

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 The draft guidance document, when finalized, is intended to provide manufacturers with updated guidance on the evaluation of platelets and of their substituted products.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 July 19, 1999, 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ADDRESSES: Submit written requests for single copies of the draft guidance entitled "Guidance for Industry: For Platelet Testing and Evaluation of Platelet Substitute Products" to the Office of Communication, Training, and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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.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 These advances have prompted FDA's development of an updated draft guidance document regarding platelet testing. The draft guidance document provides recommendations on the evaluation of platelets and platelet substitute products including: In vitro evaluation of platelet biochemistry and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 July 19, 1999, 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.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99-12649 Filed 5-19-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D-0528]

"Guidance for Industry: Efficacy Studies to Support Marketing of Fibrin Sealant Products Manufactured for Commercial Use"; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled "Guidance for Industry: Efficacy Studies to Support Marketing of Fibrin Sealant Products Manufactured for Commercial Use." FDA intends to consider, for licensure of commercially-produced fibrin sealants, data from pivotal studies in which the primary endpoint is hemostasis effectiveness. This document is intended to provide guidance to manufacturers of fibrin sealant products for the design of clinical trials intended to support licensure.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Guidance for Industry: Efficacy Studies to Support Marketing of Fibrin Sealant Products Manufactured for Commercial Use" 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 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 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 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: 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 guidance document entitled "Guidance for Industry: Efficacy Studies to Support Marketing of Fibrin Sealant Products Manufactured for Commercial Use." This document provides guidance regarding clinical data used to support licensure of safe and effective commercially-produced fibrin sealants in the United States.

The guidance document announced in this notice replaces the draft guidance entitled "Guidance for Industry: Efficacy Studies to Support Marketing of Fibrin Sealant Products Manufactured for Commercial Use" that was announced in the **Federal Register** of January 26, 1998 (63 FR 3750).

The guidance document represents the FDA's current thinking on efficacy studies to support marketing of fibrin sealant products manufactured for commercial use. 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 guidance 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

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 the brackets in the heading of this document. A copy of the 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 guidance document using the World Wide Web (WWW). For WWW access, connect to CBER at "http://www.fda.gov/cber/guidelines.htm".

Dated: May 10, 1999.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 99-12650 Filed 5-19-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-R-285]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the Information collections referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because public harm is likely to occur if the information is not collected. The beneficiaries affected by this legislation may be eligible for free Part A as early as January 1998 if certain requirements are met. One of the requirements is that the beneficiary's retirement plan or former employer verify specific information before a determination can be made regarding whether the beneficiary qualifies for free Part A. Until a decision is made, the beneficiary must continue to pay the monthly Part A premium of \$309.00; therefore, causing public harm.

HCFA is requesting OMB review and approval of this collection by 6/15/99, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by 6/11/99. During this 180-day period, we

will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Collection

Request: New Collection;

Title of Information Collection:

Request for Retirement Benefit Information;

Form No.: HCFA-R-285 (OMB# 0938-NEW);

Use: This form will be used to obtain information regarding whether a beneficiary is receiving retirement payments based on State or local government employment, how long the claimant worked for the State or local government employer, and whether the former employer or pension plan subsidizes the beneficiary's Part A premium. The purpose in collecting this information is to determine and provide those eligible beneficiaries, with free Part A Medicare coverage.;

Frequency: On Occasion;

Affected Public: State, Local or Tribal Government, and Individuals or Households;

Number of Respondents: 1500;

Total Annual Responses: 1500;

Total Annual Hours: 375.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of Information requirements. However, as noted above, comments on these Information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below, by 6/11/99:

Health Care Financing Administration,
Office of Information Services,
Security and Standards Group,
Division of HCFA Enterprise
Standards, Attention: Dawn
Willingham, Room N2-14-26, 7500
Security Boulevard, Baltimore,
Maryland 21244-1850
and

Office of Information and Regulatory
Affairs, Office of Management and
Budget, Room 10235, New Executive
Office Building, Washington, DC
20503, Fax Number: (202) 395-6974
or (202) 395-5167, Attn: Allison
Herron Eydt, HCFA Desk Officer.