Fishers Lane, Rockville, MD 20857, 301–827–2250.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''OTC Treatment of Hypercholesterolemia.'' Several sponsors have recently expressed interest in marketing cholesterol-lowering agents as OTC drug products. These requests have raised several regulatory policy and medical therapy issues.

This guidance document represents the agency's current thinking on OTC treatment of hypercholesterolemia. 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 an approach satisfies the requirement of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). 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. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain the guidance by using the World Wide Web (WWW). For WWW access, go to ''http://www.fda.gov/cder/guidance/index.htm''.

Dated: October 17, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–28298 Filed 10–24–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Treatment Observation's Study

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

PROPOSED COLLECTION: The Treatment Research Branch (TRB), intends to conduct the study for ''Treatment Observation''. The TRB is authorized by Section 452 of Part G of Title IV of the Public Health Service Act (42 U.S.C. 288) as amended by the NIH Revitalization Act of 1993 (Pub. L. 103–43).

The information proposed for collection will be used by the NIAAA to observe group treatment at up to 20 treatment facilities. At each facility, directors will be asked to provide information about treatment practices and about the client population. At each facility at least seven members of the treatment staff will be asked to provide information about their treatment activities, personal experiences and training. At each facility eight treatment groups will be observed. The group leader will be asked to complete a questionnaire about the observed session and other client demographics. At least seven group members will also be asked to complete a questionnaire about the observed group session. The target population for the study is a group of outpatient public and private providers that will include group treatment as part of their overall plan of clinical therapeutics.

The specific aim of this study is the testing of instruments and methodologies for the systematic measurement of the content, process, and context of group treatment.

The annual burden estimates are as follows:

Type and number of respondents	Responses per respondent	Total responses	Hours	Total hours
Facility Director—20	1	20	.75	15
Group Leader—160	1	160	.334	55
Treatment Staff—140	1	140	.334	48
Group Member—1120	1	1120	.334	381
Total Number of Respondents	.....	1440		
Total Number of Responses	.....	1440	.....	.....
Total Hours	.....	499	.....	.....

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. Margaret Mattson, Treatment Research Branch, Division of Clinical and Prevention Research (DCPR), NIAAA. NIH, Willco Building 6000, Room 505, 6000 Executive Boulevard, Bethesda, Maryland 20892–7003.

FOR FURTHER INFORMATION CONTACT:

To request more information on the proposed project or to obtain a copy of the data collection plans, contact Dr. Margaret Mattson, Treatment Research Branch, Division of Clinical and Prevention Research (DCPR), NIAAA, NIH, 6000 Willco Building, Room 505, 6000 Executive Boulevard, Bethesda, Maryland 20892–7003, or call non-toll-free number (301) 443–0638.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: October 20, 1997.

Martin K. Trusty,

Executive Officer, NIAAA.

[FR Doc. 97–28382 Filed 10–24–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice