FDA Gets Social

Analyzing the June 2014 FDA Draft Guidance on Social Media & Limited Character Count Platforms

June 24, 2014

StarGroup™

FDA released two draft guidance documents that further define the Agency's emerging view of the rights and responsibilities of pharma marketing organizations in the digital world. The **guidance on correcting misinformation on third-party sites** appears to be an extension of the principles presented in the January 2014 guidance on social media and user-generate content. In this case, the guidance is specific to content on third-party sites, created by users who have no affiliation with the brand in question.

The other guidance document delves into the world of microblogs and other **limited character-count platforms** (e.g. paid search ads) to establish a framework for presenting risk and benefit information in a branded communication within the stringent length restrictions imposed by these digital media.

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

ACCESS THE GUIDANCE HERE.

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

ACCESS THE GUIDANCE HERE.

June 2014

Transparent and to the Point:

Correcting Third-Party Misinformation

Transparency and clarity are the watchwords here. When correcting third-party misinformation, pharma marketers must always:

Identify themselves as representatives of the brand in question

Ensure the correction is time-stamped in some fashion

Clearly define the misinformation they are correcting (marketers are not required to correct every piece of misinformation on a given site or platform or medium)

Avoid promotional language, claims, or comparisons in the correction(s)

Provide a link to a non-promotional source of more complete information (full prescribing information, for example)

This last bullet is important because the guidance states that the marketer need not necessarily provide risk and other information as part of the correction (except of course when this is the essence of the corrective information), but can rather refer to the mandated non-promotional information described above.

Practical Considerations

A few things to keep in mind, should your organization undertake to correct third-party misinformation as described in this document.

Correct all misinformation within a defined portion

First, you should seek to correct all the misinformation within a defined portion or unit of the site or platform in question. The simplest case is a single comment on a blog post or similar that misstates risk information. But – what if the blog post itself contains misinformation? Then you should provide corrective information for ALL instances within that post, which constitutes a common sense unit. Other concepts of clearly defined portions or units of online sites and forums are left to the reader to devise.

OK to provide corrective information to site administrators

FDA recognizes that in some cases, direct corrections on the site in question may not be possible; corrective information may be provided.

Fair balance principles apply to corrective information

In other words, you can't just correct the negative misinformation. Misinformation that may be deemed positive to your brand must also be corrected, within the aforementioned defined portion of the site or forum. No cherry-picking!

Keep your records; we don't want 'em

FDA states that firms should keep careful records of corrective actions taken, but that the Agency does not expect to receive copies of such records, provided that the corrective information is free of promotional claims or language.

In so Many Words: Branded Communications within Character Limitations

That headline is 69 characters already.

Half a tweet! FDA, like everyone else, recognizes the limitations imposed by character limits. Publication of the June 2014 draft guidance on Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information… signals the agency's philosophical willingness to enable the pharmaceutical and device industries to engage with key audiences through such media.

The Long and Short of It

The guidance, as applied to prescription drugs, is built around established principles. Each branded character-limited communication conveying product benefit information must include:

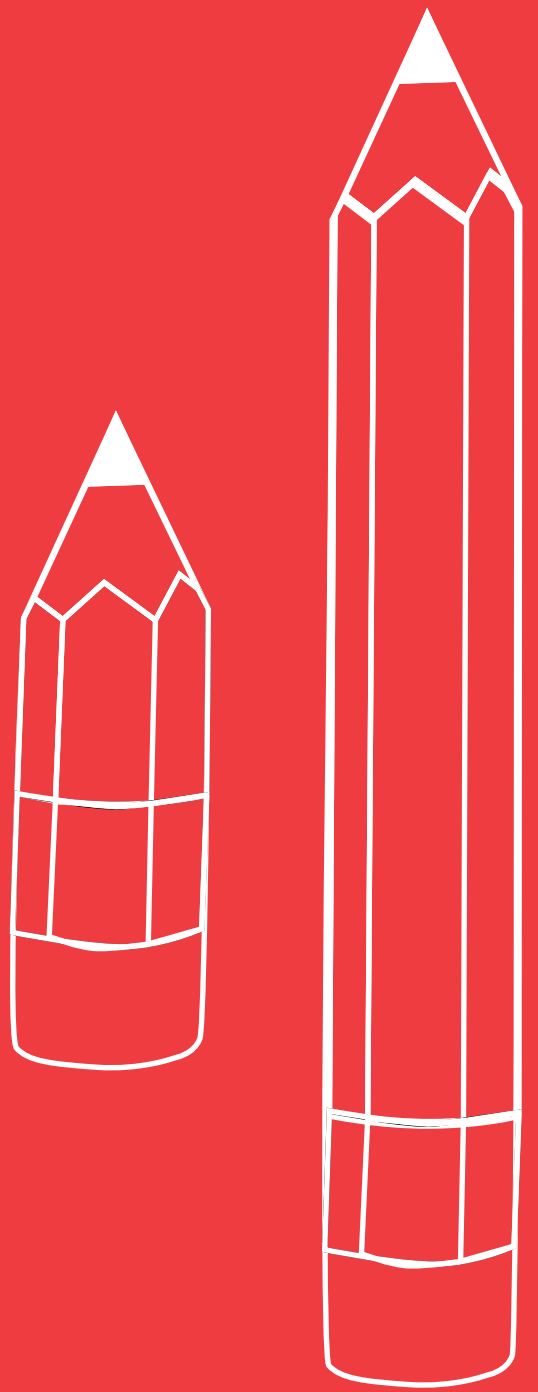
Brand Name

Generic name

Indication (at least one)

Concise safety/risk information

Link to more complete safety/risk information



As always, risk information must be presented with equal prominence to benefit information. FDA recommends that the most serious risk(s) associated with the product be stated within the communication. **However, in consideration of character limits, FDA accepts a link,** within the communication, to more comprehensive (and non-promotional) risk information. We also catch a break with the dosage form – it doesn't have to appear within the communication; only on the landing page with comprehensive risk information.

The guidance even goes on to present an example of a "BLACK BOX" PRODUCT running a branded paid search ad on Google, using the 'sitelinks' feature the company offers as an enhancement to text-based ads. Here,the sitelinks are used to convey some of the more serious risks—including those contained within the black box—associated with the product.

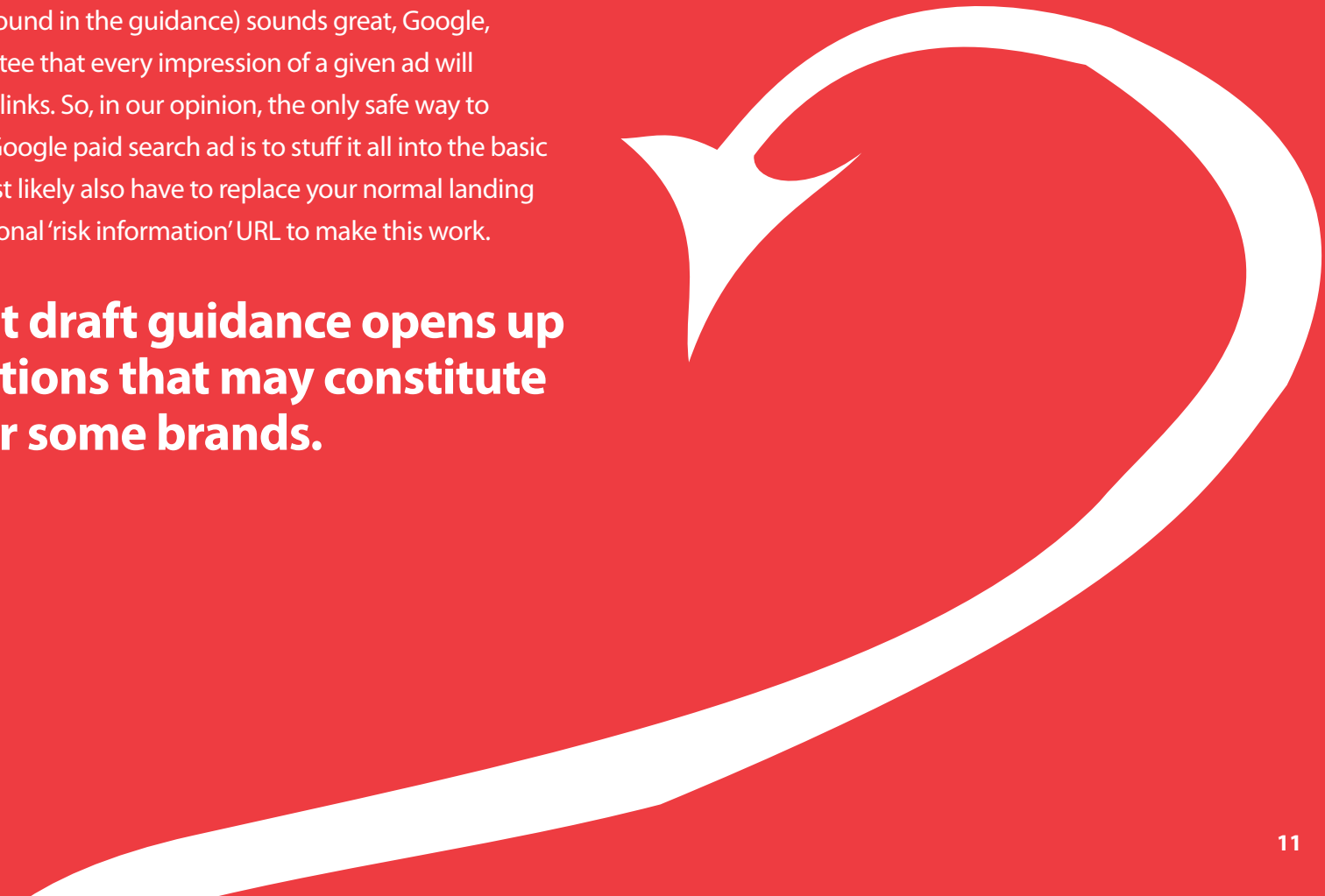
So, FDA is OK with presenting benefit and risk information within a single, branded, character-limited communication, provided a link to more comprehensive, non-promotional risk information is also provided within that communication as outlined in some detail within the draft guidance.

Simple, right?

Not So Fast!

The devil, as they say, is in the details. The first thing that jumps out at us is, if your product has a very long name, it's probably not a good candidate for a branded Twitter campaign. Another is that, while using sitelinks to convey risk information (as in the example found in the guidance) sounds great, Google, as of 6.18.2014, does not guarantee that every impression of a given ad will display all or any designated sitelinks. So, in our opinion, the only safe way to create a branded, promotional Google paid search ad is to stuff it all into the basic 25-35-35 ad format. You will most likely also have to replace your normal landing page URL with the non-promotional 'risk information' URL to make this work.

Thus, the present draft guidance opens up a few limited options that may constitute opportunities for some brands.



What's It All Mean?

These new guidance documents, as we said up front, provide more detail on FDA's nascent digital viewpoint.They are not directly prescriptive for every brand manager!

Listen Up!

The value of correcting misinformation is something that every brand team should debate. However,

every brand team should already be aware of what's being said out there, good, bad, and ugly.

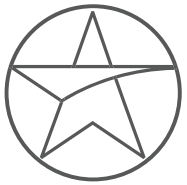
Find out what people are saying, first, and then decide whether it's appropriate to take corrective action.

Get Smart!

Remember when our communications channels and media were radio, TV, print, and outdoor? Those days are long gone; now we have new channels and formats cropping up (and often as not, dying out) overnight. The things we'll be hearing about more in the near future include beacons, over-the-top TV devices—and yes, character-limited communications will continue to evolve and grow.

Every pharmaceutical and medical device marketing organization has to invest in keeping up with technology, learning about new opportunities and challenges presented by these new forms of communication. So, whether character-limited communications of the sort described in the guidance are appropriate for your brand or not, you should have someone in house who can educate every brand's key internal stake-holders about the way these things work, to help them make an educated decision.

FDA has given us a look at their guiding philosophy with regard to digital communications; now it's up to pharma and device manufacturers to stay on top of technology, understand how it's used, how it can serve their brands, and how to execute in a way that is in accord with that philosophy, and regardless of whether a formal guidance has been issued.



#TheEnd

Want 2 learn more?

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