4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Substitutability of Generic Drugs: Perceptions and Reality; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the Johns Hopkins University Center of Excellence in Regulatory Science and Innovation, is announcing a public workshop entitled "Substitutability of Generic Drugs: Perceptions and Reality." The objective of this workshop is to discuss FDA and industry practices related to postmarket surveillance of generic drugs, postmarket generic drug research activities, public perceptions of generic drug quality and effectiveness, and verification of therapeutic equivalence of generic drugs. This workshop will also give stakeholders, including scientists from government, academia, and industry, patient advocacy groups, clinicians, pharmacists, and the general public an opportunity to provide their insights on future research needs in postmarket surveillance of generic drugs.

DATES: The public workshop will be held on November 18, 2016, from 8:30 a.m. to 4:30 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 stakeholders, including scientists from government, academia, and industry, patient advocacy groups, clinicians, pharmacists, and the general public to discuss marketed generic drugs. Generic drugs account for 88 percent of prescriptions in the United States. In light of the significant contributions of generic drugs to public health, it is important that tools are developed to monitor marketed generic drugs to ensure that they have the same safety and effectiveness as their reference listed drug. Specifically, this workshop will include presentations on: (1) Current generic drug surveillance practices at FDA and in industry, (2) public perception of generic drug quality and effectiveness, (3) generic drug substitution studies in patients, and (4) development of methods and tools to conduct postmarket surveillance of generic drugs. The workshop will include four panel sessions for interaction and discussion among the speakers and attendees.

Agenda: The agenda is available at http://www.fda.gov/scienceresearch/specialtopics/regulatoryscience/ucm521545.htm.

Registration: There is no registration fee to attend this public workshop. Seats are limited and registration will be on a first-come, first-served basis. Advance registration is required and is online only at

http://www.fda.gov/scienceresearch/specialtopics/regulatoryscience/ucm521545.htm. There will be no day-of, onsite registration.

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 registration and access to the Webcast link is available at http://www.fda.gov/scienceresearch/specialtopics/regulatoryscience/ucm521545.htm. 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. (FDA has verified these Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

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: October 11, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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