4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Gastroenterology Regulatory Endpoints and the Advancement of Therapeutics (GREAT); Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research is announcing a 4-day public workshop entitled "Gastroenterology Regulatory Endpoints and the Advancement of Therapeutics (GREAT)." The purpose of this workshop is to provide a forum to consider issues related to endpoints that can support drug development in the following disease areas: Eosinophilic esophagitis, pediatric and adult inflammatory bowel disease, and parenteral nutrition-associated liver disease.

DATES: The public workshop will be held on September 19, 20, 21, and 24, 2012, from 8:30 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at the Holiday Inn, 10000 Baltimore Ave., College Park, MD 20740.

FOR FURTHER INFORMATION CONTACT:

Kevin Bugin,

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Food and Drug Administration,

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SUPPLEMENTARY INFORMATION:

This workshop will address endpoints for registration trials. Stakeholders, including industry sponsors, academia, and FDA, will be engaged to address challenging issues related to selection of endpoints and assessment methodologies in registration trials. Facilitation of efficient drug development, in the context of these issues, will be discussed.

Each day of the workshop will be devoted to a discussion of a single relevant disease area. The goal of the workshop day dedicated to eosinophilic esophagitis is to discuss its natural history, development of patient reported outcome measures, and biomarkers that might be used to study new treatments for both children and adults. The goal of the workshop day dedicated to pediatric inflammatory bowel disease (IBD) is to discuss issues related to the extrapolation of efficacy data from adult to pediatric patients, the definition and measurement of treatment benefit, and dose-finding strategies in pediatric patients. The goal of the workshop day dedicated to adult IBD is to discuss the definition and measurement of efficacy in adult ulcerative colitis registration trials, including the timing of endpoint assessment and the roles of specific endpoints and measurement tools. The goal of the workshop day dedicated to parenteral nutrition-induced liver disease is to discuss endpoints and their measurement for clinical trials in which parenteral nutrition-induced liver disease is either an efficacy or safety outcome measure.

PARTICPATION IN THE PUBLIC WORKSHOP:

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 http://www.fda.contractmeetings.com before September 1, 2012. For those without Internet access, please contact Ann Brameyer (7910 Woodmont Ave., suite 310, Bethesda, MD 20814, Phone: 240-316-3205, FAX: 240-316-3201) to register. Onsite registration will not be available.

If you need special accommodations due to a disability, please contact Kevin Bugin (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance.

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., Element Bldg., Rockville, MD 20857. Send faxed requests to 301-827-9267.

Dated: July 31, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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