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.

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