4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Clinical Trial Design Considerations for Malaria Drug Development Media; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop regarding clinical trial design considerations for malaria drug development. FDA is interested in discussing the scientific challenges pertaining to malaria drug development and malaria parasite detection methods used as endpoints in clinical trials. This public workshop is intended to provide information for and gain perspective from health care providers, other U.S. government agencies, public health organizations, academic experts, and industry on various aspects of the design of clinical trials evaluating new drugs to treat malaria. The input from this public workshop will also help in developing topics for future discussion.

Dates and Times: The public workshop will be held on June 30, 2016, from 8:30 a.m. to 4 p.m.

Location: The public workshop will be held at FDA's White Oak campus, 10903 New Hampshire Ave., Bldg 31 Great Rm., Silver Spring, MD 20993. Entrance for the public workshop 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. Seating is limited and available only on a first-come, first-served basis.

Contact Persons: Ms. Lori Benner and/or Ms. Jessica Barnes Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 22, rm. 6221, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-1300.

Registration: Registration is free for the public workshop. Interested parties are encouraged to register early. Seating will be available on a first-come, first-served basis. To register electronically, email registration information (including name, title, firm name, address, telephone, and fax number) to Malariaworkshop2016@fda.hhs.gov Persons without access to the Internet can call 301-796-1300 to register. Persons needing a sign language interpreter or other special accommodations should notify Ms. Jessica Barnes or Ms. Lori Benner (see Contact Persons) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop regarding scientific and regulatory considerations in the design of clinical trials of antimalarial drugs. Discussions will focus on developing two or more drugs used in combination, human challenge studies, issues/challenges associated with current detection methods, use of polymerase chain reaction, and other emerging rapid diagnostic tests in clinical trials.

The Agency encourages individuals, industry, health care professionals, researchers, public health organizations and other interested persons to attend this public workshop.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug

Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857. Transcripts will also be available on the Internet at http://wcms.fda.gov/FDAgov/Drugs/NewsEvents/ucm490084.htm?SSContributor=true approximately 45 days after the workshop.

Dated: May 4, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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