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Certifier	<i>J. M. Windsor</i>

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0814]

“Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units From Prior Collections From Donors With Repeatedly Reactive Screening Test for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV;” Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document (dated September 1998) entitled “Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units From Prior Collections From Donors With Repeatedly Reactive Screening Test for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV.” The guidance document provides recommendations for donor screening and supplemental testing for antibody to hepatitis C virus (HCV), notification of consignees and quarantine of prior collections from a donor who later tests repeatedly reactive for antibody to HCV, notification of recipients of blood and blood components at increased risk for transmitting HCV.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled “Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units From Prior Collections From Donors With Repeatedly Reactive Screening

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Test for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV'' 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 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 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:

Sharon A. Carayiannis, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

For technical/scientific questions, contact Robin M. Biswas, Center for Biologics Evaluation and Research (HFM-325), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3011 or by FAX 301-496-0338.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units From Prior Collections From Donors With Repeatedly Reactive Screening Test for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV." This guidance provides recommendations for the following: (1) Quarantine (and release) of prior collections form donors

who later test repeatedly reactive for antibody to HCV; (2) supplemental testing and notification of consignees and transfusion recipients; (3) procedures and recordkeeping; (4) review of records of donor testing for "historical" repeatedly reactive donations; (5) quarantine (and release) of prior collections, notification of consignees and transfusion recipients based on the review of records; (6) additional testing following an indeterminate RIBA 2.0 test result; and (7) additional testing of donors with no record of supplemental testing on the "historical" repeatedly reactive screening test.

On March 20, 1998 (63 FR 13675), FDA announced the availability of "Guidance for Industry: Supplemental Testing and the Notification of Consignees of Donor Test Results for Antibody to Hepatitis C Virus (Anti-HCV)," (the March 1998 guidance). This guidance included a recommendation that consignee notification should commence no later than 6 months after date of issuance of the guidance, i.e., by September 20, 1998.

On June 18, 1998, FDA made known at a public meeting of its Blood Products Advisory Committee (BPAC) its intention to respond to public comments received to the docket for the guidance by reissuance of a comprehensive guidance on the same subject. At the BPAC meeting, FDA announced it was considering changes to the "HCV lookback" policy, including revision of recommendations for the additional testing of donor samples and revision of FDA recommendations for implementation timeframes. These changes were based on feasibility considerations which had been raised by the public comments and evaluated by FDA.

During June and July 1998, FDA continued to receive extensive public comments to the docket. These were reviewed and evaluated carefully by CBER. CBER continued to work on modification of the guidance. Although FDA intended to issue a revised guidance by the end of July, the revision was delayed in order to incorporate additional public comments that had been received.

Since FDA did not want to be in the position of having the guidance in place with a compliance date that was being revised, the best option, under the agency's Good Guidance

Practices, was for FDA to issue a notice to withdraw the current guidance pending issuance of another comprehensive guidance. This withdrawal was posted on September 8, 1998. The guidance now being issued reflects the agency's current position on this matter. This guidance supersedes FDA's March 1998 guidance. Additionally, this guidance supersedes the recommendations related to HCV in FDA's July 19, 1996, guidance entitled "Recommendations for Quarantine and Disposition of Units From Prior Collections From Donors With Repeatedly Reactive Screening Tests for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Human T-Lymphotropic Virus Type I (HTLV-I)" (the July 1996 guidance). This guidance does not supersede the recommendations related to HBV and HTLV-I in the July 1996 guidance.

This guidance document represents the agency's current thinking with regard to prior collections from donors testing repeatedly reactive for antibody to HCV at a later date. 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 requirement 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.

This guidance document may contain collections of information that require clearance under the Paperwork Reduction Act of 1995. FDA will seek such approval and provide opportunity for comment as appropriate.

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 individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the 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 document using the World Wide Web (WWW). For WWW access, connect to CBER at "http://www.fda.gov/cber/guidelines.htm".

Dated: October 9, 1998
October 9, 1998



William K. Hubbard
Associate Commissioner for Policy Coordination

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