Dated: September 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–23059 Filed 9–26–14; 8:45 am]

BILLING CODE 4164–01–P

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.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–23066 Filed 9–26–14; 8:45 am]

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With Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices; Draft Guidance for Industry; Reopening of the Comment Period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SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice of availability of the draft guidance entitled ''Internet/Social Media Platforms with Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical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

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. 2014–23063 Filed 9–26–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0125]

Guidance for Industry and Food and Drug Administration Staff; Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007.'' This guidance provides information on how a manufacturer may establish that a tobacco product was commercially marketed in the United States as of February 15, 2007. The guidance includes a description of the types of evidence recommended to demonstrate that a tobacco product was commercially marketed in the United States as of February 15, 2007.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007'' to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

Submit electronic comments on the 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007.'' In this guidance, FDA provides recommendations on how a manufacturer can demonstrate that a tobacco product was commercially marketed (other than exclusively in test markets) in the United States as of February 15, 2007. In the guidance document, FDA refers to tobacco products that were commercially marketed (other than exclusively in test markets) in the United States as of February 15, 2007, as grandfathered tobacco products. Grandfathered tobacco products are not considered new tobacco products and thus are not subject to the premarket requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (section 910; 21 U.S.C. 387j). A grandfathered tobacco product may serve as the predicate tobacco product in a 905(j) report (demonstrating substantial equivalence) for a new tobacco product (section 905(j)(1)A)(i) of the FD& C Act, 21 U.S.C. 387e(j)(1)(A)(i)). FDA recommends that information supporting a grandfather designation may include, among other things, dated copies of advertisements, dated catalog pages, and dated promotional material.

In the **Federal Register** of April 25, 2011 (76 FR 22903), FDA announced the availability of the draft guidance of the same title. After considering the comments on the draft guidance, FDA made minor editorial changes to improve clarity.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on this topic. 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 statute and regulations.

III. Paperwork Reduction Act of 1995

This 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 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0775.

IV. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* 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.*

V. Electronic Access

An electronic version of the guidance document is available on the Internet at *http://www.regulations.gov* and *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm.*

Dated: September 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–23058 Filed 9–26–14; 8:45 am]

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