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Employ Date	8/31/99
Publication Date	9/1/99
Certifier	<i>[Signature]</i>

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 99D-2213]

**Draft "Guidance for Industry: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors;" 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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled "Guidance for Industry: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors." This draft guidance document, when finalized, is intended to provide guidance to blood establishments on invalidating donor test results based on control reagents required by the Clinical Laboratory Improvement Act of 1988 (CLIA). The implementation of additional quality control procedures that involve the use of external control reagents should enhance overall testing accuracy and blood safety.

**DATES:** Written comments on the draft guidance document may be submitted at any time, however, comments should be submitted by (*insert date 90 days after date of publication in the Federal Register*), to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**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled "Guidance for Industry: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors" 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 the 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 The draft guidance document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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:** Astrid L. Szeto, 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: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors." This draft guidance document would provide recommendations for blood establishments in integrating current CLIA requirements for invalidating donor test results based on CLIA required control reagents. When finalized, this draft guidance document would replace the January 3, 1994, guidance document entitled "Recommendations for the Invalidation of Test Results When Using Licensed Viral Marker Assays to Screen Donors." FDA has developed revised recommendations based on discussions held during the public meetings of the Blood Products Advisory Committee (BPAC) on September 26, 1996, and December 13, 1996, and additional discussions among the Centers for Disease Control and Prevention (CDC), Health Care Financing Administration (HCFA), and FDA. At this time, the draft guidance document is being made available for comment purposes only and is not intended for use by the industry. The agency has adopted good guidance practices (GGP's) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents

(62 FR 8961, February 27, 1997). This document is being issued as a draft level 1 guidance document consistent with GGP's.

This draft guidance document represents the agency's current thinking with regard to the invalidation of test results based on the CLIA required external control reagents. 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

This 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 guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the 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 by using the World Wide Web (WWW). For WWW access, connect to CBER at “<http://www.fda.gov/cber/guidelines.htm>”.

Dated: 8/9/99  
August 9, 1999

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

*Jen Windsor*

  
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Margaret M. Dotzel  
Acting Associate Commissioner for Policy

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

**BILLING CODE 4160-01-F**