SUMMARY: The Food and Drug Administration (FDA) is announcing a request for additional comments on the chemistry, manufacturing, and control (CMC) information that a sponsor of an investigational new drug application (IND) should provide in its IND in order to meet regulatory requirements when commercially available foods or dietary supplements containing live biotherapeutic products (LBPs) are used as investigational new drugs in early phase clinical trials. The request for additional comments on the CMC information is related to the guidance entitled, ''Early Clinical Trials with Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information; Guidance for Industry,'' dated February 2012 (February 2012 guidance).

DATES: Submit either electronic or written comments on the requested CMC information by May 29, 2015.

ADDRESSES: Submit written requests for single copies of the February 2012 guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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 the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the requested CMC information to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jessica T. Walker, 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 a request for additional comments on the CMC information that a sponsor of an IND should provide in its IND in order to meet the requirements under § 312.23 (21 CFR 312.23), when commercially available foods or dietary supplements containing LBPs are subject to study as investigational new drugs in early phase clinical trials.

In the **Federal Register** of February 21, 2012 (77 FR 9947), FDA announced the publication of a final guidance entitled ''Early Clinical Trials with Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information; Guidance for Industry,'' dated February 2012. The guidance provides IND sponsors with recommendations regarding CMC information that should be included in IND submissions for early clinical trials with LBPs, including LBPs lawfully marketed as foods or dietary supplements in the United States and proposed for clinical uses regulated under section 351 of the Public Health Service Act (42 U.S.C. 262). The guidance also outlines the Drug Substance and Drug Product information that should be provided in the CMC section of an IND to meet the requirements under § 312.23 and to support proceeding to clinical evaluation of an LBP in human subjects.

II. CMC Information

FDA is considering modifying the February 2012 guidance to address the CMC information that should be provided in an IND, under certain conditions. Specifically, FDA is considering whether to revise the guidance to address when the label on the commercially available product(s) would be considered adequate to satisfy the requirement for CMC information under § 312.23. For example, we are considering whether the label would be adequate to satisfy the CMC information when the following conditions are met: (1) The LBP product that is proposed for investigational use is a commercially available food or dietary supplement; (2) the investigation does not involve a route of administration, dose, patient population, or other factor that significantly increases the risk (or decreases the acceptability of risk) associated with the use of the food or dietary supplement; (3) the investigation is not intended to support a marketing application for a drug claim for the food or dietary supplement; and (4) the investigation is conducted in compliance with the requirements for INDs (part 312), the requirements for review by an institutional review board (21 CFR part 56), and with the requirements for informed consent (21 CFR part 50). FDA is seeking public comment on this issue.

III. Comments

Interested persons may submit either electronic comments regarding the requested CMC information to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the February 2012 guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: March 25, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–07273 Filed 3–30–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1439]

Critical Path Innovation Meetings; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Critical Path Innovation Meetings.'' This guidance describes a Critical Path Innovation Meeting (CPIM), a means by which FDA's Center for Drug Evaluation and Research (CDER) and investigators from industry, academia, government, and patient advocacy groups can communicate to improve efficiency and success in drug development. The goals of the CPIM are to discuss a methodology or technology proposed by the meeting requester and for CDER to provide general advice on how this methodology or technology might enhance drug development. The discussions and background information submitted through the CPIM are nonbinding on both FDA and CPIM requesters.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Alicia Barbieri Stuart, Office of Translational Sciences, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 4547, Silver Spring, MD 20993–0002, 301–796–3852.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Critical Path Innovation Meetings.'' The guidance describes the purpose and scope of a CPIM and how to request such a meeting. A CPIM provides the opportunity to discuss a methodology or technology proposed by the meeting requester and for CDER to provide general advice on how the methodology or technology might enhance drug development. During a CPIM, CDER will identify some of the larger gaps in existing knowledge that requesters might consider addressing in the course of their work. The discussions and background information submitted through the CPIM are nonbinding on both FDA and CPIM requesters. The CPIM initiative meets Prescription Drug User Fee Act (PDUFA) V Reauthorization Goal IX.A, ''Enhancing Regulatory Science and Expediting Drug Development'' by ''Promoting Innovation Through Enhanced Communication Between FDA and Sponsors During Drug Development.''

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Critical Path Innovation Meetings.'' 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. The Paperwork Reduction Act of 1995

This 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 (investigational new drug applications) has been approved under OMB control number 0910–0014. The collection of information in 21 CFR part 314 (new drug applications) has been approved under OMB control number 0910–0001. The collection of information resulting from formal meetings between interested persons and FDA has been approved under OMB control number 0910–0429.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

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

Dated: March 24, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–07272 Filed 3–30–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pulmonary-Allergy Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 12, 2015, from 8 a.m. to 4 p.m.

Location: Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel phone number is 301–977–8900.

Contact Person: Cindy Hong, 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). 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.

Agenda: The committee will discuss new drug application (NDA) 206038, lumacaftor/ivacaftor combination tablets for oral use, submitted by Vertex Pharmaceuticals, proposed for the treatment of cystic fibrosis (CF) in patients age 12 years and older who are homozygous for the *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.

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 April 27, 2015. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals