information. Six comment submissions were received, some of which included multiple comments.

(Comment) Regarding the clarity of information collected, several comments indicated some confusion between the information being collected and the information needed to support an exemption request.

(Response) Section 1107.1(a) sets out the general requirements for requesting an exemption, but a manufacturer will need to determine how to meet the requirements for any of its new products that use the pathway. FDA intends to consider issuing a regulation or guidance to further clarify terms as experience is gained with the pathway.

(Comment) A few comments questioned the quality of the information being requested.

(Response) We disagree that the information required in an exemption request is not sufficient. We believe the information requested is what FDA needs to make a determination on an exemption request. Furthermore, several commenters also agreed with the sufficiency of the information needed to support an exemption request.

(Comment) Many comments addressed the accuracy of FDA's estimate of the burden for requesting a modification to an exemption request and questioned whether this burden was underestimated. Additionally, there was reference to the submittal of duplicative information.

(Response) FDA disagrees with these comments. We believe the burden estimates are appropriate and reflect the information needed by FDA when reviewing an exemption request. FDA also disagrees that there is duplicative information requested. The regulations implement the requirements of the FD&C Act for the exemption pathway to market. The commenters may be referring to the other notification and reporting requirements related to additives, such as those in section 904(c) of the FD&C Act (21 U.S. C. 387d(c)), but those requirements are not in the scope of this information collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
21 CFR 1107.1(b): Preparation of tobacco product exemption from substantial equivalence request	500	1	500	12	6,000
21 CFR 1107.1(c): Preparation of additional information for tobacco product exemption from substantial equivalence request	150	1	150	3	450
21 CFR 25.40: Preparation of an environmental assessment	500	1	500	12	6,000
Section 905(j)(1)(A)(ii) of the FD&C Act: If exemption granted, report submitted to demonstrate tobacco product is modified under section 905(j)(3), modifications are to a product that is commercially marketed and compliant product, and modifications covered by exemptions granted by Secretary pursuant to section 905(j)(3)	750	1	750	3	2,250
Total					14,700

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that 500 requests for exemption will be submitted annually, and that it will take approximately 12 hours to prepare an exemption request. FDA also estimates that up to 30 percent (150) of the initial requests for information may require additional information in support of the initial exemption request, and it is expected that it will take an average of 3 hours to prepare the additional information. FDA also estimates that 750 manufacturers will take approximately 12 hours to prepare and submit an EA under part 25 in accordance with the requirements of § 25.40, as referenced in § 1107.1(b)(9).

FDA estimates that 750 respondents will take 3 hours to prepare a report under section 905(j)(1)(A)(ii) of the FD&C Act, which requires a manufacturer to submit a report at least 90 days prior to making an introduction or delivery into interstate commerce for commercial distribution of a tobacco product. The report will contain the manufacturer's basis that the tobacco product is modified within the meaning of section 905(j)(3) of the FD&C Act, the modifications are to a product that is commercially marketed and compliant with the FD&C Act, the modifications are covered by exemptions granted pursuant to section 905(j)(3), and a listing of actions taken to comply with any applicable requirements of section 907 of the FD&C Act (21 U.S.C. 387g). FDA's estimates are based on experience with and information on other FDA-regulated products and indications from industry.

Dated: June 11, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–14253 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–2013–N–1439]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Adverse Event Program for Medical Devices (Medical Product Safety Network)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Adverse Event Program for Medical Devices (Medical Product Safety Network (MedSun))'' 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 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/