act was enacted as part of the Patient Protection and Affordable Care Act (Pub. L. 111–148). The BPCI Act changed the statutory authority under which certain protein products will be regulated by amending the definition of a ''biological product'' in section 351(i) of the PHS Act to include a ''protein (except any chemically synthesized polypeptide).'' FDA has interpreted the statutory terms ''protein'' and ''chemically synthesized polypeptide'' to implement the amended definition of ''biological product'' (see FDA's guidance for industry entitled ''Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009,'' available on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*).

The BPCI Act requires that a marketing application for a ''biological product'' be submitted under section 351 of the PHS Act; this requirement is subject to certain exceptions during a 10-year transition period ending on March 23, 2020 (see section 7002(e)(1)–(3) and (e)(5) of the BPCI Act). On March 23, 2020, an approved application for a biological product under section 505 of the FD&C Act shall be deemed to be a license for the biological product under section 351 of the PHS Act (see section 7002(e)(4) of the BPCI Act). Among other things, because the BPCI Act provides only that an application that is approved on March 23, 2020, shall be deemed to be a license, FDA interprets section 7002(e) of the BPCI Act to mean that the Agency will not approve any application under section 505 of the FD&C Act for a biological product subject to the transition provisions that is pending or tentatively approved ''on'' March 23, 2020, even though section 7002(e)(2) of the BPCI Act expressly permits submission of an application under section 505 of the FD&C Act ''not later than'' March 23, 2020, if certain criteria are met. Such an application may, for example, be withdrawn and resubmitted under section 351(a) or 351(k) of the PHS Act, as appropriate. FDA recognizes that this interpretation could have a significant impact on development programs for any proposed protein products intended for submission under section 505 of the FD&C Act that are not able to receive final approval by March 23, 2020, and provides recommendations to sponsors in the draft guidance.

We invite comment on the Agency's approach to implementation of the ''deemed to be a license'' provision of the BPCI Act, as described in the draft guidance.

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 implementation of the ''deemed to be a license'' provision of the BPCI Act. 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.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that 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 collection of information in 21 CFR part 312 has been approved under 0910–0014; the collection of information in 21 CFR part 314 has been approved under 0910–0001; the collection of information in 21 CFR part 601 has been approved under 0910–0338; and the collection of information for applications submitted under section 351(k) of the PHS Act has been approved under 0910–0719. In accordance with the PRA, before publication of the final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to previously approved collections of information found in FDA regulations or guidances.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *http://www.regulations.gov.*

Dated: March 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–05626 Filed 3–11–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Advancing the Development of Pediatric Therapeutics: Successes and Challenges of Performing Long-Term Pediatric Safety Studies; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA) Office of Pediatric Therapeutics (OPT) and Center for Drug Evaluation and Research are announcing a 2-day public workshop entitled ''Advancing the Development of Pediatric Therapeutics (ADEPT): Successes and Challenges of Performing Long-Term Pediatric Safety Studies.'' The purpose of this 2-day public workshop is for FDA to have an open discussion with experts in the field examining the need and path forward for long-term pediatric safety studies. Day 1 of the public workshop will focus on an exposition of the successes and challenges of long-term safety studies in children. Day 2 of the public workshop will focus on suggestions for the future on study design and implementation of long-term safety studies in children. Viewpoints of patient representatives of children with chronic conditions and industry will be included.

DATES: The public workshop will be held on April 13 and 14, 2016, from 8 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at The DoubleTree by Hilton Hotel—Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

FOR FURTHER INFORMATION CONTACT: Renan A. Bonnel, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–8654, FAX: 301–847–8640, email: *renan.bonnel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Medical product safety studies in children are usually performed for 6 months or less. In children, measurement of long-term outcomes is particularly challenging since, compared to adults, children are undergoing dramatic growth and developmental changes. This 2-day public workshop will focus on the challenges of long-term follow-up in children receiving medical products. The first day of the public workshop will focus on the problems or barriers, including; challenges with study design, data capture, infrastructure, and endpoints. Viewpoints of parents and industry will be represented. The second day of the public workshop will include panel discussions to propose solutions to the problems posed on day one and to discuss the epidemiological challenges posed by the collection of data on different types of adverse events. On both days of the public workshop there will be a certain amount of time on the agenda for attendee questions or comments.

II. Participation in the Public Workshop

Registration: There is no fee to attend the public workshop, but attendees should register in advance. Space is limited, and registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online at: *http://pediatricsafety.eventbrite.com* before April 7, 2016. For those without Internet access, please contact Renan A. Bonnel (see **FOR FURTHER INFORMATION CONTACT**) to register. In the event that a minimum number of participants have not registered, the workshop will be postponed. Registered participants will be notified of any change. Onsite registration will be available if seating permits it. Registration information, the agenda, and additional background materials can be found at *http://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm477639.htm.*

If you need special accommodations due to a disability, please contact Renan A. Bonnel (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance. Persons attending the meeting are advised that FDA is not responsible for providing access to electrical outlets.

Web cast: The live Web cast on April 13, 2016, will be available at: *https://event.webcasts.com/starthere.jsp?ei=1093258.* After the morning session, users will be automatically redirected to the afternoon link. Should you lose connection over lunch, please use the following link for the afternoon session (note that it is different from the morning's session): *https://event.webcasts.com/starthere.jsp?ei=1093259.* On April 14, 2016, the live Web cast will be available at: *https://event.webcasts.com/starthere.jsp?ei=1093263.* After the morning session, users will be automatically redirected to the afternoon link. Should you lose connection over lunch, please use the following link for the afternoon session (note that it is different from the morning's session): *https://event.webcasts.com/starthere.jsp?ei=1093265.* The Web cast will only be for listening and there will not be an opportunity for Web cast participants to speak.

The videocast will be posted after the workshop at *http://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm477639.htm.*

Transcripts: Transcripts of the workshop will be available for review at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and at *http://www.regulations.gov* approximately 30 days after the workshop. A transcript will also be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information. The Freedom of Information address is available on the Agency's Web site at