

DMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date 4-10-02
Publication Date 4-11-02
Certifier A. Corbin

Food and Drug Administration

[Docket No. 02D-0081]

Draft "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;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft 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 The draft guidance document when finalized is intended to provide recommendations to manufacturers of assays for the detection of HBsAg that are intended to be used to test blood, blood components, and Source Plasma. Topics include recommendations on minimum sensitivity specifications for HbsAg assays used to test blood, blood components, and Source Plasma donations.

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by *[insert date 90 days after date of publication in the Federal Register]*. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug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, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your

requests. The 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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 document to the Dockets Management Branch (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, 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

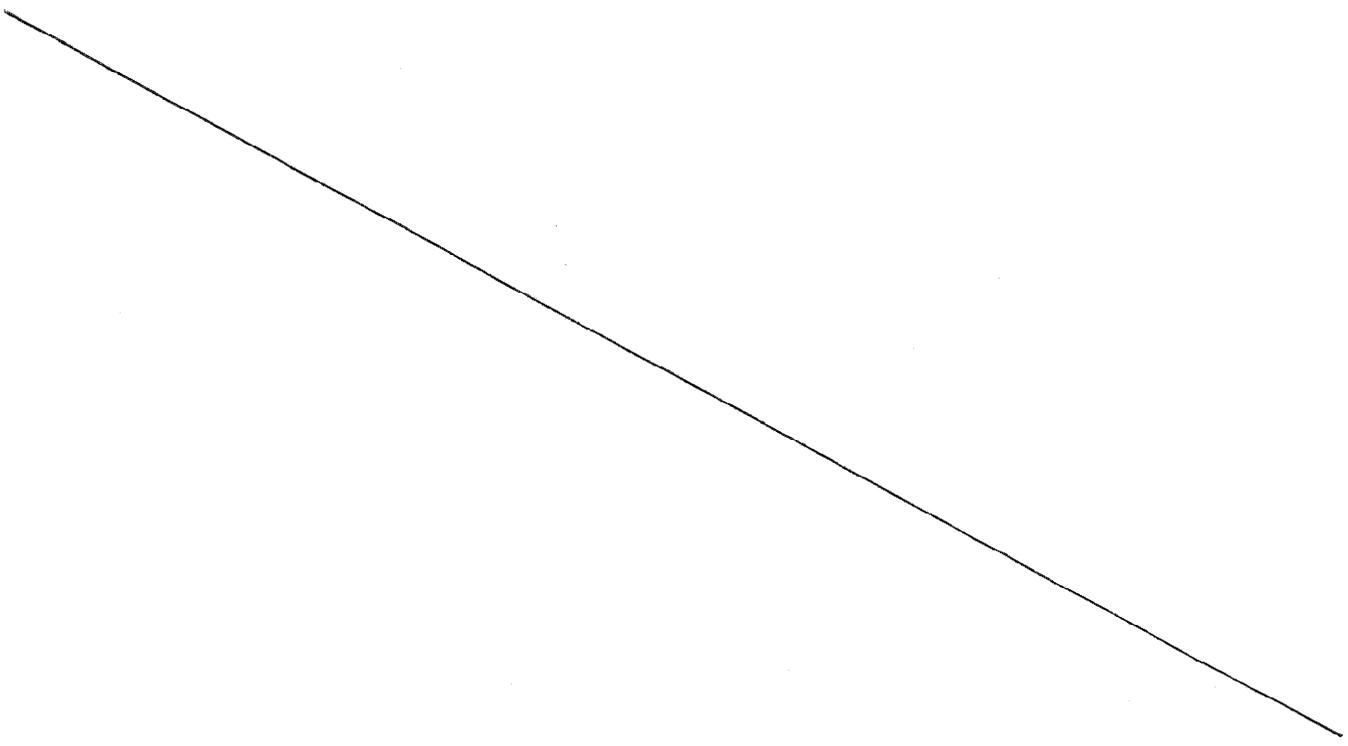
FDA is announcing the availability of a draft document entitled "Guidance for Industry: A Modified Lot-Release Specification for Hepatitis B Surface Antigen (HBsAg) Assays Used to Test Blood, Blood Components, and Source Plasma Donations," dated April 2002. Under 21 CFR 610.44, manufacturers of HBsAg 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 draft guidance document is intended to provide recommendations to manufacturers of assays for the detection of HBsAg that are intended to be used to test blood, blood components, and Source Plasma donations. The current limit of detection specification for HBsAg assays used to test blood donations corresponds to 1.0 nanogram (ng) HBsAg/milliliter (mL), and was established in 1996. The draft guidance contains the recommendation that all HBsAg detection assays that are used to test blood, blood components, and Source Plasma donations have a lower limit of detection specification of 0.50 ng HBsAg/mL or less.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance document represents the agency's current thinking on the

minimum sensitivity for the HBsAg assays used to test blood and Source Plasma donations. 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 statutes and regulations.

II. Comments

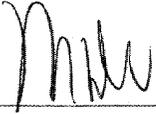
This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this draft guidance document. Submit written or electronic comments to ensure adequate consideration in preparation of the final document by [*insert date 90 days after date of publication in the **Federal Register***]. 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 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 at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 3/29/02
March 29, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

BILLING CODE 4160-01-S

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

