Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002 *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On April 22, 2014, the Agency submitted a proposed collection of information entitled ''Adverse Event Program for Medical Devices (Medical Product Safety Network (MedSun))'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0471. The approval expires on May 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: June 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–14252 Filed 6–17–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0397]

Draft Guidance for Industry on Internet/Social Media Platforms With Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Internet/Social Media Platforms with Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices.'' This draft guidance responds to, among other things, stakeholder requests for specific guidance and describes FDA's current thinking on how manufacturers, packers, and distributors (firms) of prescription human and animal drugs (drugs) and medical devices for human use (devices), including biological products, that choose to present benefit information should present both benefit and risk information within advertising and promotional labeling of their FDA-regulated medical products on electronic/digital platforms that are associated with character space limitations, specifically on the Internet and through social media or other technological venues (Internet/social media). The draft guidance represents FDA's current thinking on specific aspects of FDA's evolving consideration of social media platforms and other Internet-related matters.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 continues actively 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.

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 16, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance 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: Jean-Ah Kang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993, 301–796–1200.

Regarding prescription human 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: Dorothy McAdams, 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, Silver Spring, MD 20993, 301–796–5732.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Internet/Social Media Platforms with Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices.''

On November 12 and 13, 2009, FDA held a public hearing entitled ''Promotion of Food and Drug Administration—Regulated Medical Products Using the Internet and Social Media Tools'' to provide an opportunity for broad public participation and comment on the following questions that relate specifically to promotional issues:

1. For what online communications are manufacturers, packers, or distributors accountable?

2. How can manufacturers, packers, or distributors fulfill regulatory requirements (e.g., fair balance, disclosure of indication and risk information, and postmarketing submission requirements) in their internet and social media promotion, particularly when using tools that are associated with space limitations and tools that allow for real-time communications (e.g., microblogs and mobile technology)?

3. What parameters should apply to the posting of corrective information on Web sites controlled by third parties?

4. When is the use of links appropriate?

Subsequent to the live testimony heard at the public hearing, FDA received 72 comments to the docket.

Specifically, this draft guidance presents considerations to illustrate FDA's thinking on factors that are relevant to the communication of benefit and risk information on Internet/social media platforms with character space limitations. Examples of Internet/

social media platforms with character space limitations include online microblog messaging (e.g., messages on Twitter or ''tweets,'' which are currently limited to 140 character spaces per tweet) and online paid search (e.g., sponsored links on search engines such as Google and Yahoo, which have limited character spaces as well as other platform-imposed considerations).

Please note that this draft guidance does not address promotion via product Web sites, Web pages on social media networking platforms (e.g., individual product pages on Web sites such as Facebook, Twitter, YouTube), and online Web banners as the Agency believes that these specific types of Internet/social media platforms do not impose the same character space constraints as online microblog messaging and online paid search. This draft guidance also does not address responsive Web design or other technology-specific layout features that may result in product promotion presentations that differ depending on the technology used to view them (e.g., desktop computer monitors, mobile devices, tablets).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on presenting risk and benefit information for prescription drugs and medical devices on Internet/social media platforms with character space limitations. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collections of information in 21 CFR 202.1 and 21 CFR parts 801 and 809 have been approved under OMB control numbers 0910–0686 and 0910–0485, respectively. In accordance with the PRA, prior to publication of any final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to previously approved collections of information found in FDA regulations or guidances.

III. 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm*, *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm*, *http://www.fda.gov/MedicalDevices/deviceregulationandguidance/guidancedocuments/default.htm*, or *http://www.regulations.gov.*

Dated: June 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–14220 Filed 6–17–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0447]

Draft Guidance for Industry on Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices.'' This draft guidance responds to (among other things) stakeholder requests for specific guidance and describes FDA's current thinking on how manufacturers, packers, and distributors (firms) of prescription human and animal drugs (drugs) and medical devices for human use (devices), 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. This draft guidance 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 or an independent third-party forum or 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 continues actively 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.

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 16, 2014. Submit written comments on the proposed collection of information by August 18, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002; to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855; or to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section