4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1658]

Characterizing and Communicating Uncertainty in the Assessment of Benefits and Risks in Drug Regulatory Decision-Making; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; rescheduling of public workshop; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rescheduling of a February 13, 2014, public workshop convened by the Institute of Medicine (IOM) entitled "Characterizing and Communicating Uncertainty in the Assessment of Benefits and Risks in Drug Regulatory Decision-Making," published in the Federal Register of January 10, 2014. Due to inclement weather, the Federal Government was closed on February 13, 2014. We are rescheduling the public workshop to May 12, 2014, and extending the comment period for the public docket.

DATES: The public workshop will be held on May 12, 2014, from 9 a.m. to approximately 5 p.m. Registration to attend the workshop must be received by May 7, 2014. See the SUPPLEMENTARY INFORMATION section for information on how to register for the workshop. Submit either electronic or written comments by June 11, 2014.

ADDRESSES: The workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, Sections B and C of the Great Room (rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop participants 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.

Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Sara Eggers, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, rm. 1166, Silver Spring, MD 20993-0002, 301-796-4904, FAX: 301-847-8443, email: sara.eggers@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of January 10, 2014 (79 FR 1877), FDA announced a 2-day public workshop on February 12-13, 2014. Due to the Federal Government closure on February 13, 2014, the workshop was postponed. We are rescheduling the public workshop to May 12, 2014, and extending the comment period to June 11, 2014 (see DATES). The purpose of the workshop is twofold: (1) To explore potential approaches to addressing and communicating uncertainty and (2) to identify key considerations on developing, evaluating, and incorporating potential approaches to addressing uncertainty into the assessment of benefits and risks in the human drug review process. Additional information about the purpose of the workshop, topics for discussion, and registration is available on FDA's Web site at http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm378861.htm, and is provided in the January 10, 2014, Federal Register notice, which is also available on FDA's Web site.

Dated: April 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-08591 Filed 04/15/2014 at 8:45 am; Publication Date: 04/16/2014]