Guidance for Industry

Internet/Social Media Platforms with Character Space Limitations— Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices

DRAFT GUIDANCE

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June 2014
Advertising

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Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's or Agency's) current thinking on this topic.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. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title pages of this guidance.

I. INTRODUCTION

This draft guidance is intended to describe FDA's current thinking about how manufacturers, packers, and distributors (firms) of prescription human and animal drugs (drugs) and medical devices for human use (devices)[2] that choose to present benefit information should present both benefit and risk information within advertising and promotional labeling (sometimes collectively referred to in this guidance document as "promotion") 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). 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

[1] This draft guidance has been prepared by the Office of Prescription Drug Promotion (OPDP) in the Center for Drug Evaluation and Research (CDER) in consultation with the Center for Biologics Evaluation and Research (CBER), the Center for Veterinary Medicine (CVM), and the Center for Devices and Radiological Health (CDRH).

[2] The recommendations in this draft guidance also apply to biological products that are approved for marketing under section 351 of the Public Health Service Act (PHS Act). Because each biological product also meets the definition of "drug" or "device" under the Federal Food, Drug, and Cosmetic Act (FD&C Act), it is also subject to regulation under provisions of the FD&C Act applicable to drugs or devices, as well as the regulations implementing these provisions, except that a biological product licensed under section 351 of the PHS Act is not required to have an approved new drug application under section 505 of the FD&C Act (21 U.S.C. 355). See PHS Act section 351(j) (42 U.S.C. 262(j)). References to "drugs" and "devices" in this guidance therefore also include biological products that fall within each of those definitions. The recommendations in this draft guidance do not apply to veterinary biological products regulated under the Virus-Serum-Toxin Act (21 U.S.C. 151, et seq.) by the U.S. Department of Agriculture. This draft guidance does not address devices solely intended for use in animals.

considerations).[3] 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.[4]

Please note that this draft guidance does not address promotion via product websites, webpages on social media networking platforms (e.g., individual product pages on websites 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).

FDA's guidance documents, including this draft guidance, do not establish legally enforceable rights or responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Agency has responsibility for regulating the manufacture, sale, and distribution of drugs and medical devices in the United States. This authority includes oversight of the labeling of drugs and medical devices (21 U.S.C. 352(a)) and the advertising of prescription drugs and restricted medical devices (21 U.S.C. 352(n), (q), and (r)).[5]

Section 201(m) of the FD&C Act defines *labeling* as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article" (21 U.S.C. 321(m)).[6] The U.S. Supreme Court has explained that the language "accompanying such article" in the "labeling" definition is interpreted broadly, to include materials that supplement or explain an article. No physical attachment between the materials and the article is necessary; rather, it is the textual relationship between the items that is significant (*Kordel v.*

[3] While online microblog messaging and online paid search examples are specifically illustrated within this draft guidance, FDA's recommendations may also apply to advertising and promotional labeling on other types of Internet/social media platforms with character space limitations.

[4] This guidance document focuses on use of character-space-limited platforms by firms to make claims about their legally marketed drugs and devices that are consistent with their approved or required labeling. Representations by a firm in character-space-limited platforms may also provide evidence of the intended use of the product, but that issue is not the focus of this draft guidance.

[5] Devices may become restricted by regulation issued under section 520(e) of the FD&C Act (21 U.S.C. 360j(e)), by performance standard issued pursuant to section 514(a)(2)(B)(v) (21 U.S.C. 360d(a)(2)(B)(v)), or by order approving an application for premarket approval (i.e., a PMA) pursuant to section 515(d)(1)(B)(ii) (21 U.S.C. 360e(d)(1)(B)(ii)).

[6] See also 21 CFR 1.3(a).

United States, 335 U.S. 345, 350 (1948)). FDA generally recognizes two types of labeling: (1) FDA-required labeling[7] and (2) promotional labeling. Promotional labeling is generally any labeling, other than the FDA-required labeling, that is devised for promotion of the product. Examples of materials that may be considered promotional labeling pieces for prescription drugs are described in 21 CFR 202.1(l)(2). The scope of labeling for prescription medical devices is described in 21 CFR 801.109.

The FD&C Act does not define what constitutes an "advertisement," but FDA regulations provide several examples, including "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems" (21 CFR 202.1(l)(1)).

Under the FD&C Act and FDA's implementing regulations, promotional labeling for drugs and devices and advertisements for prescription drugs and restricted devices misbrand the product if they make representations about the use of a firm's product without disclosing certain information about the product's risk (FD&C Act sections 502(a)(n)(q)(r), 201(n); 21 CFR 1.21(a); 21 CFR 201.1). When using Internet/social media platforms with character space limitations for product promotion, firms should consider the following provisions[8]:

- Any promotional labeling for a drug or device must be truthful and non-misleading (FD&C Act sections 502(a), 201(n)).

- Any promotional labeling that makes claims about a firm's prescription drug or prescription device must include certain information, such as the indicated use of the product and the risks associated with use of the product (21 CFR 201.100(d), 201.105(d) and 801.109(d)).

- Pursuant to section 502(c) for drugs and devices, information required to appear on the label or labeling must be placed prominently thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

[7] Much FDA-required labeling is subject to FDA review and approval. For example, after drafting by the manufacturer, labeling is reviewed and approved by FDA as part of the new drug application (NDA), new animal drug application (NADA), biologics license application (BLA) or premarket approval application (PMA) review (see 21 CFR 314.50(c)(2), 514.1(b)(3), 601.2(a), 814.20(b)(10) and 814.44(d)). For devices that are subject to premarket notification (510(k)) requirements, the 510(k) must contain the proposed labeling sufficient to describe the device, its intended use, and the directions for its use (21 CFR 807.87(e)). All devices, including those exempt from premarket review, are subject to the requirements of applicable labeling regulations, including requirements for adequate directions for use (see 21 CFR Part 801). For a prescription drug or prescription device to be exempted from the FD&C Act's requirement of adequate directions for use (21 U.S.C. 352(f)(1)), its FDA-required labeling must contain, among other information, information addressing product hazards and other risk information, as specified in FDA regulations (21 CFR 201.100(d)(1), (3), 201.105(c)(1), and 801.109).

[8] This is not an exhaustive list.

- Any advertising that makes representations about the use of a firm's prescription drug must include certain risk information (FD&C Act section 502(n); 21 CFR 202.1).[9] Similarly, section 502(r) of the FD&C Act requires a "brief statement of intended uses" and relevant risk information in restricted-device advertising. Section 502(q) of the FD&C Act provides that restricted-device advertising that "is false or misleading in any particular" misbrands the device. Note that "reminder" promotion, which calls attention to the name of a product but does not make any representations or suggestions about the product, is exempt from many of these labeling and advertising disclosure requirements (21 CFR 200.200, 201.100(f), 201.105(d)(2), 202.1(e)(2)(i), 801.109(d)).[10]

- Prescription drug advertisements must present a fair balance between information relating to risk and information relating to benefit (21 CFR 202.1(e)(5)(ii)). In addition, risk information must be presented with a prominence and readability reasonably comparable to claims about drug benefits (21 CFR 202.1(e)(7)(viii)).

- Furthermore, for prescription drug advertisements to be truthful and non-misleading, they must contain risk information in each part, as necessary, to qualify any representations and/or suggestions made in that part about the drug. The risk information may be concise if supplemented by a prominent reference to the presence and location elsewhere in the advertisement of a more complete discussion (21 CFR 202.1(e)(3)(i)).

- In addition, section 201(n) of the FD&C Act provides that in determining whether a drug or device is misbranded because its labeling or advertising is misleading, it must be considered whether the labeling or advertising fails to reveal facts that are material with respect to possible consequences of the use of the product as represented in the labeling or advertising or under conditions of use that are customary or usual.

Risk information should be comparable in content and prominence to benefit claims within the product promotion (i.e., a balanced presentation). Achieving a balanced presentation requires firms to carefully consider the desired benefit claims and risk profiles for their products when choosing a promotional platform. FDA acknowledges that Internet/social media platforms associated with character space limitations may pose challenges for firms in providing a balanced presentation of both risks and benefits of medical products, as discussed above.

[9] As set forth above, with regard to devices, the Agency's authority over promotional labeling extends to all devices, whereas its authority over advertising extends to restricted devices. Regardless of the type of device, FDA encourages firms to use the practices outlined in this guidance to benefit the public health.

[10] This draft guidance does not apply to those *reminder* promotions (labeling or advertising that calls attention to the name of a drug or device but does not include indications, dosage recommendations, or other information) that are exempted by regulation from the requirements under the FD&C Act for the disclosure of risk information. See 21 CFR 200.200, 201.100(f), 201.105(d)(2), 202.1(e)(2)(i), 801.109(d). But see 21 U.S.C. 352(r) (requiring certain risk information in all restricted-device advertisements).

FDA is issuing this draft guidance to aid firms in effectively communicating benefit and risk information in product promotion using character-space-limited platforms such as online microblog messaging and online paid search.[11] However, regardless of the platform, truthful, accurate, non-misleading, and balanced product promotion best serves the public health. For some products, particularly those with complex indications or extensive serious risks, character space limitations imposed by platform providers may not enable meaningful presentations of both benefit and risk (although they may be sufficient for "reminder" promotions—see footnote 10). If an accurate and balanced presentation of both risks and benefits of a specific product is not possible within the constraints of the platform, then the firm should reconsider using that platform for the intended promotional message (other than for permitted reminder promotion).

III. OVERVIEW OF FDA'S POLICY ON PRESENTING RISK AND BENEFIT INFORMATION ON INTERNET/SOCIAL MEDIA PLATFORMS WITH CHARACTER SPACE LIMITATIONS

Regardless of character space constraints that may be present on certain Internet/social media platforms, if a firm chooses to make a product benefit claim, the firm should also incorporate risk information within the same character-space-limited communication. The firm should also provide a mechanism to allow direct access to a more complete discussion of the risks associated with its product.

Section IV discusses general factors that firms should consider in the communication of benefit information on Internet/social media platforms with character space limitations, which directly impacts the communication of risk information. Section V explains in detail the factors that FDA considers in the disclosure of risk information on Internet/social media platforms with character space limitations. Section VI provides firms with additional recommendations for the inclusion of other product information (including certain required product information other than risk/benefit information, as applicable) on Internet/social media platforms with character space limitations.

Please note that sections IV, V, and VI provide hypothetical examples[12] that, when taken in totality, illustrate FDA's recommendations for how firms may disseminate product promotion on Internet/social media platforms with character space limitations. The examples build on the considerations set forth from the previous section and are numbered accordingly to identify related examples (e.g., examples 1A, 1B, and 1C are related to the same hypothetical product—example 1A incorporates benefit information, example 1B adds risk information to example 1A, and example 1C provides additional recommendations for examples 1A and 1B to illustrate, in totality,

[11] CDER's OPDP, formerly known as the Division of Drug Marketing, Advertising, and Communications (DDMAC), issued 14 enforcement letters involving sponsored link promotion on Apr 2, 2009 (see FDA's enforcement website available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/ucm055773.htm).

[12] The hypothetical examples involve fictitious products and are not an endorsement of the fictitious product names.

a final example of promotion on an Internet/social media platform with character space limitations to which the Agency would not intend to object).

FDA recommends that firms first carefully consider the complexity of the indication and risk profiles for each of their products to determine whether a character-space-limited platform is a viable promotional tool for a particular product, and then take the factors, recommendations, and hypothetical examples outlined in this guidance document into account when developing benefit and risk presentations. The public health is best served when risk and effectiveness information about drug and device products is clearly and accurately communicated.

IV. GENERAL FACTORS CONSIDERED IN THE COMMUNICATION OF BENEFIT INFORMATION ON INTERNET/SOCIAL MEDIA PLATFORMS WITH CHARACTER SPACE LIMITATIONS

When the Agency evaluates advertising and promotional labeling for compliance with the FD&C Act and FDA's implementing regulations, it determines whether claims about both the benefits and risks of the product are accurate and non-misleading. The Agency also looks at whether benefits and risks are presented in a comparably prominent manner (as outlined above in section II). Thus, considerations involving the content and format of benefit information are an inherent part of FDA's evaluation of risk presentations on Internet/social media platforms.

In communicating benefit information on Internet/social media platforms with character space limitations, firms should consider the following points:

1. Benefit information should be accurate and non-misleading and reveal material facts within each individual character-space-limited communication (e.g., each individual message or tweet).

When communicating benefit information about its product, a firm should ensure that benefit information is accurate and non-misleading. In doing so, the firm should also reveal material facts about the use of its product, such as limitations to an indication or the relevant patient population. For example, a firm should refer to the "Indications and Usage" portion of the Highlights of Prescribing Information that is available for many human prescription drugs to help determine what information to convey, although the firm is generally not required to use the precise wording found there. Labeling for an approved premarket approval application (PMA) for class III medical devices or use information consistent with a cleared intended use for 510(k) medical devices provides the basis for the benefit information related to devices. Such information would include material facts that the firm should present within the individual character-space-limited communication because, without doing so, the benefit information in totality may be misleading.

2. Benefit information should be accompanied by risk information within each individual character-space-limited communication.

A firm should also consider whether, once benefit information is conveyed in an accurate and non-misleading manner, enough capacity will remain in the character-space-limited communication to adequately convey required risk information. Please refer to section V for factors firms should consider in the disclosure of risk information. In addition, a firm should consider whether enough capacity will remain in the character-space-limited communication to adequately convey certain other required information, as applicable. Please refer to section VI for additional recommendations firms should consider for the inclusion of other product information.

3. If a firm concludes that adequate benefit and risk information, as well as other required information, cannot all be communicated within the same character-space-limited communication, then the firm should reconsider using that platform for the intended promotional message.

***Example 1A*:** A firm is considering promotion of its prescription drug *NoFocus* on Twitter, which is limited to 140 character spaces per message or tweet. *NoFocus* is indicated for mild to moderate memory loss. Any benefit information that the firm communicates about *NoFocus* should be accurate and non-misleading and include material facts about the use of *NoFocus*, i.e., that it is indicated for **mild to moderate** memory loss.

The firm considers including the following benefit information within the tweet [the information in brackets denotes character spaces used/140 available character spaces in a tweet]:

NoFocus for mild to moderate memory loss [*40/140*]

The benefit information for *NoFocus* that is communicated within the first 40 character spaces of this tweet is accurate and non-misleading and includes material facts about the indication and limitations to the use of *NoFocus*. The firm should consider whether the remaining 100 character spaces are enough to include risk information and certain other required information, as applicable, about *NoFocus*. See examples 1B and 1C in sections V and VI in this draft guidance, respectively, for further considerations on the disclosure of risk and other information for *NoFocus* within this tweet. If the firm concludes that adequate benefit and risk information, as well as other required information, cannot all be communicated within the same tweet, then the firm should reconsider using Twitter for the intended promotional message for *NoFocus*.

***Example 2A*:** A firm is considering promotion of its prescription drug *Headhurtz* using Google's Sitelink extensions (sponsored link promotion that contains character space limitations and specific formatting requirements, sometimes referred to in this guidance document as "Sitelinks").[13] *Headhurtz* is indicated for severe headache associated with traumatic brain injury. Any benefit information that the firm communicates about *Headhurtz* should be accurate and non-misleading

[13] The example featured in this guidance relies on one specific Google formatting option (current as of Jan 22, 2014); however, it may be possible to follow the concepts outlined in this draft guidance for other types of sponsored link promotion or Internet/social media platforms with character space limitations.

and include material facts about the use of *Headhurtz*, i.e., that it is indicated for **severe** headache **associated with traumatic brain injury**.

The firm considers including the following benefit information within the sponsored link promotion [the information in brackets denotes character spaces used/available character spaces per line of the sponsored link promotion]:

> Headhurtz [*9/25*]
> www.headhurtz.com [*17/35*]
> For severe headache from traumatic brain injury [*47/70*]

The benefit information for *Headhurtz* that is communicated within the character spaces for this specific sponsored link format is accurate and non-misleading and includes material facts about the indication and limitations to the use of, and the specific patient population for, *Headhurtz*. The firm should consider whether risk information and certain other required information, as applicable, about *Headhurtz* can also be included within the remaining character spaces for this specific sponsored link format. See examples 2B and 2C in sections V and VI in this draft guidance, respectively, for further considerations on the disclosure of risk and other information for *Headhurtz* within this sponsored link format. If the firm concludes that adequate benefit and risk information, as well as other required information, cannot all be communicated within this same sponsored link format, then the firm should reconsider using Google's Sitelinks for the intended promotional message for *Headhurtz*.

V. FACTORS CONSIDERED IN THE DISCLOSURE OF RISK INFORMATION ON INTERNET/SOCIAL MEDIA PLATFORMS WITH CHARACTER SPACE LIMITATIONS

This section of the draft guidance outlines factors considered in the disclosure of risk information on Internet/social media platforms with character space limitations. As previously stated, regardless of character space constraints that may be present on certain Internet/social media platforms, if a firm chooses to make a product benefit claim, the firm should also incorporate risk information within the same character-space-limited communication. The firm should also provide a mechanism to allow direct access to a more complete discussion of the risks associated with its product.

In general, the Agency considers two primary factors to determine whether risk information is comparable in scope to benefit information within promotional materials: (1) whether the risk information qualifies any representations made about the product (i.e., content of the risk information compared to content of the benefit information) and (2) whether the risk information is presented with a prominence and readability comparable to the benefit claims about the product.[14]

[14] FDA has developed separate draft guidance that, when final, will represent the Agency's current thinking on how firms should, in general, present risk information in other types of promotional materials. See the draft guidance for

However, the Agency is aware of the challenges in balancing benefit and risk information within the character space constraints of certain Internet/social media platforms—particularly in terms of content—because of the sheer volume of information. The Agency believes that a concise disclosure of specific risk information may be presented together with benefit information within the confines of character-space-limited Internet/social media platforms if supplemented by a prominent reference to the presence and location elsewhere of a more complete discussion of the risks associated with the product (or for restricted-device advertising, a "brief statement" of intended use and relevant risk information) and that this is consistent with requirements of the FD&C Act and FDA's implementing regulations (see section II). These concepts are further elucidated below in this section of the guidance document.

In communicating risk information on Internet/social media platforms with character space limitations, firms should consider the following points:

1. Risk information should be presented together with benefit information within each individual character-space-limited communication (e.g., each individual message or tweet).

2. The content of risk information presented within each individual character-space-limited communication should, at a minimum, include the most serious risks associated with the product.

At a minimum, a firm should communicate the most serious risks associated with the product together with the benefit information within the individual character-space-limited communication. For a prescription human drug, the most serious risks would generally include all risk concepts from a boxed warning, all risks that are known to be fatal or life-threatening, and all contraindications[15] from the approved product labeling (the PI). If a prescription human drug does not have a boxed warning, fatal or life-threatening risks, or any contraindications, the most significant warnings or precautions about the product should be communicated. For animal drugs, the most serious risks would include potential injury to human handlers/animal patients and risk of drug residues entering the human food chain. For devices, if a particular risk is associated with a particular identifiable use or population, then each of those should be included. The Agency believes that communication of the most serious risks as outlined above would provide a concise statement of risk information about the product for promotion on Internet/social media platforms with character space limitations.

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industry entitled *Presenting Risk Information in Prescription Drug and Medical Device Promotion* available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM155480.pdf.

[15] For prescription human drugs, if the only contraindication listed in the PI is hypersensitivity, the Agency would not expect that contraindication to be included as part of the risk disclosure within the character-space-limited communication unless there were documented cases of hypersensitivity occurring in patients who took the product.

3. A mechanism, such as a hyperlink, should also be provided within each individual character-space-limited communication to allow direct access to a more complete discussion of risk information about the product.

In addition to presenting the most serious risks within the individual character-space limited communication, FDA recommends that a firm also include in that communication a ***direct*** hyperlink to a destination (e.g., landing page) that is devoted exclusively to the communication of risk information about the product. Examples of such landing pages providing direct and exclusive access to risk information could include a website devoted to providing comprehensive risk information about the product, a particular webpage within a website that is devoted to providing comprehensive risk information about the product, or a portable document format (PDF) file that is devoted to providing comprehensive risk information about the product. An example that the Agency would not consider to provide direct and exclusive access to risk information would include a hyperlink only to a product's home page that also includes benefit information and other claims or graphics. Firms may include *supplemental* hyperlinks (e.g., to a product home page, to a PI, or to a brief summary) either within the character-space-limited communication itself or on the landing page of risk information, but the Agency recommends that a direct hyperlink to a landing page that is devoted exclusively to comprehensive risk information about the product be initially included within the original character-space-limited communication.[16]

Many Internet/social media platforms allow the use of uniform resource locator (URL) shortening services, which are likely to result in a URL or web address with fewer character spaces. The Agency does not intend to object to the use of such URL shortening services; however, when possible, the Agency recommends that the URL or web address itself denote to the user that the landing page consists of risk information (e.g., www.product.com/risk). Please note that if the URL or web address itself is promotional in content or tone, FDA may take into consideration whether any resulting claims are false or misleading or provide evidence in support of other violations under the FD&C Act and FDA's implementing regulations (e.g., a URL such as www.bestcancercuredrug.com may be misleading).

4. The prominence of risk information should be comparable to the benefit information within each individual character-space-limited communication, taking into consideration any formatting capabilities available on the specific Internet/social media platform.

If a firm uses techniques to emphasize benefit information within the character-space-limited communication, the firm should consider similar techniques to achieve comparable emphasis of

[16] A firm should consider how to fulfill other regulatory requirements for advertising or promotional labeling as applicable, such as providing an accompanying brief summary or PI with promotion for a drug (see 202.1(e)(1) and 201.100(d)). Where such requirements apply, the Agency expects that a firm would provide access to a brief summary or PI to accompany the communication in the character-space-limited Internet/social media platform, for example, by providing a direct hyperlink to those materials either within the character-space-limited communication itself or on the landing page of risk information. However, note that a link to a brief summary or PI should not be used **in place of** disclosing risk information within the original character-space-limited communication.

risk information for its product.[17] Additionally, FDA recommends that, where the platform enables the use of different formatting, a firm utilize those formatting capabilities to highlight significant risk information, such as a boxed warning (e.g., a firm should present the boxed warning in bolded text to convey the seriousness of that particular risk for its product).

Example 1B *(continued from example 1A)*: A firm is considering promotion of its prescription drug *NoFocus* on Twitter, which is limited to 140 character spaces per message or tweet. *NoFocus* is indicated for mild to moderate memory loss. There are no boxed or other warnings and no known fatal or life-threatening risks included in the PI for *NoFocus*. The most serious precaution associated with *NoFocus* is that it may cause seizures in patients with a seizure disorder. Since benefit information was provided within the tweet (example 1A), the firm should communicate, at a minimum, the most serious risks associated with *NoFocus* within the same tweet. The firm should also include within the same tweet a direct hyperlink to a more complete discussion of risk information about *NoFocus*. Additionally, the prominence of risk information should be comparable to the benefit information contained within the tweet, taking into consideration any formatting capabilities that may be available.

The firm considers including the following benefit and risk information within the tweet:

> NoFocus for mild to moderate memory loss; may cause seizures in patients with a seizure disorder www.nofocus.com/risk [*117/140*]

In the above example, benefit information for *NoFocus* is accurate and non-misleading, and the most serious risks associated with *NoFocus* are communicated together with the benefit information within the tweet. The firm includes a direct hyperlink to the "Important Safety Information" webpage (within the product website) that is devoted to providing comprehensive risk information about *NoFocus*. In addition, the URL www.nofocus.com/**risk** (emphasis added) denotes that the landing page is comprised of risk information, and the URL is not promotional in tone. The firm conveys risk information within the tweet in a comparable manner to the benefit information. See example 1C in section VI in this draft guidance for further considerations on the inclusion of other product information for *NoFocus* within this tweet.

Example 2B *(continued from example 2A)*: A firm is considering promotion of its prescription drug *Headhurtz* using Google's Sitelinks.[18] *Headhurtz* is indicated for severe headache associated

[17] FDA acknowledges that providers of character-space-limited platforms frequently dictate aspects controlling the presentation of text that affect prominence and readability (e.g., font size and style). Where the platform provider only permits one type of text, issues affecting comparability are less likely to arise.

[18] Google's "Sitelink extensions" format allows up to six additional links (Sitelinks) to be shown in addition to the display URL (www.headhurtz.com in this example). Under parameters set by Google, the link text for each of the Sitelinks must be 25 characters or fewer. The link text must directly relate to the content on the landing page for that link and point to different content, i.e., no Sitelinks may lead to the same landing page or to the same content. In addition, Sitelinks may not direct to the same landing page as the destination URL (the landing page for www.headhurtz.com in this example). Furthermore, up to two optional description lines (35 characters or fewer per line) may be created for display underneath each of the Sitelinks. This information is current as of Jan 22, 2014;

with traumatic brain injury. The PI for *Headhurtz* includes a boxed warning about the potential for brain swelling and warnings about a potentially fatal drug reaction and a drop in heart rate that may be life-threatening. Since benefit information was provided within the sponsored link format (example 2A), the firm should communicate, at a minimum, the most serious risks associated with *Headhurtz* within the same sponsored link format. The firm should also include within the same sponsored link format a direct hyperlink to a more complete discussion of risk information about *Headhurtz*. Additionally, the prominence of the risk information should be comparable to the benefit information contained within the sponsored link format, taking into consideration any formatting capabilities that may be available.

The firm considers including the following benefit and risk information within the sponsored link promotion:

Headhurtz [*9/25*]
www.headhurtz.com [*17/ 35*]
For severe headache from traumatic brain injury [*47/ 70*]
Boxed warning [*13/25*]
Potential for brain swelling [*28/35*]
Warning [*7/25*]
Life-threatening drop in heart rate [*35/35*]

Warning [*7/25*]
Potentially fatal drug reaction [*31/35*]
Risk information [*16/25*]
Important safety information [*28/35*]

In the above example, benefit information for *Headhurtz* is accurate and non-misleading. Consistent with the Google-imposed formatting requirements outlined in footnote 18, the firm chooses to utilize three of the six Sitelinks to convey the most serious risks associated with *Headhurtz*, including the boxed warning and additional warnings about fatal and life-threatening risks. Therefore, the most serious risks associated with *Headhurtz* are communicated together with the benefit information within the sponsored link format. The firm also includes a fourth Sitelink that provides direct access to a more complete discussion of risk information about *Headhurtz*. Furthermore, consistent with the Google-imposed link requirements outlined in footnote 18, the firm creates four different landing pages, each with different content. The first Sitelink is a direct hyperlink to a webpage that is devoted to providing detailed information about the boxed warning on the potential for brain swelling. The second and third Sitelinks are direct hyperlinks to webpages that are each devoted to a discussion of the specific warning conveyed within the descriptions under these Sitelinks (i.e., a potentially fatal drug reaction and a life-threatening drop in heart rate). The fourth Sitelink is a direct hyperlink to the "Important Safety Information" webpage (within the product website) that is devoted to providing comprehensive risk information about *Headhurtz*. The firm conveys risk information within the sponsored link format in a comparable manner to the benefit information. See example 2C in section VI in this draft guidance for further considerations on the inclusion of other product information for *Headhurtz* within this sponsored link format.

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please refer to Google's website for more specific information on its advertising policies. See *Sitelink extensions* available at https://support.google.com/adwordspolicy/answer/1054210 and *Show additional links below your ad text* available at https://support.google.com/adwords/answer/2375416.

VI. RECOMMENDATIONS FOR THE INCLUSION OF OTHER PRODUCT INFORMATION ON INTERNET/SOCIAL MEDIA PLATFORMS WITH CHARACTER SPACE LIMITATIONS

This section of the draft guidance provides additional recommendations regarding the inclusion of other product information (including certain required product information other than risk/benefit information, as applicable) on Internet/social media platforms with character space limitations. In addition to including both benefit and risk information within a character-space-limited communication, there may be other applicable legal requirements to consider.

In communicating product information on Internet/social media platforms associated with character space limitations, firms should consider the following:

- Sections 502(e), (n), and (r) of the FD&C Act (21 USC 352(e), (n), and (r)) require that the established name accompany the trade or brand name in labeling and in prescription drug and restricted-device advertising. Drug regulations specifically require that the established name be in direct conjunction with the proprietary name or designation (21 CFR 201.10(g)(1) and 202.1(b)(1)).[19]

- The drug regulations also stipulate that advertisements shall prominently display the name of at least one specific dosage form and have the quantitative ingredient information required by section 502(n) of the FD&C Act in direct conjunction with such display. If other dosage forms are listed in the advertisement, the quantitative ingredient information for such dosage forms shall appear in direct conjunction and in equal prominence with the most prominent listing of the names of such dosage forms (21 CFR 202.1(d)(2)).

With regard to the above regulatory provisions when using Internet/social media platforms with character space limitations, the Agency does not intend to object where the following approaches are used:

- Firms should communicate both the proprietary (trade or brand) name and established name (for drugs, often referred to as the generic name) within the character-space-limited communication. The generic name of the product should be listed directly to the right of, or directly below, the brand name.

- On the landing page associated with each hyperlink provided in the character-space-limited communication, firms should again communicate both the brand and established names as recommended in the preceding bullet. In addition, for prescription drugs, firms should

[19] FDA has developed separate guidance that addresses product name placement and size in promotion. See the draft guidance *Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling* available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070076.pdf.

prominently display at least one dosage form and quantitative ingredient information in direct conjunction with the brand and established names.

In addition, the Agency believes that common abbreviations (including scientific and medical abbreviations), punctuations marks, and other symbols may, in many cases, reasonably be used to help address character space constraints. The following examples illustrate instances where the Agency does not intend to object to such usage:

- Commonly recognized linguistic symbols may be substituted for words. For example, the ampersand symbol (&) may be used in place of the word *and*.

- Punctuation marks may be used to help with the presentation of information. For example, dashes may be used to help separate benefit and risk information.

- A scientific abbreviation may be used to denote a chemical ingredient name (e.g., "HCl" for hydrochloride; "HBr" for hydrobromide).

Example 1C *(continued from example 1B)*: A firm is considering promotion of its prescription drug *NoFocus* on Twitter, which is limited to 140 character spaces per message or tweet. *NoFocus* is indicated for mild to moderate memory loss. There are no boxed or other warnings and no known fatal or life-threatening risks included in the PI for *NoFocus*. The most serious precaution associated with *NoFocus* is that it may cause seizures in patients with a seizure disorder. The FDA-approved name is *NoFocus (rememberine hydrochloride) Capsules*, and *NoFocus* is available as 200mg capsules. In addition to taking into consideration factors for communicating benefit and risk information within the character-space-limited communication as described in sections IV and V, the firm should also communicate the brand and established names within the tweet.

The firm considers including the following product information, together with benefit and risk information about *NoFocus*, within the tweet:

> NoFocus (rememberine HCl) for mild to moderate memory loss-May cause seizures in patients with a seizure disorder www.nofocus.com/risk [*134/140*]

In the above example, the brand and established names are communicated together within the tweet. Note that the firm uses the abbreviation *HCl* in place of *hydrochloride* within the established name presentation. The firm uses a dash with no additional spaces to separate the benefit and risk information. As specified in example 1B, the firm includes a direct hyperlink to the "Important Safety Information" webpage (within the product website) that is devoted to providing comprehensive risk information about *NoFocus*. At the top of the landing page, the firm again communicates the brand and established names together with the dosage form and quantitative information in direct conjunction as follows: NoFocus (rememberine hydrochloride)

200mg Capsules. FDA would not intend to object to this tweet for *NoFocus*, as described in totality in examples 1A, 1B, and 1C.

***Example 2C** (continued from example 2B)*: A firm is considering promotion of its prescription drug *Headhurtz* using Google's Sitelinks. *Headhurtz* is indicated for severe headache associated with traumatic brain injury. The PI for *Headhurtz* includes a boxed warning about the potential for brain swelling and warnings about a potentially fatal drug reaction and a drop in heart rate that may be life-threatening. The FDA-approved name is *Headhurtz (ouchafol) Tablets*, and *Headhurtz* is available as 200mg tablets. In addition to taking into consideration factors for communicating benefit and risk information within the character-space-limited communication as described in sections IV and V, the firm should also communicate the brand and established names within the sponsored link format.

The firm considers including the following product information, together with benefit and risk information about *Headhurtz*, within the sponsored link format:

Headhurtz (ouchafol) [*20/25*]
www.headhurtz.com [*17/ 35*]
For severe headache from traumatic brain injury [*47/ 70*]

Boxed warning [*13/25*]	Warning [*7/25*]
Potential for brain swelling [*28/35*]	Potentially fatal drug reaction [*31/35*]
Warning [*7/25*]	Risk information [*16/25*]
Life-threatening drop in heart rate [*35/35*]	Important safety information [*28/35*]

In the above example, the brand and established names are communicated together within the sponsored link format. As specified in example 2B, consistent with the Google-imposed link requirements outlined in footnote 18, the firm creates four different landing pages, each with different content, to convey risk information for *Headhurtz*. At the top of each of these landing pages, the firm again communicates the brand and established names together with the dosage form and quantitative information in direct conjunction as follows: Headhurtz (ouchafol) 200mg Tablets. FDA would not intend to object to this sponsored link format for *Headhurtz*, as described in totality in examples 2A, 2B, and 2C.