4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Quantitative Assessment of Assumptions to Support Extrapolation of Efficacy in Pediatrics; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the University of Maryland Center of Excellence in Regulatory Science and Innovation (CERSI), is announcing a public workshop entitled "Quantitative Assessment of Assumptions to Support Extrapolation of Efficacy in Pediatrics." The objective of the workshop is to discuss quantitative and qualitative approaches for verifying assumptions pertaining to disease and therapeutic response similarity between adults and children. The workshop will also provide a forum for discussion on the use of modeling and simulation for systematic assessment of extrapolation assumptions.

DATES: The public workshop will be held on June 1, 2016, from 8 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting 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: Audrey Thomas, Office of Regulatory Science and Innovation, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4220, Silver Spring, MD 20993-0002, 301-796-3520, Audrey.Thomas@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The purpose of this public workshop is to provide an opportunity for relevant stakeholders, including clinicians, academia, industry, and FDA to discuss systematic assessment of data needed to support extrapolation of efficacy in pediatric product development. Specifically, the workshop will include: 1) Presentations on approaches for assessing disease and therapeutic response similarity between adults and pediatrics, and 2) discussion of alternative approaches to the assessment of extrapolation assumptions in pediatric product development, including the use of clinical trial simulation and Bayesian approaches. Examples in partial onset seizures, inflammatory bowel diseases, and polyarticular juvenile idiopathic arthritis will be presented and discussed.

FDA has verified the Web site addresses in this document, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the Federal Register**.**

Agenda: The agenda is located at www.pharmacy.umaryland.edu/PedsExtrapolation.

Registration: There is a registration fee to attend this public workshop in person. Seats are limited and registration will be on a first-come, first-served basis. To register, please complete registration online at www.pharmacy.umaryland.edu/PedsExtrapolation**.** There will be no onsite registration. The costs of registration, to attend in person, for the different categories of attendees are as follows:

Category	Cost
Industry Representative	$50
Nonprofit Organization and Academic other than University of Maryland	$50
University of Maryland, College Park and Baltimore	$0

Federal Government	$0

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. There is no registration fee for access to the workshop via the Webcast, but registration is still required. Information regarding access to the Webcast link is available at www.pharmacy.umaryland.edu/PedsExtrapolation. If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit http://www.adobe.com/go/connectpro_overview.

Accommodations: Attendees are responsible for their own hotel accommodations. If you need special accommodations while at FDA's White Oak Campus due to a disability, please contact Shari Solomon at Shari.Solomon@fda.hhs.gov at least 7 days in advance.

Dated: April 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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