any investigational biological product trial placed on clinical hold during the past 12 months that the company wants the committee to review.

DATES: The meeting will be held in August 1996. Biological product companies may submit review requests for the August meeting by June 28, 1996.

ADDRESSES: Submit clinical hold review requests to Amanda Bryce Norton, FDA Chief Mediator and Ombudsman, Office of the Commissioner (HF–7), Food and Drug Administration, 5600 Fishers Lane, rm. 14–105, Rockville, MD 20857, 301–827–3390.

FOR FURTHER INFORMATION CONTACT: Joy A. Cavagnaro, Center for Biologics Evaluation and Research (HFM–4), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0379.

SUPPLEMENTARY INFORMATION: FDA regulations in part 312 (21 CFR part 312) provide procedures that govern the use of investigational new drugs and biologics in human subjects. If FDA determines that a proposed or ongoing study may pose significant risks for human subjects or is otherwise seriously deficient, as discussed in the investigational new drug regulations, it may order a clinical hold on the study. The clinical hold is one of FDA's primary mechanisms for protecting subjects who are involved in investigational new drug or biologic trials. FDA regulations in § 312.42 describe the grounds for ordering a clinical hold.

A clinical hold is an order that FDA issues to a sponsor to delay a proposed investigation or to suspend an ongoing investigation. The clinical hold may be ordered on one or more of the investigations covered by an investigational new drug application (IND). When a proposed study is placed on clinical hold, subjects may not be given the investigational drug or biologic as part of that study. When an ongoing study is placed on clinical hold, no new subjects may be recruited to the study and placed on the investigational drug or biologic and patients already in the study should stop receiving therapy involving the investigational drug or biologic unless FDA specifically permits it.

When FDA concludes that there is a deficiency in a proposed or ongoing clinical trial that may be grounds for ordering a clinical hold, ordinarily FDA will attempt to resolve the matter through informal discussions with the sponsor. If that attempt is unsuccessful, a clinical hold may be ordered by or on behalf of the director of the division that is responsible for the review of the IND.

FDA regulations in § 312.48 provide dispute resolution mechanisms through which sponsors may request reconsideration of clinical hold orders. The regulations encourage the sponsor to attempt to resolve disputes directly with the review staff responsible for the review of the IND. If necessary, the sponsor may request a meeting with the review staff and management to discuss the clinical hold.

CBER began a process to evaluate the consistency and fairness of practices in ordering clinical holds by instituting a review committee to review clinical holds (61 FR 1033, January 11, 1996). CBER held its first clinical hold review committee meeting on May 17, 1995. It will meet quarterly or semiannually. The committee last met in May 1996. The review procedure of the committee is designed to afford an opportunity for a sponsor who does not wish to seek formal reconsideration of a pending clinical hold to have that clinical hold considered ''anonymously.'' The committee consists of senior managers of CBER, a senior official from the Center for Drug Evaluation and Research, and the FDA Chief Mediator and Ombudsman.

Clinical holds to be reviewed will be chosen randomly. In addition, the committee will review some of the clinical holds proposed for review by biological product sponsors. In general, a biological product sponsor should consider requesting review when it disagrees with FDA's scientific or procedural basis for the decision.

Requests for committee review of a clinical hold should be submitted to the FDA Chief Mediator and Ombudsman, who is responsible for selecting clinical holds for review. The committee and CBER staff, with the exception of the FDA Chief Mediator and Ombudsman, are never advised, either in the review process or thereafter, which of the clinical holds were randomly chosen and which were submitted by sponsors. The committee will evaluate the selected clinical holds for scientific content and consistency with FDA regulations and CBER policy.

The meetings of the review committee are closed to the public because committee discussions deal with confidential commercial information. Summaries of the committee deliberations, excluding confidential commercial information, may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. If the status of a clinical hold changes following the committee's review, the appropriate division will notify the sponsor.

FDA invites biological product companies to submit to the FDA Chief Mediator and Ombudsman the name and IND number of any investigational biological product trial that was placed on clinical hold during the past 12 months that they want the committee to review at its August 1996 meeting. Submissions should be made by June 1, 1996, to Amanda B. Pedersen, FDA Chief Mediator and Ombudsman (address above).

Dated: May 17, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–13042 Filed 5–22–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[HCFA 301]

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, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. 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.

1. *Type of Request:* Revision of a currently approved collection; *Title of Information Collection:* Certification of Medicaid Eligibility Quality Control (MEQC) Payment Error Rates; *Form No.:* HCFA–301; *Use:* This certification is the new form by which States will report their MEQC payment error rate findings. This form represents aggregate data which were formerly collected through the Integrated Review Schedule; *Frequency:* Semi-annually; *Affected Public:* State, local, or tribal government; *Number of Respondents:*

51; *Total Annual Responses:* 102; *Total Annual Hours:* 22,515.

To request copies of the proposed paperwork collection referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attention: Linda Mansfield, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: May 16, 1996.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 96–12961 Filed 5–22–96; 8:45 am]

BILLING CODE 4120–03–M

National Institutes of Health

Submission for OMB Review; Comment Request; ''Screen for Alcohol Problems in the Elderly'' Study

SUMMARY: Under the provisions of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the National Institute on Alcohol Abuse and Alcoholism (NIAAA), 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 in the Federal Register on February 27, 1996, and allowed 60 days for public comment. There were seven (7) requests for additional information about this data collection activity, but no public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

The NIH 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 September 28, 1997, unless it displays a currently valid OMB control number.

PROPOSED COLLECTION: *Title:* Screening for Alcohol Problems in the Elderly. *Type of Information Collection request:* NEW. Need and Use of Information Collection: The information proposed for collection will be used by the NIAAA to develop an alcohol problem screening instrument suitable for use with the population age 65 and over and that can be administered in health care settings. The prevalence of alcohol problems among older persons is not well established. The instruments used for assessment are often not sensitive to alcohol abuse and dependence in this population, and many alcohol-related problems go undetected.

Frequency of Response: On occasion. *Affected Public:* Individuals and small businesses. *Type of Respondents:* The elderly (65 and older) and physicians. *Estimated Number of Respondents:* 636. *Estimated Number of Responses per Respondent:* 1. *Average Burden Hours per Response:* .281. *And Estimated Total Annual Burden Hours Requested:* 89.2. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

The annual burden estimates are as follows:

Type and number of respondents	Responses per respondent	Total responses	Hours	Total hours
Patients/500	1	500	.3340	167
Physicians/136	1	136	.0835	11.4
Total Number of Respondents: 636 (318 per year).				
Total Number of Responses: 636 (318 per year).				
Total Hours: 178.4 (89.2 per year).				

REQUEST FOR COMMENTS: Comments are invited on: (a) whether the proposed collection is necessary, including whether the information has practical use; (b) ways to enhance the clarity, quality, and use of the information to be collected; (c) the accuracy of the agency estimate of burden of the proposed collection; and (d) ways to minimize the collection burden of the respondents. Send written comments to Dr. Gayle Boyd, Prevention Research Branch, Division of Clinical and Prevention Research (CPR), NIAAA, NIH, Willco Building 6000, Room 505, 6000 Executive Boulevard, Bethesda, Maryland 20892–7003.

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, D.C. 20503, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans, contact Dr. Gayle Boyd, Prevention Research Branch, Division of Clinical and Prevention Research (CPR), NIAAA, NIH, 6000 Willco Building, Room 505, 6000 Executive Boulevard, Bethesda, Maryland 20892–7003, or call non-toll-free number (301) 443–8766.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before June 24, 1996.

Dated: May 10, 1996.

Martin K. Trusty,

Executive Officer, NIAAA.

[FR Doc. 96–12932 Filed 5–22–96; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Information Collection for Renewal

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: This notice announces that the Fish and Wildlife Services (Service) is planning to submit the collection of information requirement described below to the Office of Management and Budget (OMB) for continuing approval under the provisions of the Paperwork Reduction Act. Copies of the information collection requirement and related forms and explanatory material may be obtained by contacting the Service's clearance officer at the phone number listed below. The Service is soliciting comments and suggestions on the requirement as described below.

DATES: Comments must be submitted on or before July 22, 1996.