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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-4114]

Draft "Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled "Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors." The draft guidance document applies to the manufacture of gene therapy retroviral vector products intended for in vivo or ex vivo use and to followup monitoring of patients who have received retroviral vector products. When finalized, the draft guidance document is intended to supplement the guidance document entitled "Guidance for Industry: Guidance for Human Somatic Cell Therapy and Gene Therapy," dated March 1998, and a letter to Sponsors of an IND Using Retroviral Vectors, dated September 20, 1993.

DATES: Written comments may be submitted at any time, however, comments should be submitted by **(insert date 90 days after date of publication in the Federal Register)**, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical

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Trials Using Retroviral Vectors” 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, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled “Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors.” The draft guidance document applies to the manufacture of gene therapy retroviral vector products intended for in vivo or ex vivo use and to **followup** monitoring of patients who have received retroviral vector products. The draft document provides guidance for replication competent retroviruses (RCR) testing during manufacture, including timing, **amount** of material to be tested, and general testing methods. The draft document also provides guidance on monitoring patients for evidence of retroviral infection. When finalized, the draft guidance document is intended to supplement the guidance and **recommendations** pertaining to RCR testing given in the following documents: (1) “Guidance for Industry: Guidance for Human Somatic Cell Therapy

and Gene Therapy” dated March 1998 (issued on the Internet); and (2) letter to Sponsors of an IND Using Retroviral Vectors, dated September 20, 1993.

The new recommendations are based on data and analyses generated by CBER and members of the gene therapy community. Public discussion and development of these recommendations have taken place during the retroviral breakout sessions at the “1996 Gene Therapy Conference: Development and Evaluation of Phase I Products and Workshop on Vector Development” (61 FR 18749, April 29, 1996), and the “Forum 1997 Gene Therapy Conference.”

The draft guidance document represents the agency’s current thinking regarding testing for RCR in retroviral vector based gene therapy products. 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 statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

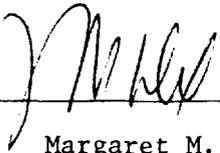
The draft guidance document is being distributed for comment purposes only, and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by ***(insert date 90 days after date of publication in the Federal Register)***, to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance document using the World Wide Web (WWW). For WWW access, connect to CBER at “<http://www.fda.gov/cber/guidelines.htm>”.

Date: 10/19/99

October 19, 1999



Margaret M. Dotzel
Acting Associate Commissioner
for Policy

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