4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Clinical Development of Drugs for the Prevention of Infections Caused by Staphylococcus aureus in the Health Care Setting; 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 the clinical development of drugs for the prevention of serious infections caused by Staphylococcus aureus in the health care setting. This public workshop is intended to provide information for and gain perspective from health care providers, patients and patient advocacy organizations, academia, and industry on various aspects of clinical development of drugs to prevent Staphylococcus aureus infections including the design of clinical trials. The input from this public workshop will help in developing topics for further discussion.

Date and Time: The public workshop will be held on September 5, 2014, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at the DoubleTree by Hilton Hotel Washington DC, 8727 Colesville Rd., Silver Spring, MD 20910. The hotel's phone number is 301-589-5200.

Contact Persons: Carole Miller or Lori Benner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6217, Silver Spring, MD 20993-0002, 301-796-1300.

Registration: Registration is free for the public workshop. Interested parties are encouraged to register early. Seating is limited and 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 FDASTAPHWORKSHOP@fda.hhs.gov. Onsite registration the day of the workshop will be available, but advanced registration is preferred. Persons without access to the Internet can call 301-796-1300 to register.

If you need a sign language interpreter or other special accommodations, please notify Carole Miller or Lori Benner (see Contact Persons) at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

FDA is announcing a public workshop regarding scientific considerations in the clinical development of drugs for the prevention of serious infections caused by Staphylococcus aureus in the health care setting. Clinical care guidelines recommend a group of interventions to reduce health care associated infections in certain patients (for example, surgical patients, patients with a central-line catheter such as dialysis patients, and patients admitted to the intensive care unit). Some experts recommend specific interventions (such as nasal decolonization) to prevent infections caused by Staphylococcus aureus. Discussions will focus on the data that may demonstrate a clinical benefit in different populations of patients. In addition, discussions will include: (1) Possible approaches to demonstrating the clinical benefit of one intervention component in the setting of a group of interventions, (2) feasible approaches to identifying and recruiting patients at increased risk for serious infections caused by Staphylococcus aureus in clinical trials, and (3) feasible clinical trial designs that may provide evidence of efficacy to support drug approval.

The Agency encourages individuals, patient advocates, industry, consumer groups, health care professionals, researchers, 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 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Transcripts will also be available on the Internet at http://www.fda.gov/Drugs/NewsEvents/ucm132703.htm approximately 45 days after the workshop.

Dated: August 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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