

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