

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

is hereby given of the following Center for Scientific Review Special Emphasis Panel (SEP) meetings:

*Purpose/Agenda:* To review individual grant applications.

*Name of SEP:* Multidisciplinary Sciences.

*Date:* November 3-4, 1997.

*Time:* 8:00 a.m.

*Place:* University Center Hotel, Gainesville, Florida.

*Contact Person:* Dr. Houston Baker, Scientific Review Administrator, 6701 Rockledge Drive, Room 5208, Bethesda, Maryland 20892, (301) 435-1175.

*Name of SEP:* Biological and Physiological Sciences.

*Date:* November 7, 1997.

*Time:* 1:00 p.m.

*Place:* NIH, Rockledge 2, Room 4202, Telephone Conference.

*Contact Person:* Dr. Calbert Laing, Scientific Review Administrator, 6701 Rockledge Drive, Room 4202, Bethesda, Maryland 20892, (301) 435-1221.

This notice is being published less than 15 days prior to the above meetings due to the urgent need to meet timing limitations imposed by the grant review and funding cycle.

*Name of SEP:* Clinical Sciences.

*Date:* November 13, 1997.

*Time:* 10:00 a.m.

*Place:* Embassy Suites, Chevy Chase, MD.

*Contact Person:* Dr. Jerrold Fried, Scientific Review Administrator, 6701 Rockledge Drive, Room 4126, Bethesda, Maryland 20892, (301) 435-1777.

*Name of SEP:* Microbiological and Immunological Sciences.

*Date:* November 13, 1997.

*Time:* 2:00 p.m.

*Place:* NIH, Rockledge 2, Room 5110, Telephone Conference.

*Contact Person:* Dr. Mohindar Poonian, Scientific Review Administrator, 6701 Rockledge Drive, Room 5110, Bethesda, Maryland 20892, (301) 435-1168.

*Name of SEP:* Biological and Physiological Sciences.

*Date:* November 17, 1997.

*Time:* 1:30 p.m.

*Place:* NIH, Rockledge 2, Room 5196, Telephone Conference.

*Contact Person:* Ms. Carol Campbell, Scientific Review Administrator, 6701 Rockledge Drive, Room 5196, Bethesda, Maryland 20892, (301) 435-1257.

*Name of SEP:* Biological and Physiological Sciences.

*Date:* November 24, 1997.

*Time:* 11:30 a.m.

*Place:* NIH, Rockledge 2, Room 5196, Telephone Conference.

*Contact Person:* Ms. Carol Campbell, Scientific Review Administrator, 6701 Rockledge Drive, Room 5196, Bethesda, Maryland 20892, (301) 435-1257.

*Name of SEP:* Clinical Sciences.

*Date:* November 26, 1997.

*Time:* 1:00 p.m.

*Place:* NIH, Rockledge 2, Room 4126, Telephone Conference.

*Contact Person:* Dr. Jerrold Fried, Scientific Review Administrator, 6701 Rockledge Drive,

Room 4126, Bethesda, Maryland 20892, (301) 435-1777.

*Name of SEP:* Chemistry and Related Sciences.

*Date:* December 2-4, 1997.

*Time:* 5:00 p.m.

*Place:* Holiday Inn-University Center, Philadelphia, PA.

*Contact Person:* Dr. Nancy Lamontagne, Scientific Review Administrator, 6701 Rockledge Drive, Room 4170, Bethesda, Maryland 20892, (301) 435-1726.

*Name of SEP:* Chemistry and Related Sciences.

*Date:* December 3, 1997.

*Time:* 8:30 a.m.

*Place:* NIH, Rockledge 2, Room 4168, Telephone Conference.

*Contact Person:* Dr. John Bowers, Scientific Review Administrator, 6701 Rockledge Drive, Room 4168, Bethesda, Maryland 20892, (301) 435-1725.

The meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 20, 1997.

**LaVerne Y. Stringfield,**

*Committee Management Officer, NIH.*

[FR Doc. 97-28379 Filed 10-24-97; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Child Health and Human Development; Notice of Meeting

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 Child Health and Human Development Special Emphasis Panel (SEP) meeting:

The meeting will be open to the public to provide concept review of proposed contract solicitations.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the Contact Person listed below in advance of the meeting.

*Name of Panel:* The Effects of Swimming Lessons on the Risk of Drowning (TELECONFERENCE).

*Date:* November 5, 1997.

*Time:* 2:00 p.m. (ET)—adjournment.

*Place:* 6100 Executive Boulevard, 6100 Building—Room 5E01, Rockville, Maryland 20852.

*Contact Person:* Hameed Khan, Ph.D., Scientific Review Administrator, NICHHD, 6100 Executive Boulevard, 6100 Building—Room 5E01, Rockville, Maryland 20852, Telephone: 301-496-1696.

*Purpose/Agenda:* To provide concept review of proposed contract solicitations.

This notice is published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program Nos. [93.864, Population Research and No. 93.865, Research Mothers and Children], National Institutes of Health)

Dated: October 21, 1997.

**LaVerne Y. Stringfield,**

*Committee Management Officer, NIH.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel meeting:

*Name of SEP:* ZDK1-GRB-7 (J1).

*Date:* November 17-19, 1997.

*Time:* 7:30 p.m.

*Place:* The Quarterage Hotel, 560 Westport Road, Kansas City, MO 64111.

*Contact Person:* Lakshmanan Sankaran, Ph.D., Scientific Review Administrator, Review Branch, DEA, NIDDK, Natcher Building, Room 6as-25F, National Institutes of Health, Bethesda, Maryland 20892-6600, Phone: (301) 594-7799.

*Purpose/Agenda:* To review and evaluate grant applications.

This meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invitation of person privacy.

(Catalog of Federal Domestic Assistance Program No. 93.847-849, Diabetes, Endocrine and Metabolic Diseases; Digestive Diseases