4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0447]

Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices; Draft Guidance for Industry; Reopening of the Comment Period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SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice of availability of the draft guidance entitled "Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices," published in the Federal Register of June 18, 2014. FDA is reopening the comment period in response to a request 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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN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:

Regarding human prescription drugs: Julie Chronis, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993-0002, 301-796-1200.

Regarding human prescription biological products: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

Regarding animal prescription drugs: Thomas Moskal, Center for Veterinary Medicine (HFV-216), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9300.

Regarding medical devices for human use: Deborah Wolf, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3414, Silver Spring, MD 20993-0002, 301-796-5732.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of June 18, 2014 (79 FR 34760), FDA announced the availability of a draft guidance for industry entitled "Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices." In that document, FDA requested comments on the draft guidance, which responds to (among other things) stakeholder requests for specific guidance. The draft guidance describes FDA's current thinking on how manufacturers, packers, and distributors of prescription human and animal drugs and medical devices for human use, including biological products, should respond, if they choose to respond, to misinformation related to a firm's own FDA-approved or cleared products when that information is created or disseminated by independent third parties. The draft guidance also updates and clarifies FDA's policies on the correction of misinformation created

or disseminated by independent third parties on the Internet or through social media platforms, regardless of whether that misinformation appears on a firm's own forum, an independent third-party forum, or a Web site. The draft guidance represents FDA's current thinking on specific aspects of FDA's evolving consideration of social media platforms and other Internet-related matters. FDA actively continues to review, analyze, and develop approaches to a variety of topics related to the labeling and advertising of medical products, including the development of this and other guidance addressing the use of social media platforms and the Internet.

Interested persons were originally given until September 16, 2014, to submit comments on the draft guidance.

II Request for Comments

Following publication of the June 18, 2014, notice, FDA received a request for additional time to develop meaningful and thoughtful comments, especially in light of the concurrent comment period with another draft guidance entitled "Internet/Social Media Platforms with Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices" published elsewhere in this volume of the Federal Register.

FDA has considered the request 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.

III. 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: September 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-23064 Filed 09/26/2014 at 8:45 am; Publication Date: 09/29/2014]