FDA’s New Online Media Draft Guidance Documents
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On June 17, 2014, the Food and Drug Administration (FDA or Agency) released two draft guidance documents for industry that offer “recommendations” regarding how pharmaceutical and medical device manufacturers can use Internet and social media platforms to (1) correct independent third-party misinformation about prescription drugs and medical devices; and (2) present risk and benefit information where there are character space limitations (e.g., Twitter). FDA developed these draft guidance documents in part to respond to requests from various manufacturers and related stakeholders. In January 2014, FDA also released draft guidance that addressed postmarketing submission requirements for interactive promotional media.¹

FDA’s first draft guidance, entitled “Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices,”² permits companies to voluntarily correct third-party misinformation related to their own products and provides recommendations about how to provide such corrections. For example, FDA recommended that manufacturers making corrections address all misinformation in a clearly defined portion of a forum on the Internet or social media platform, whether the misinformation is positive or negative.

The second draft guidance, entitled “Internet/Social Media Platforms with Character Space Limitations–Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices,”³ provides recommendations regarding the presentation of risk and benefit information for prescription drugs or

medical devices using Internet/social media sources with character space limitations, such as Twitter and
the sponsored search results links on Google and Yahoo. While FDA recognized the “challenging” nature
of communicating in such media, the Agency maintained that “benefit claims in product promotions
should be balanced with risk information” “no matter the Internet source used,” and recommended that
companies “provide a way for consumers to gain direct access to a more complete discussion of risks
associated with their products.”

These draft guidance documents are largely consistent with the Agency’s historical approach toward drug
and device promotional activities, and FDA has done little to meaningfully change its prior thinking in
order to allow more effective industry participation in these online settings. However, at a minimum, the
draft guidance documents allow companies to further calibrate their practices and policies in an uncertain
enforcement environment.

Below is a more detailed synopsis of FDA’s draft guidance documents and their potential implications for
industry. Stakeholders can submit comments on both guidance documents within 90 days of their
publication in the Federal Register.

I. Background

The Federal Food, Drug, and Cosmetic Act (FDCA) grants FDA the authority to oversee the labeling and
advertising of prescription drugs and medical devices. FDA generally recognizes two types of labeling
for drugs: (1) FDA-required labeling (e.g., the prescribing information or PI); and (2) promotional labeling.
According to FDA’s interpretation of the law, promotional labeling is generally any labeling, other than the
FDA-required labeling, that is devised and distributed for promotion of a product.

Generally, FDA regulations require promotional materials – regardless of medium – to present certain risk
information (e.g., warnings, precautions, side effects, contraindications, etc.) in a “fair and balanced”
manner. Thus, the entire promotional material or advertisement must present a fair and balanced
account of all clinically relevant information, and a drug’s risks must be presented prominently so that the

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4 Tom Abrams, FDA Issues Draft Guidances for Industry on Social Media and Internet Communications About
http://blogs.fda.gov/fdavoice/index.php/2014/06/fda-issues-draft-guidances-for-industry-on-social-media-and-internet-
communications-about-medical-products-designed-with-patients-in-
mind/?source=govdelivery&utm_medium=email&utm_source=govdelivery. FDA now also has a dedicated Industry

5 The Federal Trade Commission (FTC) has jurisdiction of advertising of non-restricted medical devices.
promotional material does not put undue emphasis on the drug’s benefits in relation to risks. Additionally, a drug is misbranded if its advertising is false or misleading, or fails to reveal material facts. FDA requires that companies submit promotional materials to FDA at the time of their initial dissemination, and the Agency’s Office of Prescription Drug Promotion (OPDP) oversees manufacturer compliance with FDA promotional regulations.

In FDA’s January 2014 guidance, which addressed postmarketing submission of promotional materials used in social media or online platforms, the Agency addressed the “unique technological features” and “novel presentation and content features” of “interactive promotional media,” which FDA defines to include “modern tools and technologies that often allow for real-time communications and interactions (e.g., blogs, microblogs, social networking sites, online communities, and live podcasts) that manufacturers use to promote their drugs.” In its previous and most recent guidance on this topic, FDA recognized that these Internet and Internet-based technologies make it easier for individuals or third parties to create information or user-generated content (UGC).

II. Correcting Independent Third-Party Misinformation

While FDA recognized that the Internet has allowed patients and other interested parties the opportunity to share experiences and to communicate with others about drugs and devices, FDA notes that UGC “might not always be accurate and may be dangerous or harmful to the public health.” FDA refers to such UGC as “misinformation,” which the guidance defines as “positive or negative incorrect representations or implications about a manufacturer’s product created or disseminated by independent third parties who are not under the manufacturer’s control or influence and that is not produced by, or on behalf of, or prompted by the manufacturer in any particular.”

Given the potential risks inherent in misinformation, FDA determined that it may benefit the public health for manufacturers to correct misinformation about their products (including, for example, situations in which a manufacturer is aware of misinformation that may be dangerous or harmful to the public health). FDA maintained that if a manufacturer voluntarily corrects misinformation in a truthful and non-misleading manner and as described in the draft guidance, FDA does not intend to object if these voluntarily corrections do not satisfy otherwise applicable regulatory requirements regarding labeling or advertising, if any. Conversely, FDA may object if a manufacturer responds to misinformation about its products using false or misleading information or in a manner other than that recommended in the draft guidance, or the manufacturer does not otherwise comply with applicable promotional labeling regulations.
A. Applicability of the Guidance

FDA clarifies that this guidance does not apply when the manufacturer creates the initial product communication that contains misinformation. Consistent with FDA’s previous guidance, manufacturers are responsible for communications that are owned, controlled, created, or influenced, by, or on behalf of, the manufacturer, including by its employees or any agents acting on behalf of the manufacturer to promote its product, as well as communications that a manufacturer has affirmatively adopted or endorsed.6 The guidance also does not apply when a manufacturer writes, collaborates on, or exerts control or influence on product-specific content provided by a third party, to the extent that responsibility for the development of the content is imputable to the manufacturer.7

The draft guidance explains that manufacturers are generally not responsible for third-party UGC about their products when the UGC is truly independent of the manufacturer (e.g., is not produced by, or on behalf of, or prompted by the manufacturer in any particular) regardless of whether the manufacturer owns or operates the platform on which the communication appears.8 If the manufacturer owns or operates the platform or created or initiated the forum on which such UGC appears, FDA recommends that the manufacturer include an overarching clear and conspicuous statement that the manufacturer did not create or control the UGC.

For example, the guidance would apply if a manufacturer became aware of a blogger that is posting inaccurate information about the manufacturer’s product. If the blogger has no relationship with and is not being paid by the manufacturer, the manufacturer is not responsible for the content of the blog and may voluntarily attempt to correct the information. Similarly, a manufacturer would not be responsible for information posted in a discussion forum and could voluntarily correct misinformation if the manufacturer hosted a forum on its corporate website and: (1) did not participate in the discussion; (2) included an overarching clear and conspicuous statement that the manufacturer did not create the content; and (3)

6 See Postmarketing Guidance supra n. 1. For example, if a member of a manufacturer’s marketing department posts incorrect statements about a product’s safety or efficacy, the firm is responsible for the content of the communication because the member was acting on the manufacturer’s behalf, and thus, this guidance would not apply.

7 For example, the guidance would not apply if a manufacturer hosted a group discussion on its own website, monitors the discussion for content that does not speak positively about its product, then removes or edits postings that portray its product in a negative light, and adds positive postings about the product. FDA would consider the manufacturer to be “exerting control over the UGC” and thus “responsible for the resulting content.”

8 Cf. 47 U.S.C. § 230(c)(1) (“no provider or user of an interactive computer service shall be treated as the publisher or speaker of any information provided by another information content provider”). The Communications Decency Act further defines “information content provider” as someone “responsible, in whole or in part, for the creation or development of information provided through the Internet or any other interactive computer service” (47 U.S.C. § 230(f)(3)). This position is also consistent with FDA’s Postmarketing guidance.
only monitored for profanity or obscenity, assuming that such actions are consistent with the terms of use applicable to the website.

Nevertheless, FDA recognized that manufacturers might be responsible for UGC that they “solicit or influence, regardless of forum,” even when generated by a third party. Thus, FDA likely will take a case-by-case approach, considering the extent to which a manufacturer has control over, involvement with, or influence over a product-related communication.

B. Appropriate Corrective Information and Approaches

A manufacturer may choose to provide appropriate truthful and non-misleading corrective information or, alternatively, it may provide a reputable source from which to obtain the correct information, such as the manufacturer’s contact information. To provide “appropriate corrective information,” a manufacturer’s communication should:

- Be relevant and responsive to the misinformation;
- Be limited and tailored to the misinformation;¹⁰
- 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 manufacturer), 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 manufacturer that manufactures, packages, or distributes the product.

FDA also recommends that manufacturers include the FDA-required labeling in the corrective communication or provide it in a “readily accessible format,” such as a “link that goes directly to the FDA-required labeling” or a link that opens a new window to a portable document format (PDF) file. Notably,

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⁹ For example, a firm may choose to provide contact information for the firm’s Medical Affairs Department. Third-Party Misinformation Guidance at 5, n. 8.

¹⁰ For example, FDA recommended that while a product may have multiple approved indications, manufacturers should “limit [their] correction information to the relevant [] indication being discussed.” Id. at 6.
the link should not take individuals to a promotional website even if the information is available there. FDA notes that if the link, web address, or URL to which viewers are directed to obtain the FDA-required labeling is “promotional in content or tone,” the corrective information would fall outside of the scope of the draft guidance. Thus, if a company responds with a link to correct information, it appears that FDA contemplates that companies will set up sites for linking that are designed to provide non-promotional, correct information, or will link to third-party sites with such information.

Recognizing that Internet or social media platforms may have large quantities of misinformation that may be difficult for a manufacturer to correct, FDA recommends that manufacturers “clearly identify the misinformation it is correcting, define the portion of the forum it is correcting, and correct all the misinformation that appears in that clearly defined portion.” Manufacturers should also “describe the location or the nature of the misinformation that was corrected and should provide a date the correction is made to ensure that parties reading the information do not assume the manufacturer has responded to the entire forum.”

For example, if a manufacturer identifies one page of an interactive website that has three consecutive sentences of misinformation about their product, FDA recommends that the manufacturer (1) correct all three sentences; (2) provide a statement that the manufacturer is responding only to this specified information on this one page; and (3) provide the date the change is made. The manufacturer is not expected to correct any other misinformation that may appear on other pages of the website. Similarly, if a manufacturer chooses to correct misinformation from comments in a blog post, it should correct each piece of misinformation in that particular comment to which it is responding.

FDA further clarifies that manufacturers must truly correct all misinformation in the defined portion of a forum it identifies. Thus, a manufacturer cannot only correct misinformation that portrays its product in a negative light; it must also correct misinformation that overstates the benefits or exaggerates efficacy if such misinformation is “in the same clearly defined portion of the communication.” Otherwise, the correction falls outside the scope of the guidance. Additionally, if a manufacturer chooses to correct more than one piece of misinformation in a forum, the portion of the forum FDA expects the manufacturer to correct may be “defined in part, by the locations of the pieces of misinformation the manufacturer corrects and the location of additional pieces of misinformation.” For example, if a manufacturer decides to correct misinformation on several blog postings that include comments.

For example, the nature of the forum, the quantity of information, and the length of time the forum encompasses all present difficulties. In addition, certain platforms or technologies affect what information will simultaneously be displayed to users (e.g., Facebook, YouTube, etc.).
FDA suggests several acceptable approaches for manufacturers to correct information: (1) directly on the forum (e.g., post corrective information in a comment); (2) provide the corrective information to the independent author for the author to incorporate; (3) request that the author remove the misinformation or allow comments to be posted; or (4) request that the site administrator remove the misinformation or allow comments to be posted. Recognizing that independent third parties may not be cooperative, FDA said it would “not hold a manufacturer accountable for an independent third party’s subsequent actions or lack thereof.” For example, a Wikipedia page for a manufacturer’s product may contain misinformation. Under FDA’s draft guidance, it appears that the manufacturer could either become an editor and comply with the requirements outlined above when correcting the information, or the manufacturer could provide Wikipedia’s editors with the corrective information, such as through Wikipedia “talk pages.”

After corrective action is taken, FDA does not expect the manufacturer to continue to monitor the website or communication that previously included UGC containing misinformation. However, when a communication by or on behalf of the manufacturer to the UGC author, site administrator, or the forum goes beyond the correction of misinformation, the communication falls outside the scope of the draft guidance. For example, while a manufacturer may initially correct misinformation and subsequently post additional corrective information, such communications fall within the scope of the draft guidance if they are consistent with the original corrective information. However, if a manufacturer introduces information that goes beyond providing corrective information (e.g., slogans and examples of patient profiles), the communication is subject to promotional regulations.12

Finally, manufacturers are not required to submit corrections to the Agency, but FDA recommends that manufacturers keep records to assist with any questions, including the content of the misinformation, where it appeared, the date it appeared or was located, the corrective information that was provided, and the date the corrective information was provided.

III. Presenting Risk and Benefit Information

In this draft guidance, FDA provides that manufacturers that choose to use electronic/digital platforms that are associated with character space limitations (e.g., Internet/social media) should present both benefit and risk information of their FDA-regulated medical products within the same character-space-limited communication. 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

12 Similarly, a manufacturer could provide corrective information about contraindications where an independent third party downplays this contraindication on an email distribution list, however, the manufacturer could not also provide additional information unrelated to the contraindication comparing the safety profile of its product to a competitor’s.
character spaces per tweet) and online paid search (e.g., “sponsored links” on search engines such as Google and Yahoo). FDA recommends that manufacturers also provide a mechanism, such as a hyperlink, to allow direct access to a more complete discussion of the risks associated with its product.

While the draft guidance addresses the provision of benefit and risk information, FDA explains that “representations by a manufacturer in character-space-limited platforms may also provide evidence of the intended use of the product.” In addition, FDA notes that the draft guidance is not applicable to 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 because they do not impose character space constraints. The 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). Moreover, the draft guidance does not apply to 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 FDCA for the disclosure of risk information.

When using Internet/social media platforms with character space limitations for product promotion, FDA recommends that manufacturers consider the following provisions:

- Promotional labeling is truthful and non-misleading (FDCA §§ 502(a), 201(n));
- Promotional labeling with product claims include indicated use(s) and associated risks (21 C.F.R. §§ 201.100(d), 201.105(d) and 801.109(d));
- Required information appears prominently on the label or labeling in an understandable format (FDCA § 502(c));
- Advertising with product claims include required risk information (e.g., brief statement) (FDCA § 502(n); 21 C.F.R. § 202.1);
- Advertisements must present a fair balance between information relating to risk and information relating to benefit (21 C.F.R. § 202.1(e)(5)(ii)), and risk information must be presented with a prominence and readability reasonably comparable to claims about drug benefits (21 C.F.R. § 202.1(e)(7)(viii));

13 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.

Advertisements, to be truthful and non-misleading, 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 C.F.R. § 202.1(e)(3)(i)); and

Labeling and advertising should not fail 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.

FDA also explains that risk information should be comparable in content and prominence to benefit claims within the product promotion (i.e., a balanced presentation).

Thus, FDA recommends that manufacturers first 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 the draft guidance document into account when developing benefit and risk presentations. FDA recognizes that 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)” If an accurate and balanced presentation of both risks and benefits of a specific product is not possible within the constraints of the platform, FDA recommends that manufacturers “reconsider using that platform for the intended promotional message (other than for permitted reminder promotion).” For example, for most products with black box warnings, this may effectively eliminate the possibility of utilizing these media platforms.

A. Factors for Communicating Benefit Information

FDA evaluates both the content and format of benefit information when evaluating risk presentations. In communicating benefit information on Internet/social media platforms with character space limitations, FDA offers three points to consider. First, 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). FDA explains that manufacturers should reveal material facts about the use of its product, such as limitations to an indication or the relevant patient population (e.g., refer to the “Indications and Usage” portion of the Highlights of Prescribing Information).

Second, benefit information should be accompanied by risk information within each individual character-space-limited communication. Thus, manufacturers should consider whether once benefit information is conveyed in an accurate and non-misleading manner, enough capacity remains to adequately convey required risk information. Third, if a manufacturer 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 manufacturer should reconsider using that platform for the intended promotional message.

B. Factors for Communicating Risk Information

FDA 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.¹⁵

FDA explains that manufacturers may use a concise disclosure of specific risk information 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).

In communicating risk information on Internet/social media platforms with character space limitations, manufacturers 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;
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; and
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.

FDA explained that at “a minimum,” manufacturers “should communicate the most serious risks associated with the product together with the benefit information within the individual character-space-

¹⁵ 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 industry entitled Presenting Risk Information in Prescription Drug and Medical Device Promotion available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM155480.pdf.
limited communication,” which for drugs generally include risks in boxed warnings, risks known to be fatal or life-threatening, and all contraindications from the Prescribing Information. With respect to the mechanism, FDA recommended that the hyperlink destination (e.g., landing page) be “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 PDF file that is devoted to providing comprehensive risk information about the product. A link to a product’s “home page that also includes benefit information and other claims or graphics” would not be sufficient.

While manufacturers 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, FDA 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. FDA did not object to manufacturers using URL shortening services, but recommended 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).

Lastly, FDA recommends that manufacturers use similar techniques to achieve comparable emphasis of benefit and risk information for its product (e.g., bold or italics). Similarly, where a platform enables the use of different formatting, FDA asks that manufacturers utilize those formatting capabilities to highlight significant risk information, such as a boxed warning (e.g., a manufacturer should present the boxed warning in bolded text to convey the seriousness of that particular risk for its product).

C. Additional Recommendations by FDA

In addition to including both benefit and risk information within a character-space-limited communication, FDA recommends that manufacturers 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.

16 FDA explained 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).

17 FDCA §§ 502(e), (n) and (r); 21 C.F.R. §§ 201.10(g)(1) and 202.1(b)(1).
character-space-limited communication, FDA recommends that manufacturers again communicate both the brand and established names. For prescription drugs, FDA asks that manufacturers prominently display at least one dosage form and quantitative ingredient information in direct conjunction with the brand and established names.18

FDA also states that manufacturers may use common abbreviations (including scientific and medical abbreviations), punctuations marks, and other commonly recognized linguistic symbols to substitute for words to help address space limitations (e.g., & instead of and). FDA explains further that manufacturers can use punctuation marks to help present information, such as dashes (e.g., Benefit–Risk). For several hypothetical examples of character-space-limited communications that FDA provided in the draft guidance, see Appendix A.

IV. Conclusion

The new draft guidance documents do not break significant new ground, and largely adhere to FDA’s past thinking on these issues. Despite recently acknowledging a need to consider the impact of developing First Amendment case law on its policies relating to pharmaceutical and medical device industry speech,19 the Agency appears to have paid little heed to such issues in framing these draft guidance documents – the requirements are pervasive, highly limiting, and unlike constraints applied to other classes of online speakers, including those with commercial interests. FDA may ultimately need to further adapt its policies to developing case law and associated challenges to it assertion of authority over industry speech.

In the interim, while the draft guidance documents are non-binding, FDA may now decide to step up enforcement, so companies must carefully consider their internal policies and employee handbooks in light of the Agency’s positioning on these issues. Given the potential for increased enforcement, manufacturers should evaluate whether planned online promotional activities implicate any of OPDP’s “high priority” areas of promotional enforcement, which will likely continue, and include communications regarding: (1) new products; (2) products with significant risks; (3) products cited for violations in past; (4) products cited in complaints; and (5) products with far-reaching campaigns. FDA also considers (1) the

18 FDCA § 502(n); 21 CFR 202.1(d)(2).
19 See FDA, Leslie Kux, J.D., Assistant Commissioner for Policy, Letter to the Medical Information Working Group (MIWG) in response to Citizen Petitions Nos. FDA-2011-P-0512 and FDA 2013-P-1079 (noting that FDA intends to “harmonize … First and Fifth Amendment considerations” as it examines applicable promotional and advertising regulations, guidance and policies) (Jun. 6, 2013), available at http://assets.law360news.com/0545000/545989/Citizen_Petition_Approval_Response_from_FDA_CDER_to_Ropes_a nd_Gray LLP and Sidley Austin LLP.pdf.
nature of the violation and how egregious; (2) the magnitude of impact on public health; (3) the need for corrective action; and (4) repeated violations.

While disappointing in many respects, the draft guidance documents are nonetheless useful in providing insight into FDA’s thinking and the attendant risks for companies, and more companies may decide to engage in online promotional and corrective activities. However, industry participation in online media – particularly with respect to product information – will continue to be a cumbersome prospect, with mixed effectiveness in conveying meaningful information to physicians and patients.
APPENDIX A

FDA Examples of Appropriate Character-Space-Limited Communications

Taking into consideration the factors and regulations cited above, FDA provides several hypothetical examples involving fictitious products that, “when taken in totality, illustrate FDA’s recommendations for how [manufacturers] may disseminate product promotion” on platforms with character space limitations. For example:

- NoFocus for mild to moderate memory loss; may cause seizures in patients with a seizure disorder [www.nofocus.com/risk](http://www.nofocus.com/risk) [117/140]21

- Headhurtz (ouchafol) [20/25]
  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]

In the Headhurtz example, the manufacturer provided the benefit and risk information within a sponsored link. FDA stated that this example was accurate and non-misleading because the manufacturer: (1) utilized multiple links to convey the most serious risks associated with Headhurtz (which had a boxed warning and additional warnings);22 (2) provided a link for direct access to a more complete discussion of risk information; (3) created different landing pages, each with different content, and each webpage is devoted solely to the risk information; (4) the brand and established names are communicated together.

20 The numbers in the brackets represent the number of characters used; the underlining represents a hyperlink.

21 FDA considered this example to be accurate and non-misleading because: (1) the most serious risks are communicated together with the benefit information within the tweet; (2) the manufacturer included a direct hyperlink to the “Important Safety Information” webpage (within the product website) that is devoted to providing comprehensive risk information; (3) the hyperlink denotes risk ([www.nofocus.com/risk](http://www.nofocus.com/risk)) (emphasis added); and (4) the risk information within the tweet is conveyed in a comparable manner to the benefit information. However, this example does not include the additional FDA recommendations shown in the second example. See Character Space Limitation Guidance at 11.

22 The guidance cites Google’s “Sitelink extensions” format, which allows up to six additional links (Sitelinks) to be shown in addition to the display URL (www.headhurtz.com in this example). See Character Space Limitation Guidance at 11, n. 18.
within the sponsored link format; (5) at the top of the landing pages, the brand and established names are again communicated, along with the dosage form and quantitative information (e.g., Headhurtz (ouchafol) 200mg Tablets); and (6) the risk information in the sponsored link format is comparable to the benefit information. 23

If you have any questions about any of the topics discussed in this advisory, please contact your Arnold & Porter attorney or any of the following attorneys:

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23 Id. at 12, 15 (specifically examples 2B and 2C of the draft guidance).