SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by September 5, 1997.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance:

Filing Objections and Requests for a Hearing on a Regulation or Order—21 CFR Part 12—(OMB Control Number 0910–0184—Extension)

Under section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)(2)), within 30 days after publication of a regulation or order, any person adversely affected by such regulations or order may file objections and request a public hearing. The implementing regulations for these statutory requirements are found at 21 CFR 12.22, which sets forth the format and instructions for filing objections and requests for a hearing. Each objection for which a hearing has been requested must be separately numbered and specify with particularity the provision of the regulation or the proposed order objected to. In addition, each objection must include a detailed description and analysis of the factual information to be presented in support of the objection as well as any report or other document relied on, with some exceptions. Failure to include this information constitutes a waiver of the right to a hearing on that objection. FDA uses the description and analysis only for the purpose of determining whether a hearing request is justified. The description and analysis do not limit the evidence that may be presented if a hearing is granted.

Respondents to this information collection are those parties that may be adversely affected by an order or regulation.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
12.22	60	1	60	20	1,200

There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate for this collection of information is based on agency data received on this administrative procedure for the past 3 years. Agency personnel responsible for processing the filing of objections and requests for a public hearing on a specific regulation or order, estimate approximately 60 requests are received by the agency annually, with each requiring approximately 20 hours of preparation time.

Dated: July 30, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–20600 Filed 8–5–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Public Workshop on FDA Regulatory Requirements for the Bioresearch Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) (Office of Regulatory Affairs, Florida District Office, and Center for Drug Evaluation and Research) is announcing the following meeting: A public workshop on FDA regulatory requirements for the bioresearch industry. The workshop is designed to assist the industry in complying with regulations for institutional review boards and clinical investigators. FDA's survey of the bioresearch industry shows that many firms are either unaware of applicable regulations and guidelines or not in compliance with applicable requirements.

Date and Time: The meeting will be held on Monday, September 15, 1997, 8:30 a.m. to 5 p.m.

Location: The meeting will be held at University of Florida Campus, Reitz Union—The Rion Ballroom, Museum Rd., Gainesville, FL 32611.

Contact: Julie D. Bringger, Jacksonville Resident Post, Food and Drug Administration, 400 West Bay St., Drawer #35069, Jacksonville, FL 32202, 904–232–3596, FAX 904–232–2880.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and facsimile number) to the contact person by September 1, 1997. There is no registration fee for this workshop. Space is limited, therefore interested parties are encouraged to register early.

If you need special accommodations due to a disability, please contact Julie D. Bringger at least 7 days in advance.

Dated: July 30, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–20599 Filed 8–5–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–R–77]

Agency Information Collection Activities: Proposed Collection; Comment Request

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 the 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.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Procedures for determining whether providers, practitioners, or other suppliers of services are liable for certain noncovered services; *Form No.:* HCFA–R–77; *Use:* BERC–273–F requires Peer Review Organizations (PROs) to provide written notification of noncovered services to beneficiaries and/or providers, practitioners and suppliers. The notification provides provider, practitioner or supplier with knowledge that Medicare will not pay for items or services mentioned in the notification. After this notification, any future claim for the same or similar services will not be paid. *Frequency:* Monthly; *Affected Public:* Business or other for-profit, Individuals or Households; *Number of Respondents:* 724,271; *Total Annual Responses:* 2,897,085; *Total Annual Hours:* 241,424.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Indirect Medical Education (IME) and Supporting Regulations 42 CFR 412.105; *Form No.:* HCFA–R–64; *Use:* The collection of information on Interns and Residents (IR) is needed to properly calculate Medicare program payments to hospitals that incur indirect costs for medical education. The reports provide contractors with information to ensure that hospitals are properly reimbursed for IME, and eliminate IME duplicate reporting. *Frequency:* Annually; *Affected Public:* Not-for profit institutions, Business or other for-profit; *Number of Respondents:* 1300; *Total Annual Responses:* 1300; *Total Annual Hours:* 3,250.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address:

HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: John Rudolph, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: July 29, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards, Health Care Financing Administration HCFA, Office of Financial and Human Resources.

[FR Doc. 97–20610 Filed 8–5–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–R–199]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

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, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the 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.

1. *Type of Request:* Reinstatement, with change, of previously approved collection for which approval has expired; *Title of Information Collection:* Medicaid Report on Payables and Receivables; *Form No.:* HCFA-R–199; *Use:* The Chief Financial Officers Act of 1990 requires government agencies to produce financial statements. Form R–199 will collect accounting data from the States on Medicaid Payables and Receivables. The information collected on this form will be used in HCFA's financial statements and shared with auditors who validate HCFA's financial position.; *Frequency:* Annually; *Affected Public:* State, local or tribal government; *Number of Respondents:* 57; *Total Annual Responses:* 57; *Total Annual Hours:* 171.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: July 29, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

[FR Doc. 97–20608 Filed 8–5–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration (SAMHSA) Notice of Meeting

Pursuant to Pub.L. 92–463, notice is hereby given of the following meeting of the SAMHSA Special Emphasis Panel II in August.

A summary of the meeting may be obtained from: Ms. Dee Herman, Committee Management Liaison, SAMHSA Office of Extramural Activities Review, 5600 Fishers Lane, Room 17–89, Rockville, Maryland 20857. Telephone: 301–443–7390.

Substantive program information may be obtained from the individual named as Contact for the meeting listed below.

The meeting will include the review, discussion and evaluation of individual contract proposals. This discussion could reveal personal information concerning individuals associated with the proposals and confidential and financial information about an individual's proposal. This discussion may also reveal information about procurement activities exempt from disclosure by statute and trade secrets and commercial or financial information obtained from a person and privileged and confidential. Accordingly, the