

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.

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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.

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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.