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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Pediatric Neurocognitive Workshop; Advancing the Development of Pediatric Therapeutics Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA) Division of Gastroenterology and Inborn Errors Products Division and Division of Pediatric and Maternal Health in the Center for Drug Evaluation and Research, and the Office of Pediatric Therapeutics in the Office of the Commissioner are announcing a 2-day public workshop. Day 1 of the workshop is entitled "Assessment of Neurocognitive Outcomes in the Inborn Errors of Metabolism". Day 2 of the workshop is entitled, "Advancing the Development of Pediatric Therapeutics: Assessment of Pediatric Neurocognitive Outcomes". The purpose of this 2-day workshop is to provide a forum to consider issues related to advancing pediatric regulatory science in the evaluation of neurocognitive outcomes in pediatric patients.

DATES: The public workshop will be held on April 16 and 17, 2015, from 8 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held in the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503A), Silver Spring, MD 20993-0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to

http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

FOR FURTHER INFORMATION CONTACT: For questions regarding Day 1 of the workshop, contact Richard (Wes) Ishihara, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-0069, richard.ishihara@fda.hhs.gov.

For questions regarding Day 2 of the workshop, contact Denise Pica-Branco, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002,Telephone: 301-796-1732, FAX: 301-796-9858, denise.picabranco@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

The first day of the workshop will focus on approaches for assessing the efficacy of therapeutic products on neurocognitive outcomes in patients diagnosed with inborn errors of metabolism disorders. The session will address the role of natural history studies and methodological approaches for selecting appropriate assessment scales and standardizing neurocognitive assessments. The second day of the workshop will discuss identification of signals in animal studies and clinical trials that warrant further clinical investigation and testing that may be predictive of neurocognitive outcome in children. Additionally, strategies and methods to address the challenges of assessing long-term neurocognitive outcomes for products used to treat pediatric patients will be discussed.

Participation in the Public Workshop:

Registration: There is no fee to attend the public workshop, but attendees should 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 neurocognitive_workshop@fda.hhs.gov before March 31, 2015. For those without Internet access, please contact Denise Pica-Branco (see FOR FURTHER INFORMATION CONTACT) to register. Onsite registration will not be available.

If you need special accommodations due to a disability, please contact Denise Pica-Branco (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 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: February 24, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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