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Regulatory Alert: FDA Releases Guidances on Presenting Risk & Correcting Misinformation Online

On June 17, 2014, the Food and Drug Administration (FDA) released two new draft guidances regarding social media and Internet communications addressing the issues of how to present risk and benefit information in space-limited contexts and correcting third-party misinformation on the Internet.[i] The two guidances are a direct outcome of the 2009 hearings on using the Internet and social media to promote prescription products and part of the extended series of social media and Internet guidances.[ii]

In light of these guidances, Digitas Health LifeBrands recommends companies take the following actions[iii]:

1. Ensure that all messages (regardless of length) that require risk information include presentation of actual risks and not merely a link to risk information.
2. Review exsiting product websites to guarantee that they include a page dedicated to the presentation of risk information.
3. Establish self-evident, shareable URLs for pages dedicated to product risk information.
4. Review product indication and risk profiles to determine whether abbreviated versions of risk and indication information can be developed for use in space-limited contexts.
5. Review existing policies about correcting misinformation on third-party platforms to ensure compliance with the procedure set out in the new guidance.
6. Develop a plan and rationale for determining which sites/locations will be monitored for misinformation and what material will be corrected.

PRESENTING RISK AND BENEFIT INFORMATION IN SPACE-LIMITED CONTEXTS

The draft guidance on presenting risk and benefit information begins by setting out basic requirements applicable to all product promotion[iv]:

- “must be truthful and non-misleading”
- “must include certain information, such as indicated use of the product and the risks”
- required information “must be placed prominently...to render it likely to be read and understood”
- “must include certain risk information” if the promotion includes information about the product’s use

- "must present a fair balance between…risk and…benefit"
- "must contain risk information in each part"
- must "reveal [material] facts" regarding risks

FDA explicitly acknowledges in multiple locations that these requirements apply only to full product promotions (whether promotional labeling or advertising) and do not apply to reminder advertising and promotion labeling.[v] Reminder communications do not include any indication about the product's use (21CFR200.200) and are not required to include any corresponding risk information to balance the claims about the product's efficacy. Reminder communications are not permitted for any drugs with black box warnings. (21CFR201.100(f)) Reminder communications fall outside the scope of this guidance,[vi] but it is worth noting that reminder communications and analogous communications for drugs with black box warnings are frequently used in space-limited contexts such as social media. It is unfortunate that this guidance does not further clarify the Agency's stance on such communications.

FDA makes clear that "[r]egardless of character space constraints" risk information must be presented when it is required by the presence of benefit information in the discussion of a product. [vii] FDA is not providing an exemption to the requirement to provide risk information or declaring its intention to exercise enforcement discretion regarding any of the requirements for a product promotion. Indeed, FDA emphasizes that some products will not be able to abide by the requirements above (and additional requirements detailed below) within space-limited contexts. In such cases, FDA recommends that "the firm should reconsider using that platform for the intended promotional message."[viii]

Each individual promotional message including benefit information for a product is required to contain in the space-limited message itself:

1. Proprietary product name[ix]
2. Established (generic) product name[x]
3. Accurate, non-misleading benefit statement, including any material facts such as "limitations to an indication or the relevant patient population"[xi]
4. Risk information, which may be abbreviated due to space constraints[xii]
5. Link to a webpage dedicated to the presentation of the full risk information[xiii]

Presenting Risk Information in Space-limited Contexts

Regarding the risk information that is presented in the space-limited context, FDA requires that the risk information include "the most serious risks associated with the product."[xiv] FDA states that all boxed warnings, "all risks that are known to be fatal or life-threatening, and all contraindications" should be included in the space-limited context.[xv]

It is difficult to imagine a product that has fatal or life-threatening risks, contraindications or boxed warnings that could be contained within the space-limited context of a Tweet, which has a 140-character limitation. For example, one product chosen at random has a 692-character boxed warning, not including additional contraindications and other life-threatening risks. Yet as presented, the

guidance appears to require that all of that information be presented within the space-limited communication itself. If correct, this would limit the availability of space-limited communications to the small subset of prescription products whose risk and benefit information can meet the requirements set forth in this guidance within character-limited contexts.

If, however, there are no such life-threatening risks associated with the product, then it is permissible to include only the most serious warnings or precautions in the space-limited communication itself.[xvi] Thus, the framework set forth in this guidance seems more amenable to the participation of products with limited risks and short benefit statements.

Even there, however, it will be difficult for brands to participate in a genuinely social fashion while sharing benefit and risk information. Here is the example Tweet provided by the FDA in its guidance:

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

Complying with all of the requirements to provide benefit, risk, product name info, plus a link to additional risk information takes up 134 of the 140-character total available on Twitter. That leaves a six characters to actually engage with another user, such as by answering a question. Of course, if the other user's name were more than five characters (plus the @ symbol in front of the user's name), it would not even be possible to send this Tweet directly to a user who had asked a question such as, "What is NoFocus, and should I ask my doctor about it?"[xviii] Consequently, it might still be challenging for most brands to engage successfully with Twitter or other space-limited communications while abiding by the framework established in this guidance.

Link to the Full Risk Information

The FDA encourages product manufacturers to make use of URLs for the pages with the full risk information that both include the product name and the word risk (i.e., www.BRAND.com/risk) to make clear to the consumer viewing the message that the destination location will include risk information about the product. To this end, FDA discourages the use of URL shorteners, which typically make it difficult to determine the destination page.[xix]

On this point, it is important to note that social media and Internet sharing platforms may automatically replace unshortened URLs with shortened versions. To address this issue, Digitas Health LifeBrands recommends that marketers who wish to make sure of these platforms develop URL redirects that clearly indicate the destination while limiting the character count to minimize the distortion provided by automatic shorteners.

In addition to providing the full risk information on the destination webpage, the FDA enables sponsors to fulfill some of their other regulatory requirements via that destination page. Sponsors are not required to include the dosage form and quantitative ingredient information in the space-limited context. Instead, that information can be prominently displayed with the brand and established names on the landing page.[xx]

Sponsors also may fulfill their obligation to provide the prescribing information or brief summary as a link from the landing page with the full risk information rather than presenting a separate link within the space-limited communication itself.[xxi] Though, of course, the FDA would not object to including a separate link to the PI in the space-limited communication in addition to the link to the webpage with the full risk information.

CORRECTING THIRD-PARTY MISINFORMATION

FDA acknowledges that misinformation about a company's product can be promulgated by third parties completely independent of the company, and that such misinformation can be presented both in locations created and maintained by the company itself (such as a hosted discussion forum on a product website) or on locations completely independent of the company, such as Wikipedia.[xxii] FDA acknowledges that "it may benefit the public health for firms to correct misinformation about their products."[xxiii]

The key principles espoused by the FDA in this guidance are that:

1. Companies are **not** expected to attempt to police the entire Internet to search out every piece of misinformation about their products. Correcting misinformation is completely voluntary.[xxiv]
2. Companies are **not** responsible for whether the information is actually corrected in response to their efforts, i.e., if the third party refuses to correct the information, the FDA will not hold the company responsible for the misinformation.[xxv]
3. Attempts to correct misinformation should not be promotional in tone or content. Even when promotional material contains the appropriate corrective information, it should not be used as part of the corrective messaging. Instead, non-promotional communications should be provided.[xxvi]
4. Corrective messaging should be consistent with the FDA-required labeling for the product.[xxvii]
5. People providing the corrective message should disclose their connection to the company responsible for the product.[xxviii]
6. Companies may use multiple methods for attempting to correct misinformation including posting publically, reaching out to administrators/authors directly, or leaving comments in public forums.[xxix]
7. Attempts to correct misinformation should clearly define the scope of the area, page, or comment that has been reviewed and where the misinformation has been located.[xxx]
8. Attempts to correct misinformation should not be limited only to the negative misinformation presented but should also include any positive misinformation presented in the same area.[xxxi]

Correcting Misinformation Is Not Subject to Promotional Requirements

Perhaps one of the most significant aspects of the guidance on correcting misinformation is presented in the guidance's final two paragraphs. There, FDA makes clear that the attempts to correct misinformation "do not satisfy otherwise applicable regulatory requirements."[xxxii] In particular, FDA explicitly states that companies will not be required to submit the corrections themselves to the FDA,

though FDA does expect that records will be kept about what corrections are being proposed.

RECOMMENDATIONS

In light of these guidances, Digitas Health LifeBrands recommends companies take the following actions:

1. Ensure that all messages (regardless of length) that require risk information include presentation of actual risks and not merely a link to risk information.
2. Review exsiting product websites to guarantee that they include a page dedicated to the presentation of risk information.
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[i] Guidance for Industry: Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (Hereinafter, "Space Limitations") last accessed June 17, 2014 from http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401087.pdf
Guidance for Industry: Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices (Hereinafter, "Correcting") last accessed June 17, 2014 from http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401079.pdf

[ii] In addition to these two new guidances, see the page dedicated to discussion of social media guidance on the FDA website: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm397791.htm
See also the guidance agenda for 2014 that indicates another guidance to be developed on the topic of the appropriate use of links: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM314767.pdf

[iii] In this Regulatory Alert, I make no distinction among medical devices, biologic products, human, and non-human animal drugs. The essential regulatory requirements for all are the same, and the descriptions and recommendations of this alert should be applied to all categories with only minor modifications.

[iv] Space Limitations, page 3f. Following FDA's lead, I am presenting merely the abbreviated list of requirements presented in the guidance, which is not exhaustive.

[v] Space Limitations, page 4, page 4 note 10, page 5

[vi] Space Limitations, page 4 note 10

[vii] Space Limitations, page 6

[viii] Space Limitations, page 7

[ix] Space Limitations, page 13

[x] Space Limitations, page 13

[xi] Space Limitations, page 6

[xii] Space Limitations, page 9

[xiii] Space Limitations, page 10

[xiv] Space Limitations, page 9

[xv] Space Limitations, page 9

[xvi] Space Limitations, page 9

[xvii] Space Limitations, page 14

[xviii] It is a standard convention on Twitter to direct a communication to a user by including the user's name at the beginning of a Tweet. That allows the other user to know that the Tweet is intended for them and to locate the communication within a Twitter stream. So, a typical Tweet might read:
@PhillyCooke check out this cool website http://regulatoryrx.blogspot.com [67 characters]

[xix] Space Limitations, page 11

[xx] Space Limitations, page 14

[xxi] Space Limitations, page 10 note 16

[xxii] Correcting, page 1

[xxiii] Correcting, page 3

[xxiv] Correcting, page 6f

[xxv] Correcting, page 8

[xxvi] Correcting, page 5, 6, and 9

[xxvii] Correcting, page 6

[xxviii] Correcting, page 6

[xxix] Correcting, page 8

[xxx] Correcting, page 6

[xxxi] Correcting, page 7

[xxxii] Correcting, page 9