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Please note that this draft guidance does not address promotion via product Web sites, Web pages on social media networking platforms (e.g., individual product pages on Web sites such as Facebook,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 This draft guidance also does not address responsive Web design or other technology-specific layout features that may result in product promotion presentations that differ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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on presenting risk and benefit information for prescription drugs and medical devices on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This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995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

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: 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

FDA 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.'' On November 12–13, 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.

This draft guidance provides FDA's recommendations regarding 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 created or disseminated by independent third parties related to a firm's own FDA-approved or cleared products on the Internet or through social media platforms.

This draft guidance provides FDA's recommendations to firms that voluntarily choose to correct misinformation that appears on the Internet or through social media platforms. This draft guidance discusses the type of information that is considered misinformation, recommends parameters for corrective information, and recommends approaches to correcting misinformation. It refers only to misinformation that is created or disseminated by an independent third party and that is not produced by, or on behalf of, or prompted by the firm in any particular. When a firm chooses to correct misinformation in a truthful and non-misleading manner and according to the recommendations in this draft guidance, FDA does not intend to object if the corrective information voluntarily provided by the firm does not satisfy otherwise applicable regulatory requirements regarding labeling or advertising, if any. If a firm chooses to respond to misinformation about its products using non-truthful or misleading information or in a manner other than that recommended in this draft guidance, however, FDA may object if the information provided by the firm does not comply with applicable regulatory requirements related to labeling or advertising, if any.

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 correcting misinformation created or disseminated by independent third parties. 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

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices.

Description of Respondents: Respondents to this collection of information are manufacturers, packers, and distributors (firms) of prescription human and animal drugs and medical devices for human use, including biological products.

Burden Estimate: The draft guidance pertains to the correction of misinformation created or disseminated by independent third parties related to a firm's own FDA-approved or -cleared products on the Internet or through social media platforms.

The draft guidance explains FDA's current policy position that a firm may voluntarily correct misinformation about its own FDA-approved or -cleared products that is created or disseminated by independent third parties who are not under the firm's control or

influence. If a firm does so in a truthful and non-misleading manner and in accordance with the recommendations in the draft guidance, FDA does not intend to object if the corrective information voluntarily provided by the firm does not satisfy otherwise applicable regulatory requirements related to labeling and advertising, if any.

Because the draft guidance recommends that a firm disclose certain information to others when correcting misinformation created or disseminated by independent third parties, this ''third-party disclosure'' constitutes a ''collection of information'' under the PRA. In addition, the PRA is triggered because the draft guidance also recommends that a firm maintain certain records related to this disclosure—the content of the misinformation, where the misinformation appeared, the date the misinformation appeared or was located, the corrective information that was provided, and the date the corrective information was provided.

Specifically, the draft guidance recommends that firms provide appropriate truthful and non-misleading corrective information, or alternatively, it may provide a reputable source from which to obtain the correct information. For the purposes of the draft guidance, to be considered ''appropriate corrective information,'' a firm's communication should:

- Be relevant and responsive to the misinformation;
- Be limited and tailored to the misinformation;
- Be non-promotional in nature, tone, and presentation;
- Be accurate;
- Be consistent with the FDA-required labeling for the product;
- Be supported by sufficient evidence, including substantial evidence, when appropriate, for prescription drugs;
- Either be posted in conjunction with the misinformation in the same area or forum (if posted directly to the forum by the firm), or should reference the misinformation and be intended to be posted in conjunction with the misinformation (if provided to the forum operator or author); and
- Disclose that the person providing the corrective information is affiliated with the firm that manufactures, packs, or distributes the product.

The FDA-required labeling should be included or provided in a readily accessible format. (As two examples, a firm may provide a link that goes directly to the FDA-required labeling or may provide a link that opens a new window to a portable document format (PDF) file.)

The draft guidance also recommends that a firm correct all the misinformation in one clearly defined portion of a forum, but it is not expected to correct each occurrence of independent third-party misinformation throughout an entire forum. When a firm decides to correct all the misinformation in one clearly defined portion of a forum, the firm should clearly identify the misinformation it is correcting, define the portion of the forum it is correcting, describe the location or the nature of the misinformation that was corrected, and provide a date the correction is made.

A firm may provide the correct information to the independent author for the author to incorporate or request the author remove the misinformation or allow comments to be posted. The firm may request that the site administrator remove the misinformation or allow comments to be posted.

FDA estimates that approximately 400 firms annually undertake correcting 50 pieces of misinformation created or disseminated by independent third parties on the Internet or through social media. FDA estimates that it will take firms approximately 3 hours to correct misinformation as recommended in the draft guidance.

FDA also estimates that approximately 20,000 records will be maintained by firms that have chosen to correct misinformation created or disseminated by independent third parties on the Internet or through social media and that each record will take approximately 30 minutes to prepare and maintain.

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Draft guidance on correcting independent third-party misinformation	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Hours per record	Total hours
Records related to the correction of independent third-party misinformation.	400	50	20,000	0.5 (30 minutes)	10,000

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

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Draft guidance on correcting independent hird-party misinformation	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Hours per disclosure	Total hours
Corrections of independent third-party misinformation	400	50	20,000	3	60,000

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

III. Comments

In addition to general comments, FDA specifically requests comments on the following issue: The draft guidance recommends that a firm should identify the misinformation or define the portion of the forum it is correcting and should correct all the misinformation that appears in that clearly defined portion. Is this an appropriate and effective way for firms to correct misinformation without correcting all misinformation that might appear in a forum? When or under what conditions should a sponsor choose a specific portion of a forum to correct? What factors, such as the platform(s) or technology(ies) that can be used to view the forum, the relative location of pieces of misinformation the firm chooses to correct, the nature of the forum, the quantity of information, and the length of time the forum encompasses, should be taken into account in choosing the portion of a forum to correct?

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. 2014–14221 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–P–0231]

Medical Devices; Exemption From Premarket Notification: Wheelchair Elevator

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has received a petition requesting exemption from the premarket notification requirements for a wheelchair elevator device commonly known as a manually operated portable wheelchair lift. This device is used to provide a means for a disabled person to move a wheelchair from one level to another. FDA is publishing this notice to obtain comments in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit either electronic or written comments by July 18, 2014.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2014–P–0231, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following way:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2014–P–0231 for this notice. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michael J. Ryan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1615, Silver Spring, MD 20993–0002, 301–796–6283, *michael.ryan@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (1976 amendments) (Public Law 94–295), as amended by the Safe Medical Devices Act of 1990 (Public Law 101–629), devices are to be classified into class I (general controls) if there is information showing that the general controls of the FD&C Act are sufficient to assure safety and effectiveness; into class II (special controls) if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval) if there is insufficient information to support classifying a device into class I or class II and the device is a life sustaining or life supporting device, or is for a use which is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the FD&C Act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices), are classified through the premarket notification process under section 510(k) of the FD&C Act (21 U.S.C. 360(k). Section 510(k) of the FD&C Act and the implementing regulations, 21 CFR part 807, require persons who intend to market a new device to submit a premarket notification (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Public Law 105–115). Section 206 of FDAMA, in part, added a new section, 510(m), to the FD&C Act. Section 510(m)(1) of the FD&C Act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the FD&C Act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the FD&C Act provides that 1 day after date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and