DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0622]

Draft Guidance for Industry on Best Practices in Developing Proprietary Names for Drugs; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the draft guidance entitled ''Best Practices in Developing Proprietary Names for Drugs,'' which published in the **Federal Register** of May 29, 2014 (79 FR 30852). FDA is reopening the comment period in response to several requests for additional time and to allow interested persons more time to submit comments.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 15, 2014.

ADDRESSES: 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.

FOR FURTHER INFORMATION CONTACT: Kellie Taylor, Center for Drug Evaluation and Research, Food and Drug Administration, Office of Surveillance and Epidemiology, 10903 New Hampshire Ave., Bldg. 22, Rm. 4418, Silver Spring, MD 20993–0002, 301–796–0157.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 29, 2014 (79 FR 30852), FDA announced the availability of a draft guidance for industry entitled ''Best Practices in Developing Proprietary Names for Drugs.'' In that document, FDA requested comments on the draft guidance, which describes best practices for developing and selecting proposed proprietary names to minimize medication errors. Interested persons were originally given until July 28, 2014, to submit comments on the draft guidance to ensure that the Agency considers their comments before it begins work on the final version of the guidance.

The Agency has received several requests to reopen the comment period for an additional 60 days. The requests conveyed concern that the original 60-day comment period did not allow sufficient time to develop a meaningful or thoughtful response.

FDA has considered the requests and will reopen the comment period for an additional 30 days. The Agency believes that an additional 30 days allows adequate time for interested persons to submit comments without significantly delaying the Agency's consideration of these important issues.

II. How to Submit Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: August 8, 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]

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