at *http://www.regulations.gov* or from the Center for Biologics Evaluation and Research at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* To receive ''*De Novo* Classification Process (Evaluation of Automatic Class III Designation)'' from CDRH you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to (301) 847–8149 to receive a paper copy. Please use the document number 1769 to identify the guidance you are requesting.

Dated: November 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–28766 Filed 11–4–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0427]

Guidance for Industry: Clinical Considerations for Therapeutic Cancer Vaccines; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Clinical Considerations for Therapeutic Cancer Vaccines'' dated October 2011. The guidance document provides sponsors who wish to submit an Investigational New Drug application (IND) for a therapeutic cancer vaccine with recommendations on critical clinical considerations for investigational studies of these products. The guidance also provides recommendations for the design of clinical trials for cancer vaccines conducted under an IND to support a subsequent biologics license application (BLA) for marketing approval. The guidance applies to therapeutic cancer vaccines that are intended for the treatment of patients with an existing diagnosis of cancer. The guidance does not apply to vaccines for preventative and therapeutic infectious disease indications, to products intended to induce or augment a non-specific immune response, or to products intended to prevent or decrease the incidence of cancer in individuals without a prior history of that cancer. Furthermore, the guidance does not apply to adoptive immunotherapeutic products which may mediate their therapeutic effect by targeting the tumor directly, such as T cell or NK cell products. The guidance announced in this notice finalizes the draft guidance of the same title dated September 2009.

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

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. 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 (301) 827–1800. 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: Lori Jo Churchyard, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, (301) 827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Clinical Considerations for Therapeutic Cancer Vaccines,'' dated October 2011. The guidance document provides sponsors who wish to submit an IND for a therapeutic cancer vaccine with recommendations on critical clinical considerations for investigational studies of these products. Further, the guidance provides recommendations for the design of clinical trials for cancer vaccines conducted under an IND (Title 21 Code of Federal Regulations (21 CFR) part 312) to support a subsequent BLA for marketing approval. The guidance is applicable to therapeutic cancer vaccines that are intended for the treatment of patients with an existing diagnosis of cancer. The guidance does not apply to vaccines for preventative and therapeutic infectious disease indications, to products intended to induce or augment a non-specific immune response, or to products intended to prevent, or decrease the incidence of cancer in individuals without a prior history of that cancer. Furthermore, the guidance does not apply to adoptive immunotherapeutic products which may mediate their therapeutic effect by targeting the tumor directly, such as T cell or NK cell products.

FDA has held or participated in several meetings to discuss development of cancer vaccines. For example, on February 8–9, 2007, CBER co-sponsored a workshop with the National Cancer Institute entitled ''Bringing Therapeutic Cancer Vaccines and Immunotherapies through Development to Licensure.'' In consideration of the input FDA received from stakeholders, the guidance provides recommendations for the design of clinical trials for cancer vaccines conducted under an IND to support a subsequent BLA for marketing approval.

In the **Federal Register** of September 18, 2009 (74 FR 47947), FDA announced the availability of the draft guidance of the same title dated September 2009. FDA received numerous comments on the draft guidance and those comments were considered as the guidance was finalized. Changes incorporated in the final guidance included adding new sections in response to comments, clarification of assay standardization, and additional references were included. In addition, organizational and editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated September 2009.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This 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 part 312 have been approved under OMB control number 0910–0014; and the collection of information in 21 CFR part 50 on informed consent laws

have been approved under OMB control number 0910–0130.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

IV. Electronic Access

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

Dated: November 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–28726 Filed 11–4–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Bridging the Idea Development Evaluation Assessment and Long-Term Initiative and Total Product Life Cycle Approaches for Evidence Development for Surgical Medical Devices and Procedures; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Bridging the IDEAL and TPLC Approaches for Evidence Development for Surgical Medical Devices and Procedures.'' The purpose of the public workshop is to provide a forum for discussion among FDA, governmental agencies, academia, physicians, and various stakeholders to further refine and advance the Idea Development Evaluation Assessment and Long-Term (IDEAL) initiative and Total Product Life Cycle (TPLC) frameworks related to evidence generation and evaluation for surgical devices and procedures.

Date and Time: The meeting will be held on December 2, 2011, from 8 a.m. to 5:30 p.m. Participants are encouraged to arrive early to ensure time for parking and security screening before the meeting. Submit electronic and written comments by January 6, 2012.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Bldg. 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Persons: Samantha Jacobs, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4113, Silver Spring, MD 20993, (301) 796–6897, email: *Samantha.jacobs@fda.hhs.gov;* or Danica Marinac-Dabic, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4113, Silver Spring, MD 20993, (301) 796–6689, email: *danica.marinac-dabic@fda.hhs.gov.*

Registration: There is no fee to attend the public workshop, but attendees must register in advance. Registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/* by November 25, 2011. Non-U.S. citizens are subject to additional security screening, and they should register as soon as possible. For those without Internet access, please call the contact person to register. Onsite registration is not available.

If you need special accommodations due to a disability, please contact Susan Monahan at *susan.monahan@fda.hhs.gov* at least 7 days in advance.

Comments: Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments until January 6, 2012. Submit electronic comments 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. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific topics as outlined in section III of this document, please identify the topic you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

I. Why are we holding this public workshop?

The purpose of the public workshop is to facilitate discussion among FDA, governmental agencies, academia, clinicians, and the key stakeholders in the scientific community on issues related to evidence generation and evaluation for surgical devices and procedures. Based on complementary methodological frameworks of the IDEAL and TPLC initiatives, more comprehensive and applicable models and methodologies will be developed.

II. Who is the target audience for this public workshop? Who should attend this public workshop?

This workshop is open to all interested parties. The target audience is comprised of professionals in the scientific community interested in advancing the infrastructure and methodology for evaluating surgical devices and procedures.

III. What are the topics we intend to address at the public workshop?

We intend to discuss a large number of issues at the workshop, including, but not limited to, the following:

- The IDEAL and the FDA TPLC approach for evaluation of new medical devices, surgical operations, and invasive medical procedures;
- Unique study designs and reporting methods for evaluation of medical devices and surgeries;
- Innovative methodologies and scientific infrastructure to promote innovation;
- The role of registries and observational studies during device life cycle; and
- Integrating innovation, evaluation, and dissemination pathways for medical devices, surgical operations, and invasive medical procedures.

IV. Where can I find out more about this public workshop?

Background information on the public workshop, registration information, the agenda, information about lodging, and other relevant information will be posted, as it becomes available, on the Internet at *http://www.fda.gov/cdrh/meetings.html.*

Transcripts: Please be advised that as soon as a transcript is available, it will