

Dated: April 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

Advancing the Development of Pediatric Therapeutics: Pediatric Bone Health; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; rescheduling of public workshop.

The Food and Drug Administration's (FDA) Pediatric and Maternal Health Staff in the Center for Drug Evaluation and Research and the Office of Pediatric Therapeutics are announcing the rescheduling of a 1-day public workshop entitled "Advancing the Development of Pediatric Therapeutics (ADEPT): Pediatric Bone Health." The purpose of this initial workshop is to provide a forum to consider issues related to advancing pediatric regulatory science in the evaluation of bone health in pediatric patients. The workshop scheduled for March 4, 2014, was postponed due to unanticipated weather conditions and rescheduled for June 3, 2014.

Date and Time: The public workshop will be held on June 3, 2014, from 8 a.m. to 5:30 p.m. This workshop is being rescheduled because of a postponed workshop announced in the **Federal Register** of February 6, 2014 (79 FR 7205), originally scheduled for March 4, 2014.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 2, Rm. 2047, Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security procedures will be performed. Please visit the following Web site for location, parking, security, and travel information: <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

Contact Person: Denise Pica-Branco, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002,

301-796-1732, FAX: 301-796-9858, email: denise.picabranco@fda.hhs.gov.

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 PediatricBoneHealth@fda.hhs.gov before May 23, 2014. If you registered for the workshop before March 4, 2014, you *must re-register* for the workshop. For those without Internet access, please contact Denise Pica-Branco (see *Contact Person*) to register. Onsite registration *will not* be available.

If you need special accommodations due to a disability, please contact Denise Pica-Branco (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA has engaged experts to address challenging issues related to the evaluation of effects on bone health for products used to treat pediatric patients. Identification of signals in animal studies and adult clinical trials that warrant further clinical investigation and identification of biomarkers that may be predictive of bone health in children will be discussed. Additionally, strategies and methods to address the challenges of assessing long-term bone health for products used to treat pediatric patients will be discussed.

Information about this meeting is also available at <http://www.fda.gov/Drugs/NewsEvents/ucm132703.htm>.

Dated: April 10, 2014.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0406]

Proposed Strategy and Recommendations for a Risk-Based Framework for Food and Drug Administration Safety and Innovation Act Health Information Technology; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled "Proposed

Strategy and Recommendations for a Risk-Based Framework for Food and Drug Administration Safety and Innovation Act Health Information Technology." FDA, the Office of the National Coordinator for Health Information Technology (ONC), and the Federal Communication Commission (FCC) (collectively referred for the purpose of this notice as "the Agencies" ¹) seek broad input from stakeholders and experts on the proposed strategy and recommendations for a risk-based framework for the Food and Drug Administration Safety and Innovation Act (FDASIA) Health Information Technology (IT). The topic to be discussed is the FDASIA Health IT report that contains a proposed strategy and recommendations on an appropriate, risk-based framework for health IT that promotes innovation, protects patient safety, and avoids regulatory duplication.

DATES: Dates and Times: The public workshop will be held on May 13-15, 2014, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at National Institute of Standards and Technology, 100 Bureau Dr., Building 101, Red Auditorium, Gaithersburg, MD 20899-1070.

Contact Person: Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993, 301-796-5528, email: Bakul.patel@fda.hhs.gov.

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m. on May 2, 2014. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. Onsite registration on the day of the public workshop will not be available.

If you need special accommodations due to a disability, please contact Susan Monahan, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 4321, Silver Spring MD 20993, 301-796-5661, email: susan.monahan@fda.hhs.gov no later than April 29, 2014.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public

¹ ONC is not an agency, but an office, within the Department of Health and Human Services.