protocols for devices used to treat/diagnose rare pediatric diseases?

3. What barriers related to statistical analyses must be addressed in order to promote device development for rare pediatric diseases?

4. How can new registries be developed or current registries be leveraged to provide robust data on the safety and effectiveness of pediatric medical devices to support premarket approval and clearance, and/or enhance postmarket surveillance activities related to pediatric medical devices?

E. Pediatric Needs Assessment

1. Describe the parameters that should be used in determining priority areas of development of devices, including both therapeutic and diagnostic devices, in pediatric rare diseases.

2. What is the best approach to conduct needs assessment of medical devices required for use with pediatric rare diseases?

F. Device Related Issues for Diagnostic Devices

1. What are medical device related issues that need to be addressed for development of diagnostic medical devices?

G. Advancing Development

1. What incentives could help advance the development of diagnostic and therapeutic medical devices to treat pediatric rare diseases?

2. How can possible or probable use in pediatric practice be considered early in the development stages of all devices designed to treat a rare disease or condition?

3. What are potential private resources (e.g., registries, industry, or patient advocacy groups) that could be tapped to advance the development of medical devices for rare diseases in the pediatric population?

4. What are potential improvements or changes that can be made to FDA guidance, regulations, or current science in order to help develop and improve medical devices to address the needs of the pediatric population affected by rare diseases?

Dated: September 17, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–22960 Filed 9–20–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Clinical Trial Design for Intravenous Fat Emulsion Products; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, in cosponsorship with the American Society for Parenteral and Enteral Nutrition, is announcing a 1-day public workshop entitled ''Clinical Trial Design for Intravenous Fat Emulsion Products.'' This workshop will provide a forum to discuss trial design of clinical trials intended to support registration of intravenous fat emulsion products.

Date and Time: The public workshop will be held on October 29, 2013, from 8 a.m. to 5 p.m. (EST).

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002.

Contact Person: Wes Ishihara, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–0069, FAX: 301–796–9904, email: *richard.ishihara@fda.hhs.gov.*

Registration: There is no fee to attend the public workshop, but attendees must register in advance. Space is limited, and registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online at *https://netforum.avectra.com/eweb/DynamicPage.aspx?Site=ASPEN&WebCode=EventDetail&evt_key=eb9c4068-8b66-4ac0-ae4f-ac266c08e33e* before October 22, 2013. For those without Internet access, please contact Wes Ishihara (see *Contact Person*) to register. On-site registration will not be available.

If you need special accommodations because of disability, please contact Wes Ishihara (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: This workshop will provide a forum to discuss the key issues in clinical trial design for intravenous fat emulsions. Stakeholders, including industry sponsors, academia, patients receiving parenteral nutrition, and FDA, will discuss challenging issues related to selection of endpoints and assessment methodologies in registration trials. Trial design strategies and possible candidates for endpoints will be explored.

Transcripts: Transcripts of the workshop will be available for review at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and on the Internet at *http://www.regulations.gov* approximately 30 days after the workshop. A transcript will also be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857. Send faxed requests to 301–827–9267.

Dated: September 17, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–23020 Filed 9–20–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day Comment Request: The Framingham Heart Study (FHS)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on May 7, 2013, pages 26639–41 and allowed 60-days for public comment. No public comments were received. The National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health, 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 October 1, 1995, unless it displays a currently valid OMB control number.

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, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

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.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of data collection plans and instruments, contact Dr. Gina Wei, Division of Cardiovascular Sciences, NHLBI, NIH, Two Rockledge Center, 6701 Rockledge Drive, MSC 7936, Bethesda, MD, 20892–7936, or call non-toll-free number (301) 435–0416, or email your request, including your address to: *weig@nhlbi.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: The Framingham Heart Study, 0925–0216, Revision National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Framingham Heart Study will continue to conduct morbidity and mortality follow-up, as well as examinations, for the purpose of studying the determinants of cardiovascular disease. Morbidity and mortality follow-up will continue to occur in all of the cohorts (Original, Offspring, Third Generation, Omni Group 1, and Omni Group 2). Examinations will continue to be conducted on the Original, Offspring, and Omni Group 1 Cohorts. The numbers of Offspring and Omni Group 1 participants to be examined for this OMB submission are much smaller than those during the last OMB approval period. This is because a great majority of these two cohorts have already completed their examinations. The small number of participants remaining to be examined is reflected in the decrease in the estimated annualized burden hours for these two cohorts as well as for the entire study, compared to the last OMB approval period.

OMB approval is requested for 3 years. There is no cost to the respondents other than their time. The total estimated annualized burden hours are 4264.

ESTIMATED ANNUALIZED BURDEN HOURS, ORIGINAL COHORT

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
I. PARTICIPANT COMPONENTS				
A. PRE-EXAM:.				
a. Telephone contact to set up appointment	60	1	10/60	10
b. Exam Appointment, Scheduling, Reminder, and Instructions	55	1	35/60	32
B. EXAM—Cycle 32:.				
a. Clinic exam	25	1	45/60	19
b. Home or nursing home visit	25	1	65/60	27
C. ANNUAL FOLLOW-UP:.				
a. Records Request	60	1	15/60	15
b. Health Status Update	45	1	15/60	11
SUB-TOTAL: PARTICIPANT COMPONENTS	*60			114
II. NON-PARTICIPANT COMPONENTS				
A. Informant Contact (Pre-exam and Annual Follow-up)	25	1	10/60	4
B. Records Request (Annual follow-up)	50	1	15/60	13
SUB-TOTAL: NON-PARTICIPANT COMPONENTS	75			17

* Number of participants as reflected in Rows I.A.a and I.C.a. above

ESTIMATED ANNUALIZED BURDEN HOURS, OFFSPRING COHORT AND OMNI GROUP 1 COHORT

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
I. PARTICIPANT COMPONENTS				
A. PRE-EXAM:				
a. Telephone contact to set up apt or Health status update	300	1	10/60	50
b. Appt. or update Confirmation	250	1	10/60	42
c. Food Frequency Form	250	1	10/60	42
B. EXAM:				
a. Clinic Exam	100	1	175/60	292
b. Home or nursing home visit	100	1	60/60	100
c. Consent Forms	200	1	20/60	67
C. ANNUAL FOLLOW-UP:				
a. Records Request	2292	1	15/60	573
b. Health Status Update	1833	1	15/60	458
SUB-TOTAL: PARTICIPANT COMPONENTS	*2292			1624
II. NON-PARTICIPANT COMPONENTS				
A. Informant contact (Pre-exam and Annual Follow-up)	229	1	10/60	38
B. Records Request (Annual follow-up)	2292	1	15/60	573
SUB-TOTAL: NON-PARTICIPANT COMPONENTS	2521			611

* Number of participants as reflected in Rows I.C.a. above.

ESTIMATED ANNUALIZED BURDEN HOURS, GENERATION 3 COHORT AND OMNI GROUP 2 COHORT

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
I. PARTICIPANT COMPONENTS—ANNUAL FOLLOW-UP				
A. Records Request	3212	1	15/60	803
B. Health Status Update	3212	1	15/60	803
SUB-TOTAL: PARTICIPANT COMPONENTS	*3212			1606
II. NON-PARTICIPANT COMPONENTS—ANNUAL FOLLOW-UP				
A. Informant contacts	160	1	10/60	27
B. Records Request	1060	1	15/60	265
SUB-TOTAL: NON-PARTICIPANT COMPONENTS	1220			292

*Number of participants as reflected in Rows I.A. and I.B. above.

SUMMARY OF 3 TABLES COMBINED—TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
Participants	5564	1	36/60	3344
Non-Participants	3816	1	14.5/60	920
Totals	9380			4264

(NOTE: reported and calculated numbers differ slightly due to rounding.)

Lynn Susulske,

NHLBI Project Clearance Liaison, National Institutes of Health.

Michael Lauer,

Director, DCVS, National Institutes of Health.

[FR Doc. 2013–23060 Filed 9–20–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 USC, as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel GOMED: Grand Opportunity in Medications Development for Substance-Related Disorders (U01).

Date: October 15, 2013.

Time: 9:00 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Washington, DC/Bethesda, 7301 Waverly Street, Bethesda, MD 21045.

Contact Person: Jose F. Ruiz, Ph.D., Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, Room 4228, MSC 9550, 6001 Executive Blvd., Bethesda, MD 20892–9550, (301) 451–3086, *ruizjf@nida.nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel Strategic Alliances for Medications Development to Treat Substance Use Disorders (R01) (PAS–12–122).

Date: October 15, 2013.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Washington, DC/Bethesda, 7301 Waverly Street, Bethesda, MD 21045.

Contact Person: Jose F. Ruiz, Ph.D., Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, Room 4228, MSC 9550, 6001 Executive Blvd., Bethesda, MD 20892–9550, (301) 451–3086, *ruizjf@nida.nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Medications Development Centers of Excellence Cooperative Program.

Date: October 15–16, 2013.

Time: 2:00 p.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Washington, DC/Bethesda, 7301 Waverly Street, Bethesda, MD 21045.

Contact Person: Jose F. Ruiz, Ph.D., Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, Room 4228, MSC 9550, 6001 Executive Blvd., Bethesda, MD 20892–9550, (301) 451–3086, *ruizjf@nida.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: *September 17, 2013.*

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–22992 Filed 9–20–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which