

Dated: September 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0623]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Voluntary Cosmetic Registration Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Voluntary Cosmetic Registration Program” has been approved by the Office of Management and 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 July 8, 2014, the Agency submitted a proposed collection of information entitled “Voluntary Cosmetic Registration Program” 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 0910-0027. The approval expires on August 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: September 23, 2014.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0397]

Internet/Social Media Platforms With Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices; Draft Guidance for Industry; Reopening of the Comment Period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SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice of availability of the draft guidance entitled “Internet/Social Media Platforms with Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical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 October 29, 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:

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, Rm. 3414, Silver Spring, MD 20993, 301-796-5732.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of June 18, 2014 (79 FR 34759), FDA announced 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.” 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, 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. 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: Correcting Independent Third-Party Misinformation About 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