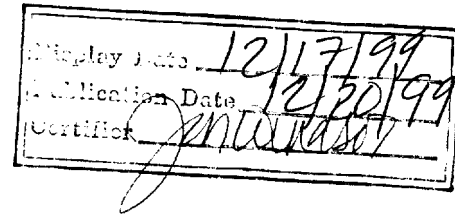


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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0483]

Guidance for Industry: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled “Guidance for Industry: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2.” The guidance document addresses general and specific concerns for gene based detection techniques for human immunodeficiency virus (HIV). The document provides guidance on manufacturing and clinical trial design issues pertaining to the validation of tests based on nucleic acid detection either in the presence or absence of an amplification step.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled “Guidance for Industry: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2” 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

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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: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2.” The guidance document announced in this notice finalizes the draft guidance entitled “Guidance for Industry in the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Virus Type 1” published in the **Federal Register** of July 10, 1998 (63 FR 37402). The guidance document clarifies the following issues as a result of public comments submitted on the draft guidance document: (1) The definition of limit of detection and limit of quantitation for a nucleic acid test and laboratory studies recommended for validation of these limits; (2) the analytical sensitivity study recommendations, including the FDA standard for sensitivity of the pool test in the case of nucleic acid testing, for testing pooled plasma; (3) the numbers of sites, specimens, and design of clinical specificity and sensitivity studies recommended for pooled plasma tests; and (4) the clinical studies to validate a claim for viral load tests used in patient management, i.e., prognosis and therapy.

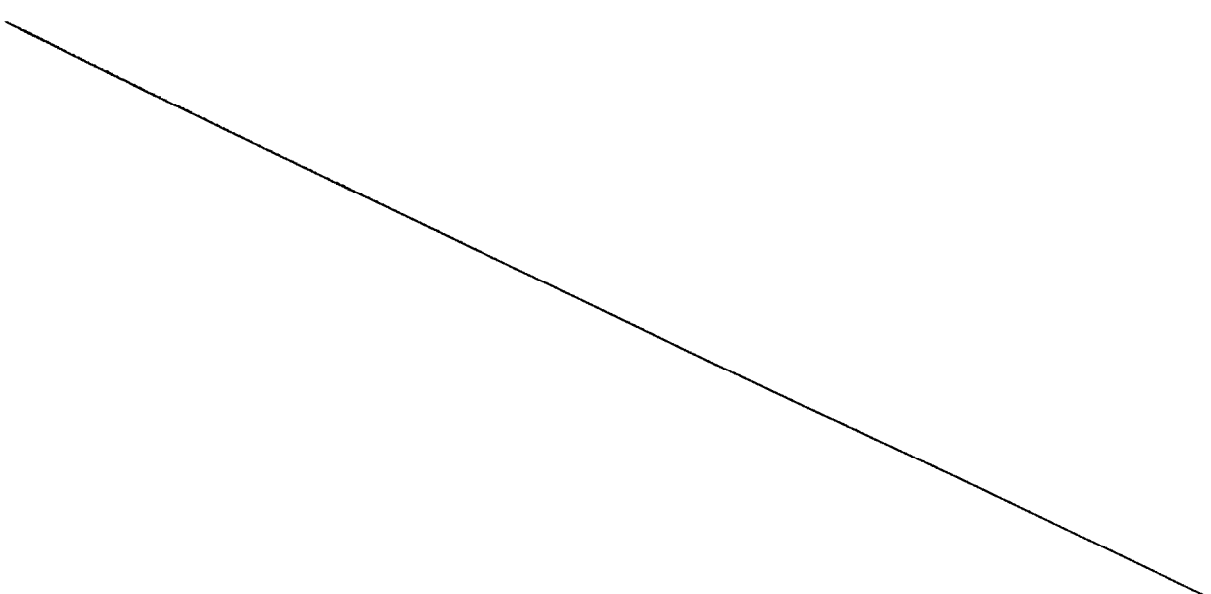
The guidance document outlines some of the major regulatory and scientific issues concerning gene based tests for HIV-1 and HIV-2. These considerations also apply to tests for other

transfusion transmitted viruses including hepatitis C virus, hepatitis B virus, and human T-cell Lymphotropic viruses types I and II.

The guidance document represents the agency's current thinking with regard to the manufacture and clinical evaluation of in vitro testing to detect specific nucleic acid sequences of HIV types 1 and 2. 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 guidance to be all-inclusive and cautions that not all information may be applicable to all situations. The guidance document is intended to provide information and does not set forth requirements.

II. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding the guidance document. Two copies of any comments are to be submitted, except 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.

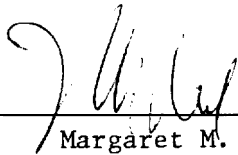


III. Electronic Access

Persons with access to the Internet may obtain the guidance document at <http://www.fda.gov/cber/guidelines.htm>.

Dated: 2094
December 10, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



Margaret M. Dotzel
Acting Associate Commissioner for Policy

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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