

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0379]

Draft Guidance for Industry: Nucleic Acid Testing to Reduce the Possible Risk of Parvovirus B19 Transmission by Plasma-Derived Products; Availability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: Nucleic Acid Testing (NAT) to Reduce the Possible Risk of Parvovirus B19 Transmission by Plasma-Derived Products," dated July 2008. The draft guidance document provides to manufacturers of plasma-derived products recommendations for performing parvovirus B19 NAT as an in-process test for Source Plasma and recovered plasma to identify and help to prevent the use of plasma units containing high levels of parvovirus B19. The draft guidance also recommends how to report to the FDA implementation of parvovirus B19 NAT.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by *[insert date 90 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-

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Display Date 7-29-08
Publication Date 7-30-08
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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 The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, 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 draft document entitled "Guidance for Industry: Nucleic Acid Testing (NAT) to Reduce the Possible Risk of Parvovirus B19 Transmission by Plasma-Derived Products" dated July 2008. Parvovirus B19 is a small, non-enveloped single strand DNA virus that is highly resistant to all commonly used inactivation methods. The parvovirus B19 can be transmitted by blood components and certain plasma derivatives and may cause morbidity to susceptible recipients such as pregnant women, persons with underlying hemolytic disorders, and immune compromised individuals. The disease transmission from transfusion of blood components is rare; however, extremely high levels of parvovirus B19 in plasma of acutely infected but asymptomatic donors may present a greater risk in plasma

derivatives due to pooling of large numbers of plasma units in the manufacture of these products.

The draft guidance provides recommendations for performing parvovirus B19 NAT as an in-process test for Source Plasma and recovered plasma used in the further manufacturing of plasma-derived products to identify and help to prevent the use of plasma units containing high levels of parvovirus B19. The draft guidance also recommends how to report to the FDA implementation of parvovirus B19 NAT.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 211.165 and 211.194 have been approved under 0910–0139; the collections of information in 21 CFR 600.12 have been approved under 0910–0308.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic

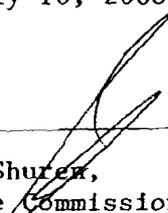
comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *<http://www.regulations.gov>*.

IV. Electronic Access

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

Dated: 7/16/08
July 16, 2008.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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