4164-01-P

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Draft Guidance for Industry on Best Practices in Developing Proprietary Names for Drugs; Reopening of the Comment Period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SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the draft guidance entitled "Best Practices in Developing Proprietary Names for Drugs," which published in the Federal Register of May 29, 2014 (79 FR 30852).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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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In the Federal Register of May 29, 2014 (79 FR 30852), FDA announced the availability of a draft guidance for industry entitled "Best Practices in Developing Proprietary Names for Drugs." In that document, FDA requested comments on the draft guidance, which describes best practices for developing and selecting proposed proprietary names to minimize medication errors. Interested persons were originally given until July 28, 2014, to submit comments on the draft guidance to ensure that the Agency considers their comments before it begins work on the final version of the guidance.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 08/13/2014 at 8:45 am; Publication Date: 08/14/2014]