

DDM

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Display Date 10-26-07
Publication Date 10-29-07
Certifier A. Corbin

[Docket No. 2005D-0047]

Guidance for Industry: Considerations for Plasmid Deoxyribonucleic Acid Vaccines for Infectious Disease Indications; 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: Considerations for Plasmid DNA Vaccines for Infectious Disease Indications" dated November 2007. The guidance document is intended to assist manufacturers and sponsors in the development of deoxyribonucleic acid (DNA) vaccines to prevent infectious diseases. The guidance supersedes the guidance document entitled "Points to Consider on Plasmid DNA Vaccines for Preventive Infectious Disease Indications" dated December 1996. In addition, the guidance announced in this notice finalizes the draft guidance of the same title dated February 2005.

DATES: Submit written or electronic comments on agency guidances at any time. Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (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

cb0536 2005D.0047

NAD2

or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

ADDRESSES: Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Joseph L. Okrasinski, Jr., 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: Considerations for Plasmid DNA Vaccines for Infectious Disease Indications,” dated November 2007. The guidance is intended to assist manufacturers and sponsors in the development of DNA vaccines to prevent infectious diseases. The document describes the manufacturing information that should be submitted to CBER for a new vaccine product for clinical study under an investigational new drug application (IND). Plasmid DNA products intended for non-infectious therapeutic indications are not addressed in the guidance. This guidance supersedes the guidance document entitled “Points to Consider on Plasmid DNA Vaccines for Preventive Infectious Disease Indications” dated December 1996. In addition, the guidance announced in this notice finalizes the draft guidance dated February 2005.

In the **Federal Register** of February 18, 2005 (70 FR 8378), FDA announced the availability of the draft guidance of the same title dated February 2005. FDA received several comments on the draft guidance, and those comments

were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity.

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 collection of information mentioned in the guidance regarding the submission of manufacturer's information in an IND was approved under OMB control number 0910–0014.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination 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/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: 10-22-07
October 22, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

BILLING CODE 4160-01-S

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

