

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The guidance document announced in this notice replaces the draft guidance entitled "Guidance for Industry: Efficacy Studies to Support Marketing of Fibrin Sealant Products Manufactured for Commercial Use" that was announced in the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.

Date: May 12, 1999.

John Parmigiani,

Manager, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards. [FR Doc. 99-12731 Filed 5-19-99; 8:45 am] BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request, Special Volunteer and Guest Researcher Assignment

SUMMARY: Under the provisions of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Director, National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a

request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on February 10, 1999, pages 6666-6667 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to an information collection that has been extended, revised, or implemented on or after October 1, 1999, unless it displays a currently valid OMB control number.

PROPOSED COLLECTION: Title: Special Volunteer and Guest Research Assignment. Type of Information Collection: Revision of OMB NO.0925-0177; 4/30/00. Need and Use of Information Collection: Form NIH-590

records, names, address, employer, education, and other information on prospective Special Volunteers and Guest Researchers, and is used by the responsible National Institutes of Health approving official to determine the individual's qualifications and eligibility for such assignments. The form is the only official record of approved assignments. *Frequency of Response:* On occasion. *Affected Public:* Individuals seeking to provide uncompensated services to the NIH. *Type of Respondents:* Guest Researcher and Special Volunteer candidates. *Estimated Number of Respondents:* 1,630. *Estimated Number of Responses Per Respondent:* 1. *Average Burden Hours Requested:* 0.1. *Estimated Total Annual Burden Hours Requested:* 163. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Type of respondent	Estimated number of respondents	Estimated number of response per respondent	Average burden hours per response	Estimated total annual burden hours requested
Guest Researcher	400	1	0.1	40
Special Volunteer	1230	1	0.1	123
Total	1630	1	0.1	163

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and the clarity of information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or

to obtain a copy of the data collection plans and instruments, contact: Ms. Yetta L. Patterson, Personnel Management Specialist, Office of Human Resource Management, OD, NIH, Executive Plaza South, 6120 Executive Blvd., Suite 100, Rockville, MD 20892, or call (301) 496-2404 or E-Mail your request, including your address to: yp3k@nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before June 21, 1999.

Dated: May 7, 1999.

Stephen C. Benowitz,

Director of Human Resources. [FR Doc. 99-12780 Filed 5-19-99; 8:45 am] BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be open to the public with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Cancer Institute Special Emphasis Panel The Early Detection Research Network: Biomarkers Developmental Laboratories.

Date: June 14-16, 1999.

Time: 7 pm to 5 pm.

Agenda: To provide concept review of proposed grant applications.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852

Contact Person: Lalita D Palekar, Scientific Review Administrator, Special Review, Referral and Resources Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6130 Executive Boulevard/EPN-622B, Rockville, MD 20892-7405, 301/496-7575.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)