anticipated. Therefore, FDA has determined that the important health issues involved in the draft guidance provide good cause for reopening of the comment period on the original draft guidance in accordance with section 520(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(d)). FDA is reopening the comment period for an additional 90 days.

Interested persons may, on or before August 20, 1997, submit to the Dockets Management Branch (address above) written comments regarding the notice. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 7, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–13378 Filed 5–21–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0146]

A Primer on Medical Device Interactions With Magnetic Resonance Imaging Systems; Draft Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems.'' The purpose of this document is twofold. It should serve to sensitize medical device reviewers to the meaning and ramifications of magnetic resonance (MR) safety or MR compatibility claims. It will also provide for FDA reviewers a background of MR theory and the effect the MR environment may have on medical devices.

DATES: Submit written comments on the draft guidance document by August 20, 1997.

ADDRESSES: Requests for single copies of the draft guidance document and any written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Marlene Skopec, Center for Devices and Radiological Health (HFZ–133), Food and Drug Administration, 12721 Twinbrook Pkwy., Rockville, MD 20852, 301–443–3840.

SUPPLEMENTARY INFORMATION: FDA recognizes that there is an increasing number of medical device manufacturers seeking to make MR safe or MR compatibility claims for their devices. It is important that medical device reviewers are aware of the potential implications of these claims. With the advent of open magnetic resonance imaging (MRI) systems and interventional MR, the trend of making MR claims for medical devices will continue and accelerate. This draft guidance document is intended to serve as a general background document on medical device interactions in MRI systems. It is not intended to replace documents created that address specific devices or device areas.

A guidance document does not bind FDA or the public, and does not create or confer any rights, privileges, or benefits for or on any person; however, it does represent the agency's current thinking on the subjects discussed therein. The draft guidance document announced in this notice represents the agency's tentative thinking of the subjects discussed therein.

Interested persons may, on or before August 20, 1997, submit to the Dockets Management Branch (address above) written comments on ''A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems.'' Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. ''A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems'' and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 21, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–13377 Filed 5–21–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

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:* 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 auditable financial statements. Form R–199 will collect accounting data from the States on Payables and Receivables; *Frequency:* Annually; *Affected Public:* State, local or tribal government; *Number of Respondents:* 57; *Total Annual Responses:* 57; *Total Annual Hours:* 171.

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 Analysis and Planning Staff, Attention: Linda Mansfield, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: May 15, 1997.

Edwin J. Glatzel,

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

[FR Doc. 97–13387 Filed 5–21–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–668-B]

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.

Type of Information Collection Request: Reinstatement, with change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Post Laboratory Survey Questionnaire—Laboratory, and Supporting Regulation 42 CFR section 493; *Form No.:* HCFA–668-B; *Use:* This form will allow Laboratories to assess the CLIA survey process and report their satisfaction with the survey process. This information will help HCFA evaluate the survey process from the laboratory's prospective. *Frequency:* Biennially; *Affected Public:* Federal Government, Business or other for-profit, Not-for-profit institutions and, State, Local or Tribal Government.; *Number of Respondents:* 40,000; *Total Annual Responses:* 20,000; *Total Annual Hours:* 5,000.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov/regs/prdact95.htm, 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: May 7, 1997.

Edwin J. Glatzel,

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

[FR Doc. 97–13397 Filed 5–21–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; ''A Native American Tribe With Low Alcoholism Prevalence: Transmission Analysis, Linkage Analysis and Gene/Environment Interactions (a 1 Tribe 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 (NIAA), 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 July 1, 1996, and allowed 60 days for public comment. There were no requests for additional information about this data collection activity, 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 June 30, 1999, unless it displays a currently valid OMB control number.

PROPOSED COLLECTION: *Title:* 'A Native American Tribe with Low Alcoholism Prevalence: Transmission Analysis, Linkage Analysis and Gene/Environment Interactions (a 1 tribe study)'. *Type of Information Collection request:* NEW. Need and Use of Information Collection: The information proposed for collection in this study will be used by the NIAAA to define the prevalence in alcoholism and associated problems in tribes in which the rates of alcoholism have been reported to be widely divergent. Additional information will be collected on severe trauma and stress, alcohol availability and socioeconomic factors to identify how these variables interact with hereditary factors in the development of alcoholism and related problems.

Frequency of Response: One time. *Affected Public:* Individuals. *Type of Respondents:* Native American adults. *Estimated Number of Respondents:* 300. *Estimated Number of Responses per Respondent:* 1. *Average Burden Hours per Response:* 5.00. *And Estimated Total Annual Burden Hours Requested:* 1500. 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
Clients 300	1	300	5.00	1500
Total Number of Respondents: 300.				
Total Number of Responses: 300.				
Total Hours: 1500.				