4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-2390]

Evidentiary Considerations for Integration of Biomarkers in Drug Development; Notice of Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS

ACTION: Notice of public meeting; request for comments

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the University of Maryland's Center of Excellence in Regulatory Science and Innovation and the Critical Path Institute, is announcing a public workshop entitled "Evidentiary Considerations for Integration of Biomarkers in Drug Development." The purpose of the meeting is to discuss current scientific approaches to biomarker development, acceptance, and utility in drug and biologic (hereafter referred to as therapeutic product) development programs.

DATES: The meeting will be held on August 21, 2015, from 9 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the University of Maryland, Pharmacy Hall, 20 North Pine St., Baltimore, MD 21201. For additional travel and hotel information, please refer to www.pharmacy.umaryland.edu/cersibiomarkers. (FDA has verified the Web site addresses throughout this notice, but FDA is not responsible for subsequent changes to the web sites after this document publishes in the Federal Register).

FOR FURTHER INFORMATION CONTACT: Ann Anonsen, University of Maryland, Fischell Dept. of Bioengineering, 2207 Jeong H. Kim Bldg., College Park, MD 20742, 301-405-0285, FAX: 304-405-9953, aanonsen@umd.edu.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of this public workshop is to facilitate a unique opportunity for relevant stakeholders from industry, academia, and FDA to discuss biomarker development and provide a framework for evidentiary considerations required for biomarker qualification. The objective of the workshop is to discuss evidentiary considerations for use of clinical safety and enrichment biomarkers in drug development.

A. Registration

There is a registration fee to attend this meeting. The registration fee is charged to help defray the costs for facilities, materials, and food. Seats are limited, and registration will be on a first-come, first-served basis.

To register, please complete registration online at http://www.pharmacy.umaryland.edu/cersibiomarkers. (FDA has verified the Web address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the Federal Register). The costs of registration for the different categories of attendees are as follows:

Category	Cost
Industry Representatives	$50
Charitable Nonprofit/Academic	$50
Government	$0

B. Accommodations

Attendees are responsible for their own hotel accommodations. If you need special accommodations due to a disability, please contact Ann Anonsen (see FOR FURTHER INFORMATION CONTACT).

II. Comments

Interested persons may submit electronic comments to http://www.regulations.gov or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify all comments with the corresponding docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: July 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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