

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D-0081]

Guidance for Industry: Adequate and Appropriate Donor Screening Tests for Hepatitis B; Hepatitis B Surface Antigen Assays Used to Test Donors of Whole Blood and Blood Components, Including Source Plasma and Source Leukocytes; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Adequate and Appropriate Donor Screening Tests for Hepatitis B; Hepatitis B Surface Antigen (HBsAg) Assays Used to Test Donors of Whole Blood and Blood Components, Including Source Plasma and Source Leukocytes," dated July 2007. The guidance document provides recommendations to manufacturers of HBsAg assays that are intended to test donors of Whole Blood and blood components, including Source Plasma and Source Leukocytes, and to establishments using an HBsAg assay. Topics include recommendations on minimum sensitivity standards for HBsAg assays. This guidance finalizes the draft guidance entitled "Guidance for Industry: A Modified Lot-Release Specification for Hepatitis B Surface Antigen (HBsAg) Assays Used to Test Blood, Blood Components, and Source Plasma Donations," dated April 2002.

DATES: Submit written or electronic comments on agency guidances at any time.

DDM
Display Date 8-7-07
Publication Date 8-8-07
Certifier SR/EE

ADDRESSES: Submit written requests for single copies of the guidance 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, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Joseph L. Okrasinski, Jr., Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: Adequate and Appropriate Donor Screening Tests for Hepatitis B; Hepatitis B Surface Antigen (HBsAg) Assays Used to Test Donors of Whole Blood and Blood Components, Including Source Plasma and Source Leukocytes," dated July 2007. The guidance document provides recommendations to manufacturers of HBsAg assays that are approved donor screening tests intended to screen donors of Whole Blood and blood components, including Source Plasma and Source Leukocytes for Hepatitis B, and to establishments using an HBsAg assay (See § 610.40(b) (21 CFR

610.40(b)). The document represents FDA's current thinking on minimum sensitivity for such HBsAg assays as they relate to donor testing "to reduce adequately and appropriately the risk of transmission of communicable disease" under § 610.40(b). Under 21 CFR 610.44, the manufacturers of HBsAg assays used to test donations must verify acceptable sensitivity and specificity of such kits by testing the kit-lots using an FDA reference panel. This guidance document recommends that all HBsAg detection assays used to test donors of Whole Blood and blood components, including Source Plasma and Source Leukocytes, have a lower limit of detection standard of 0.5ng HBsAg/mL or less.

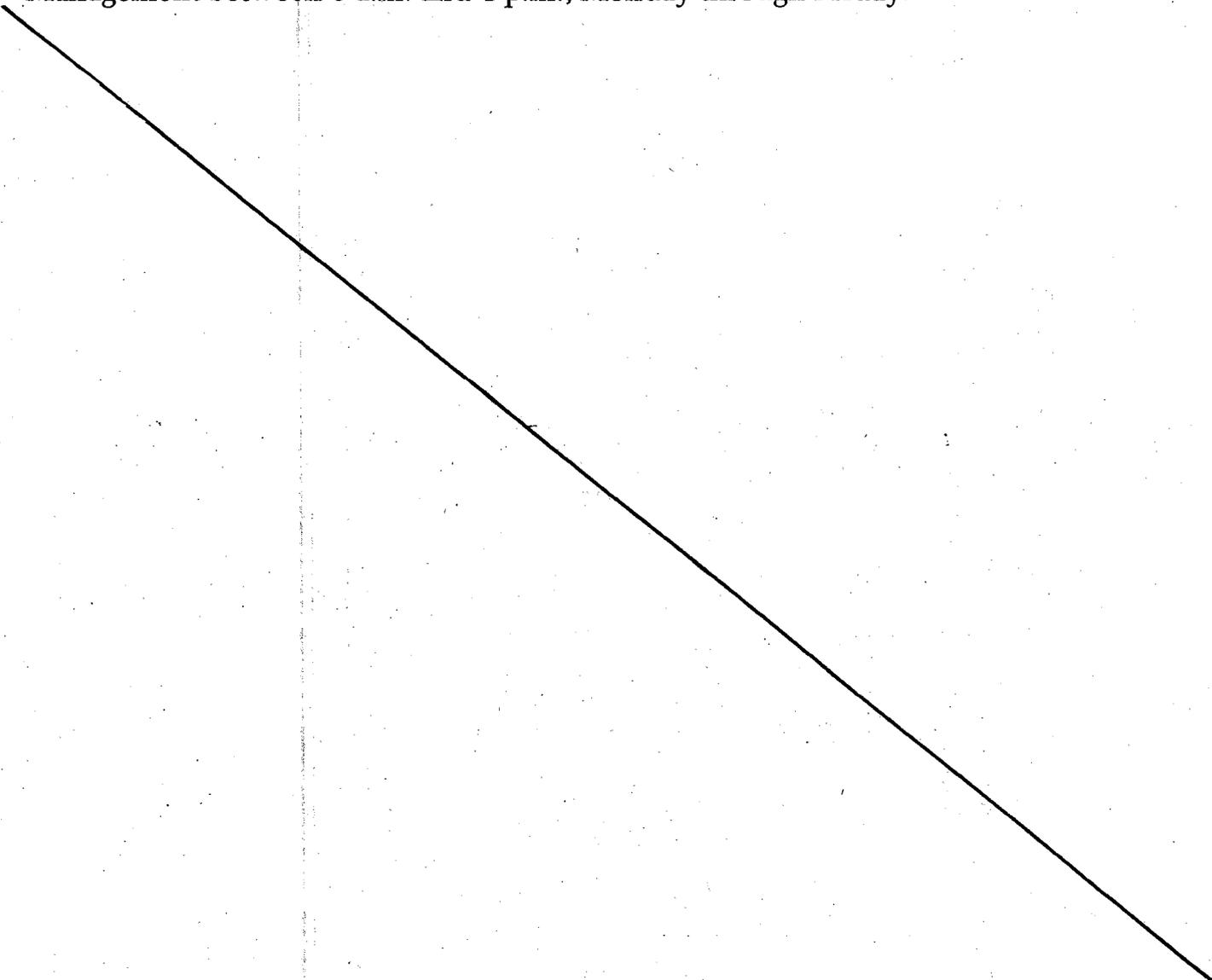
In the **Federal Register** of April 11, 2002 (67 FR 17704), FDA announced the availability of the draft guidance entitled "Guidance for Industry: A Modified Lot-Release Specification for Hepatitis B Surface Antigen (HBsAg) Assays Used to Test Blood, Blood Components, and Source Plasma Donations." FDA received a few comments on the draft guidance, and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity. The recommended implementation date for the recommendations in this guidance is January 31, 2008. This guidance document finalizes the draft guidance document entitled "Guidance for Industry: A Modified Lot-Release Specification for Hepatitis B Surface Antigen (HBsAg) Assays Used to Test Blood, Blood Components, and Source Plasma Donations," dated April 2002.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the FDA's current thinking on this topic. 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 statutes and regulations.

II. Comments

Interested persons may, at any time, submit to the Division of Dockets Management written or electronic comments (see **ADDRESSES**) regarding the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



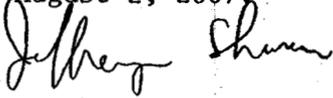
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II. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 8/2/07

August 2, 2007



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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