understanding of their reporting responsibilities and guidance to aid in the completion of the MDR forms; (3) give an overview of required written MDR procedures, records and files; and (4) supply information on sources for forms, instructions, and other MDR information.

Comments were requested and the guidance has been revised. FDA addressed the changes mandated by the Safe Medical Devices Act and the Medical Device Amendments of 1992.

''Medical Device Reporting (MDR) for Manufacturers'' represents the agency's current thinking on medical device reporting for manufacturers. 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 requirements of the applicable statute, regulations, or both.

II. Electronic Access

In order to receive the ''Medical Device Reporting (MDR) for Manufacturers'' guidance document via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt, press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number 987 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may do so by using the World Wide Web (WWW). The Center for Devices and Radiological Health (CDRH) maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a PC with access to the Web. The CDRH home page is updated on a regular basis and includes the ''Medical Device Reporting (MDR) for Manufacturers'' guidance document, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Medical Device Reporting for Manufacturers'' is available on the medical device reporting page at: http://www.fda.gov/cdrh/mdr.html.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

Dated: June 13, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–18918 Filed 7–17–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Submission for OMB Review; 30-Day Comment Period Proposed Information Collection: Evaluation of the IHS–Supported Alcohol and Substance Abuse Treatment Programs for American Indian/Alaska Native Women

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed information collection projects, the Indian Health Service (IHS) 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 project was previously published in the **Federal Register** (62 FR 15191) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow 30 days for public comment to be submitted to OMB.

Proposed Collection.

Title: Evaluation of the IHS–Supported Alcohol and Substance Abuse Treatment Program for American Indian/Alaska Native (AI/AN) women. *Type of Information Collection Request:* New. *Need and Use of the Information Collection:* Section 703, ''Indian Women Treatment Programs'' of Public Law 102–573, the Indian Health Care Amendments of 1992, (the act) authorizes the IHS to develop and implement a comprehensive alcohol and alcohol and substance abuse (A/SA) program that specifically addresses the cultural, historical, social, and child care needs of AI/AN women. Section 801 of these Amendments requires a report on the progress made in meeting the objectives of the Act, a review of programs established or assisted pursuant to the Act, and an assessment of such programs. Support Services International, Inc, (SSI) an Indian-owned consulting firm, will develop the data collection instruments and conduct the study. The information collected will be used to assess and improve the effectiveness of the IHS-supported A/SA treatment program.

Data will be collected from a sample of AI/AN women who use the services provided by the IHS-supported A/SA treatment programs, and from a sample of treatment program staff. Findings from the study will be used to determine (1) What works, what does not work, and why; (2) what resources are required for successful A/SA treatment for AI/AN women; (3) what factors help or hinder women from maintaining sobriety; (4) how many women achieve success (3–, 6–, and 12-months after admission into A/SA treatment; (5) what are the characteristics, life conditions, and service needs of the women who use the treatment programs; (6) what are the common strengths and problems of the treatment programs, and what are recommendations for improvement. The study is expected to be completed in FY 1998. *Affected Public:* Individuals.

See Table 1 below for Types of Data Collection Instruments, Estimated Number of Respondents, Number of Responses per Respondent, Average Burden Hour per Response, and Total Annual Burden Hour.

TABLE 1

Data collection Instrument	Estimated no. of respondents	Responses per respondent	Average burden hour per response*	Total annual burden hrs
Project Director	24	1	0.75 hr (45 minutes)	18.0
Project Staff	216	1	0.50 hr (30 minutes)	108.0

TABLE 1—Continued

Data collection Instrument	Estimated no. of respondents	Responses per respondent	Average burden hour per response*	Total annual burden hrs
Client Intake	550	1	0.50 hr (30 minutes)	275.0
Client History	550	1	1.00 hr (60 minutes)	550.0
Client Discharge	523	1	0.50 hr (30 minutes)	261.5
Client 3-month follow-up	467	1	0.4175 hr (25 minutes)	194.9
Client 6-month follow-up	440	1	0.50 hr (30 minutes)	220.0
Client 12-month follow-up	412	1	0.41752 hr (25 minutes)	172.0
Total	790			1,799.4

*For ease of understanding, burden hours are alos provided in actual minutes.

There are no Capital Costs, Operating Costs and/or Maintenance Costs to report for this information collection.

Request for Comments

Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function and whether the IHS processes the information collected in a useful and timely fashion; (b) the accuracy of the public burden estimate (this is the amount of time needed for individual respondents to provide the requested information) and the methodology and assumptions used to determine the estimate; (c) way to enhance the quality, utility, and clarity of the information being collected; and (d) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology

Direct Comments To OMB

Send your written comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time, to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for IHS. To request more information on the proposed collection or to obtain a copy of the data collection plan(s) and/or instruction(s), contact: Mr. Lance Hodahkwen, Sr., M.P.H., IHS Reports Clearance Officer, 12300 Twinbrook Parkway, Suite 450, Rockville, MD 20852. 1601, or call non-toll free (301) 443–0461, or send via facsimile to (301) 443–1522, or send your E-mail requests, comments, and return address to: Ihodahkw@smtp.ihs.gov.

Comment Due Date

Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: July 8, 1997.

Michael H. Trujillo,

Assistant Surgeon General Director.

[FR Doc. 97–18907 Filed 7–17–97; 8:45 am]

BILLING CODE 4160–16–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute of Health

Meeting of the Advisory Committee on Blood Safety and Availability

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Advisory Committee on Blood Safety and Availability, Department of Health and Human Services, August 11–12, 1997. This meeting will be held at the National Library of Medicine in the Lister Hill National Center for Biomedical Communications, Building 38A, 1st Floor–Auditorium 8600 Rockville Pike, Bethesda, Maryland 20892.

The entire meeting will be opened to the public from 9:30 a.m. to 5:30 p.m. on August 11 and from 8:00 a.m. to 3:00 p.m. on August 12. The Committee will continue its discussion of hepatitis C lookback issues and will be expected to provide recommendations for a course(s) of action for the Department of Health and Human Services. Limited time has been set aside for additional public comment. Prospective speakers should notify the Acting Executive Secretary for this meeting of their intent to make a presentation and should plan for no more than five minutes of comments.

Contact: Paul R. McCurdy, M.D., Acting Executive Secretary, Advisory Committee on Blood Safety and Availability, Director, Blood Resources Program, DBDR, Two Rockledge Center, 6701 Rockledge Drive, Room 10138, MSC–7950, NHLBI, NIH, Bethesda, Maryland 20892–7950. Phone: 301–435–0065; Fax: 301–480–1060; E-Mail: paul__mccurdy@nih.gov.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the Acting Executive Secretary in advance of the meeting.

Dated: July 14, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–18981 Filed 7–17–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences, Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Environmental Health Sciences Special Emphasis Panel (SEP) meetings:

Name of SEP: Modulation by Growth Factors and Signal Transduction Pathways of Environmentally Induced Disease/Dysfunction (Telephone Conference Call).

Date: July 21, 1997.

Time: 1:00 p.m.

Place: National Institute of Environmental Health Sciences, 79 T.W. Alexander Drive, Building 4401, Room 3453, Research Triangle Park, NC 27709.

Contact Person: Dr. Linda K. Bass, National Institute of Environmental Health Sciences, P.O. Box 12233, Research Triangle Park, NC 27709, (919) 541–1307.

Purpose/Agenda: To review and evaluate grant applications.

Name of SEP: Pregnancy, Heredity, and Environment; a Case-Control Study of Facial Clefts (Telephone Conference Call).

Date: July 30, 1997.

Time: 1:00 p.m.