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 The guidance announced in this notice finalizes the draft guidance of the same title dated September 2009.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:

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Center for Biologics Evaluation and Research (HFM-17),

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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.

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