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Draft Guidance for Industry on Best Practices in Developing Proprietary Names for Drugs; Reopening of the Comment Period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SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the draft guidance entitled ''Best Practices in Developing Proprietary Names for Drugs,'' which published in the **Federal Register** of May 29, 2014 (79 FR 30852).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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 15, 2014.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In the **Federal Register** of May 29, 2014 (79 FR 30852), FDA announced the availability of a draft guidance for industry entitled ''Best Practices in Developing Proprietary Names for Drugs.'' In that document, FDA requested comments on the draft guidance, which describes best practices for developing and selecting proposed proprietary names to minimize medication errors. Interested persons were originally given until July 28, 2014, to submit comments on the draft guidance to ensure that the Agency considers their comments before it begins work on the final version of the guidance.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.

[FR Doc. 2014–19261 Filed 8–13–14; 8:45 am]

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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

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.

[FR Doc. 2014–19257 Filed 8–13–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0334]

Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule entitled ''Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements'' that appeared in the **Federal Register** of June 10, 2014 (79 FR 33072). The document amended FDA's postmarketing safety reporting regulations for human drug and biological products to require that persons subject to mandatory reporting requirements submit safety reports in an electronic format that FDA can process, review, and archive. The document was published with incorrect information regarding the availability of the International Conference on Harmonization's (ICH) data elements for postmarketing safety reports. The document also published with an incorrect statement regarding the impact of the final rule on small entities. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Jean Chung, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4466, Silver Spring, MD 20993–0002, 301–796–1874; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7268, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 10, 2014, in FR Doc. 2014–13480, the following corrections are made:

1. On page 33074, in the first column, under ''Introduction'', footnote 6 is corrected to read: ''ICH data elements for postmarketing safety reports are provided in the guidance for industry entitled 'E2B Electronic Transmission of Individual Case Safety Reports Implementation Guide—Data Elements and Message Specification,' available at *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm.''*

2. On page 33084, in the second column, under ''Analysis of Impacts'', the first full sentence is corrected to read: ''Because the average small entity submits few safety reports and the Agency's Web-based system for submitting reports electronically will require little additional cost per report, the Agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.''

Dated: August 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–19255 Filed 8–13–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than September 15, 2014.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Federal Tort Claims Act (FTCA) Free Clinic Application OMB No. 0915–0293—Revision.

Abstract: Under 42 U.S.C. 233(o) and Program Assistance Letter (PAL) 2014–04, ''Calendar Year 2015 Federal Tort Claims Act (FTCA) Deeming Application for Free Clinics,'' free clinics are required to submit annual applications for deeming of qualified health care professionals, board members, officers, and contractors for purposes of FTCA medical malpractice coverage for negligent acts and omissions that arise from the performance of medical, surgical, dental, or related functions within the scope of the covered individual's deemed employment. HRSA proposes modifying the application forms to reflect changes to eligible personnel made by section 10608 of the Affordable Care Act, which extended FTCA medical malpractice liability protection to free clinic board members, officers, employees, and contractors. Additionally, HRSA proposes upgrading the application to provide for electronic submissions. Specifically, the modifications include: (1) Inclusion of board members, officers, employees, and contractors into one comprehensive application that also includes volunteer health care professionals and (2) a fully electronic application that can be submitted via HRSA's web-based application system, the Electronic Handbooks (EHBs). It is anticipated that