

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

*DMB*

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Certifier	<i>S. Reese</i>

[Docket No. 99D-4114]

**“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.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a 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” dated October 2000. The 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 The guidance document announced in this notice finalizes the draft guidance document entitled “Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy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 Trials Using Retroviral Vectors,” announced in the **Federal Register** of November 3, 1999. The guidance document also supplements 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 investigational new drug using retroviral vectors, dated September 20, 1993.

**DATES:** Submit written comments at any time.

**ADDRESSES:** Submit written requests for single copies of the 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,” dated October 2000 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 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 guidance document.

Submit written comments on the 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 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” dated October 2000. The 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 document provides guidance for replication competent retrovirus (RCR) testing during manufacture, including timing, amount of material to be tested, and general testing methods. The document also provides guidance on monitoring patients

for evidence of retroviral infection. The recommendations are based on data and analyses generated by CBER and members of the gene therapy community. The guidance document finalizes the draft 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," announced in the **Federal Register** of November 3, 1999 (64 FR 59783). The guidance document also supplements 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 investigational new drug using retroviral vectors, dated September 20, 1993.

The 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**

Interested persons may, at any time submit written comments to the Dockets Management Branch (address above) regarding this guidance 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 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 guidance document at <http://www.fda.gov/cber/guidelines.htm>.

Dated: \_\_\_\_\_  
October 5, 2000

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Margaret M. Dotzel  
Associate Commissioner for Policy

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Suzette N. Reese