

groups.<sup>2</sup> We believe having the training provided by CE organizations will be an incentive and will not create new burdens on prescribers because most healthcare professionals are routinely engaged in CE activity.

#### *D. The Blueprint Will Provide the Basic Outline and Core Messages for CE*

In response to the April REMS notification letter, application holders, through an industry working group, submitted an expanded outline of the potential topics to be covered in the CE, noting that education incorporating all of the topics in the outline could require 30 or more hours of education. FDA's expectation is that the initial or basic REMS related CE that should be offered to all prescribers of long-acting and extended-release opioids should consist of a "core" content of about 2 to 3 hours. FDA has reviewed the industry submission and developed a basic outline and the core messages that FDA believes should be conveyed to prescribers in this basic educational module. After it is completed and approved as part of the REMS, the Blueprint will be posted on FDA's Web site for use by CE providers in developing CE courses. Although FDA recognizes that additional training modules could be helpful, FDA's goal is to require basic education for all prescribers of long-acting and extended-release opioids, and at this time, FDA does not intend to develop or approve messages as part of the REMS beyond those approved in the basic core module. Using the Blueprint on FDA's Web site, CE providers can develop accredited CE in the manner they choose.<sup>3</sup>

With this document, FDA is announcing the availability of the Agency's draft Blueprint for prescriber education and soliciting public comment. The draft Blueprint is available on the Internet at [www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/](http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/)

<sup>2</sup> See FDA Opioid REMS Meeting with Industry (May 16, 2011), at <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm258184.htm> and Preliminary Responses to Industry Questions About Opioid REMS at <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm258113.htm>.

<sup>3</sup> Since early May 2011, FDA has held teleconferences and met with representatives from the CE accreditor and provider communities. We have expressed our interest in understanding the challenges of the CE providers, including the need to be in compliance with the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support and the need to ensure that the content of CE remains beyond the control of industry. We are confident that the ACCME standards will be met and ACCME will be satisfied that FDA will control the content of REMS CE.

*UCM277916.pdf*. FDA will consider any comments submitted and make appropriate revisions before approving the Blueprint as a part of the Opioid REMS.

## II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments on the draft Blueprint. 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.

Dated: November 1, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-28669 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-D-0689]

#### **Draft Guidance for Industry and Food and Drug Administration Staff; De Novo Classification Process (Evaluation of Automatic Class III Designation); Availability; Extension of Comment Period**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending to January 3, 2012, the comment period for the notice entitled "Draft Guidance for Industry and Food and Drug Administration Staff; De Novo Classification Process (Evaluation of Automatic Class III Designation); Availability," that appeared in the **Federal Register** of October 3, 2011 (76 FR 61103). In that document, FDA announced the availability of a draft guidance for industry and FDA staff and requested comments. The Agency is taking this action due to a discrepancy in the comment period in the notice as compared to the comment period listed in the guidance document.

**DATES:** Submit either electronic or written comments by January 3, 2012.

**ADDRESSES:** Submit electronic comments on the draft 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. Identify comments with the docket number found in brackets in the heading of this document.

#### **FOR FURTHER INFORMATION CONTACT:**

Melissa Burns, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 1646, Silver Spring, MD 20993-0002, (301) 796-5616; or

Stephen Ripley, Center for Biologics Evaluation and Research (HF-17), Food and Drug Administration, 1401 Rockville, Pike, Suite 200N, Rockville, MD 20852, (301) 827-6210.

## I. Background

In the **Federal Register** of October 3, 2011 (76 FR 61103), FDA published a notice with a 60-day comment period to request comments on the draft guidance for industry and FDA staff entitled "De Novo Classification Process (Evaluation of Automatic Class III Designation)." Comments on the draft guidance will assist FDA in the development of a final guidance for industry and FDA staff on the de novo classification process.

The Agency received a comment that the 60-day comment period in the notice was inconsistent with the 90-day comment period in the draft guidance document. FDA is extending the comment period for the notice until January 3, 2012. The Agency believes that this extension allows adequate time for interested persons to submit comments without significantly delaying action by the Agency.

## II. Request for 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.

## III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all Center for Devices and Radiological Health (CDRH) guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available

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 CDHR you may either send an email request to [dsmica@fda.hhs.gov](mailto: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.*

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**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 Churtyard, 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