

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 98D-1171]

**Draft "Guidance for Industry: For Platelet Testing and Evaluation of Platelet Substitute Products;" 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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled "Guidance for Industry: For Platelet Testing and Evaluation of Platelet Substitute Products." Recent technological advances regarding platelet physiology and biochemistry have altered the way that platelets can be evaluated. The draft guidance document, when finalized, is intended to provide manufacturers with updated guidance on the evaluation of platelets and of their substituted products.

**DATES:** Written comments may be submitted at any time, however, comments should be submitted by (*insert date 60 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**ADDRESSES:** Submit written requests for single copies of the draft guidance entitled "Guidance for Industry: For Platelet Testing and Evaluation of Platelet Substitute Products" to the Office of Communication, Training, and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 that 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

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.

**FOR FURTHER INFORMATION CONTACT:** Valerie A. Butler, 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**

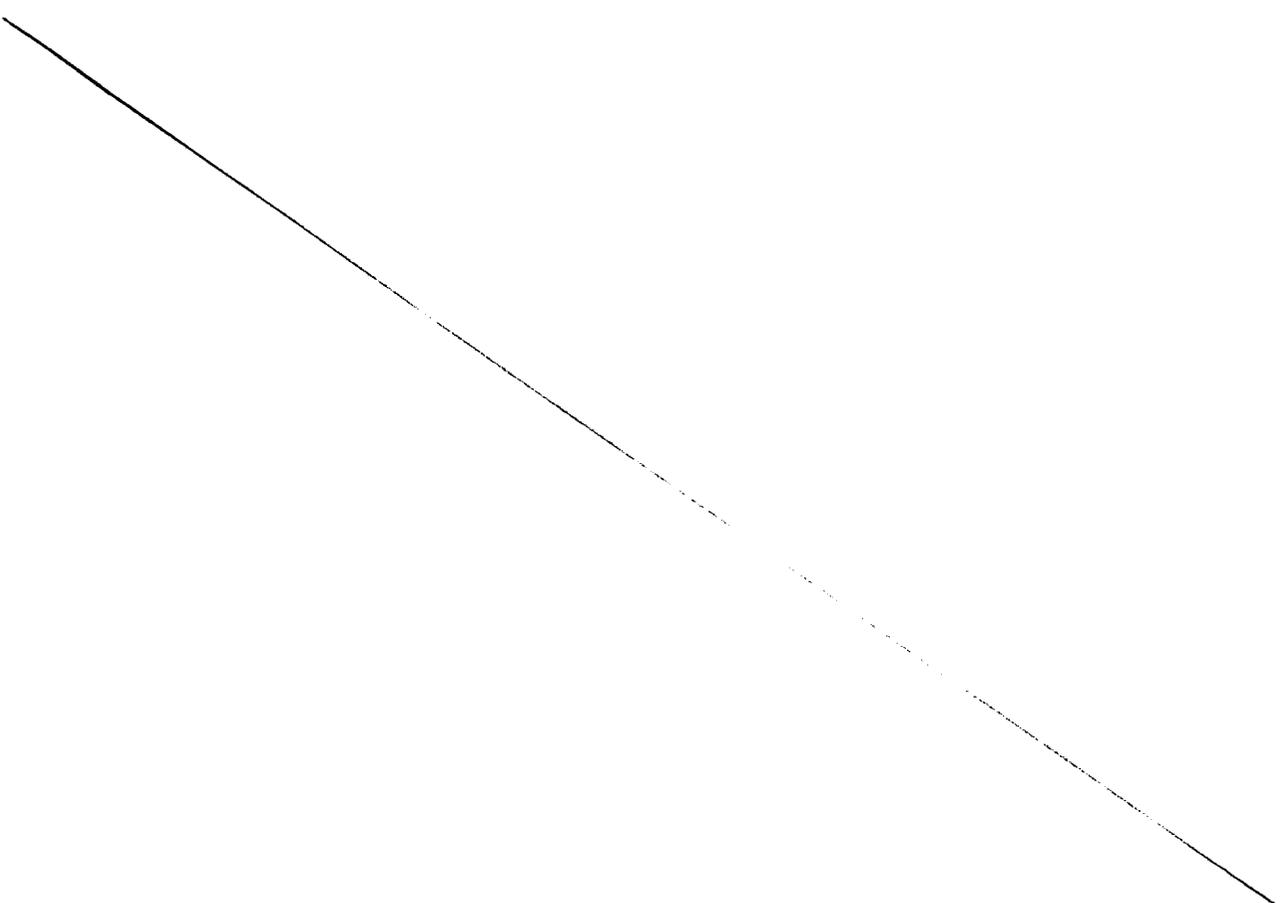
FDA is announcing the availability of a draft document entitled “Guidance for Industry: For Platelet Testing and Evaluation of Platelet Substitute Products.” New instrumentation and information about platelet physiology and biochemistry have altered the way that platelets can be evaluated. These advances have prompted FDA’s development of an updated draft guidance document regarding platelet testing. The draft guidance document provides recommendations on the evaluation of platelets and platelet substitute products including: In vitro evaluation of platelet biochemistry and function, evaluation of platelet survival in circulation, clinical hemostatic efficacy, and guidance for testing potential platelet substitutes. The draft guidance document, when finalized, is intended to delineate principles of general applicability for evaluation of platelets collected and processed by novel technologies and would replace the document entitled “Platelet Testing Guidelines” (July 1981) published in the **Federal Register** of October 2, 1981 (46 FR 48768).

The draft guidance document represents the agency’s current thinking on platelet testing and evaluation of platelet substitute products. 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

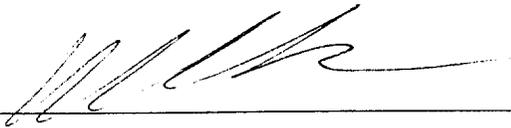
This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by (*insert date 60 days after date of publication in the **Federal Register***), to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments and requests for copies should be identified with the docket number found in 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: May 10, 1999  
May 10, 1999



William K. Hubbard  
Associate Commissioner for Policy Coordination

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

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