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The Revolution Can Wait–Recent Social Media Marketing Guidance from FDA Gives Manufacturers More of the Same

By Natasha Thoren and Benjamin Zegarelli

I. Introduction

Pharmaceuticals and medical devices are big business, and nothing drives business like advertising that reaches the widest audience possible. Ever since the U.S. Food & Drug Administration (''FDA'' or the ''Agency'') lifted the moratorium on direct-to-consumer (''DTC'') advertising for regulated products in 1985,[1] the Agency has attempted, in the name of consumer protection, to hold manufacturers to particular rigorous standards through rule-making and guidance to the industry.[2] Throughout that period, the advertising landscape changed dramatically as the Internet evolved into a medium through which marketing could reach a much larger audience than through traditional media, such as print publications, television, and radio.

The rise of social media use in the past few years has presented the pharmaceutical and device industries with a tantalizing outlet for DTC marketing. With Facebook and Twitter topping one billion users[3] and two-hundred-fifty million users worldwide,[4] respectively, and statistics showing that people spend more and more time socializing on these platforms than in person, it is no wonder that manufacturers are interested in reaching these online audiences. Social media platforms also offer a number of distinct advantages, such as access to large, self-identifying populations, the ability to target those populations, and ease of communication in short bursts of memorable, visible information. However, drug and device companies have hesitated to enter this space because no guidance documents seemed to apply to the unique tools offered by social media. Therefore, since the surge in social media's popularity began, many industry participants have been asking FDA to update drug and device promotion guid-

[1] *See* 56 Fed. Reg. 36,677 (Sept. 9, 1985).

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[2] *See, e.g.*, U.S. Food & Drug Admin., Draft Guidance for Industry: Direct-to-Consumer Television Advertisements – FDAAA DTC Television Ad Pre-Dissemination Review Program (2012); U.S. Food & Drug Admin., Draft Guidance for Industry – Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements (2004).

[3] Craig Smith, How Many People Use 700 of the Top Social Media, Apps and Digital Services?, DMR: Digital Marketing Ramblings (Sept. 4, 2014).

[4] *Id.*

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ance to include the Agency's expectations for social media marketing.

Finally, FDA responded by releasing three draft guidance documents in the first two quarters of 2014. The guidances demonstrate that, for the most part, the Agency currently considers social media platforms relatively indistinguishable from the rest of the Internet when it comes to marketing drugs. Although the basic tenets are indeed nearly identical to previous promotion guidance, FDA addresses some of the interactive elements of social media by adding certain nuances. However, these nuances fail to address critical functions of social media that make these platforms so attractive and engaging, such as the ''like'' and ''retweet'' capabilities of Facebook and Twitter, respectively.

This article will discuss what the new social media marketing guidance has contributed to FDA's enforcement scheme, as well as the major issues that the Agency has not yet addressed. We also examine the broader implications of the elements FDA has included and omitted in the new guidance. Drug and device manufacturers may find that, even with the release of the long-awaited guidance, social media promotion still presents too much risk to warrant significant participation in these platforms.

II. Background

A. Initial Regulation of Social Media Marketing

Even in the absence of FDA guidance directly applicable to social media, manufacturers began to take advantage of the marketing opportunities these platforms offered. In April 2009, however, FDA sent industry a strong message by issuing Untitled Letters to fourteen different pharmaceutical companies on the same day for marketing certain drug products through sponsored links on the search engine Google.[5] Sponsored links allow a purchaser to include in ninety-five characters a message about the landing page, and the companies had used this space to make brief claims about the uses or efficacy of the advertised drugs.

Although the sponsored links sent users to webpages containing full information on risks and approved indications for the respective drug, the description in the link itself contained none of this information. The companies had relied on the Federal Trade Commission's ''one-click'' rule for online advertising which stated that advertising did not need to disclaim risks associated with the product, as long as the ad contains a link to a webpage displaying all risk information (hence, one click away).[6] However, no FDA regulation or guidance had ever endorsed use of the one-click rule for drug or device advertising.

The Untitled Letters stated that the sponsored links violated current FDA labeling regulations and promotion guidance by failing to communicate any risk information, complete information about the drugs' approved indications, and substantiation for certain claims. Even though guidance for the promotion of regulated products in traditional media defined these standards, no guidance directly applied them to Internet advertising, let alone online platforms with strict space limitations. FDA's response was that regardless of the new capabilities or limitations of the Internet, ''[o]ur laws for how products that are approved by the agency can be marketed to consumers are the same regardless of the medium, whether they are print ads, radio ads, television ads or Internet ads.''[7]

The sponsored link Untitled Letters sent two clear messages to manufacturers: (1) FDA intended to enforce strictly the rules of drug and device promotion when manufacturers sought to use social media and other Internet platforms to advertise their products, and (2) the Agency was actively monitoring manufacturers' online promotion activity.

B. Other Enforcement Activities

After FDA released the sponsored link Untitled Letters, industry waited for the Agency to clarify its position on Internet marketing in new or revised guidance; however, that guidance took five years to appear. In the interim, FDA continued to track online drug and device promotions through the active monitoring and surveillance program administered by the Office of Prescription Drug Promotion (''OPDP''). During this time, FDA relied completely on Warning Letters and Untitled Letters to communicate its expectations for Internet marketing activities.

The unfolding pattern of enforcement actions confirmed that FDA intended industry to follow the same rules for social media advertising as it had for promotions in traditional media. However, without guidelines specifically tailored for interactive web pages, where companies could have ongoing dialogues with consumers about regulated products, drug and device makers were essentially paralyzed because they could not predict how FDA would react. Whereas the content of a static webpage could be submitted to FDA upon first publication to fulfill a reporting requirement,[8] a social media site's constantly changing content presented a fundamental problem: Is a company obligated to submit all content on such interactive sites as it evolved, or only when the company itself posted content to the site? In the absence of solid answers, many in the drug and device industry chose to avoid all but the most uncontroversial activities on social media platforms (e.g. restricted Facebook pages, LinkedIn pages, etc.).

However, some manufacturers sought to test the boundaries of FDA's reactive social media marketing rules. In July 2010, Novartis received an Untitled Letter stating that the company's use of the Facebook Share widget was misleading because the generated links, which users could share with their Facebook contacts, omitted all risk information about the advertised product.[9] Then, in February 2014, FDA notified Institut Biochimique SA that the Facebook webpage for one of its products was false and misleading because it con-

[5] All fourteen Untitled Letters may be accessed on FDA's Warning Letter database. *Drugs: Warning Letters 2009*, FDA.gov, http://tinyurl.com/ydll38u (last updated June 27, 2011).

[6] *See* U.S. Fed. Trade Comm., .com Disclosures: How to Make Effective Disclosures in Digital Advertising 10 (2013), *available at* http://www.business.ftc.gov/sites/default/files/pdf/bus41-dot-com-disclosures-information-about-online-advertising.pdf.

[7] Stephanie Clifford, *F.D.A. Rules on Drug Ads Sow Confusion as Applied to Web*, N.Y. Times, Apr. 17, 2009, at B7.

[8] 21 C.F.R. § 514.80(b)(5)(ii) (2014).

[9] Letter from Karen R. Rulli, Acting Group Leader, Div. of Drug Mktg., Adver. & Commc's, U.S. Food & Drug Admin., to Lisa Drucker, Director, Regulatory Affairs – Oncology, Novartis Pharmaceuticals Corp. (Aug. 4, 2010).

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tained information about the drug's efficacy but omitted all risk information, as well as material facts about the drug.[10] These recent enforcement actions illustrated that FDA was taking a strict stance on compliance with then current marketing guidance and would grant no leeway for promotional media with character space limitations.

III. The Arrival of Social Media Guidance

Five years after FDA put the drug and device industry on notice that social media marketing would be enforced in accordance with traditional promotion policies and regulations, the Agency finally released guidance describing *how* companies could advertise their products in compliance with these standards. The following sections briefly describe the three social media marketing draft guidance documents FDA released in the first half of 2014.

A. Submissions of Interactive Promotional Media

In January, FDA released draft guidance that addressed the fundamental problem of how drug companies[11] should submit marketing materials to the FDA that are published on social media platforms in order to comply with postmarket labeling rules.[12] According to the Draft Guidance, FDA intends to exercise enforcement discretion under ''certain circumstances'' with respect to postmarketing submission rules when companies publish interactive promotional media.[13] In its determination of whether a company is responsible for submitting specimens of interactive promotional media,[14] FDA will consider the following criteria:

- Whether the company owns, controls, creates, influences, or operates, or contracts with a third party to operate, the website on which the promotional content is posted. This includes sites such as Facebook, Twitter, blogs hosted by the company, and any other website over whose content the firm has influence, ''even if the influence is limited in scope.''[15]
- Whether the company has control or influence over a third-party website on which promotional content appears. This includes third-party websites over which the company has editorial, preview, or review privileges, or any sort of collaboration, even if limited in scope. However, this does not include third-party websites for which the firm provides only financial support.[16]
- Whether interactive promotional content is generated by an employee or agent acting on behalf of the company to promote a product. This includes postings on Facebook, Twitter, or a blog, as well as responses to consumer questions on an electronic forum or discussion board. Notably, however, FDA will not hold companies accountable for third-party user-generated content posted to a site the company controls.[17]

To clarify its expectations on what materials to submit, FDA included specific suggestions, summarized in Table 1, which are based on the type of website to which the promotional materials are posted. In each instance, companies may submit social media promotions using the same formats as for other forms of advertising.[18]

[10] Letter from Kendra Y. Jones, Regulatory Review Officer, Office of Prescription Drug Promotion, U.S. Food & Drug Admin., and Adora Ndu, Acting Team Leader, Office of Prescription Drug Promotion, U.S. Food & Drug Admin., to Clarence E. Jones, Agent, Institut Biochimique SA U.S. (Feb. 24, 2014).

[11] The guidance applies to manufacturers, packers, and distributors of prescription human and animal drugs and biological products. U.S. Food & Drug Admin., Draft Guidance: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics at 1 (2014) (hereinafter ''Postmarketing Submission Guidance''), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM381352.pdf.

[12] *See* 21 C.F.R. § 341.81(b)(3)(i) (requiring responsible releasing new promotional labeling for a drug product to submit such materials to FDA ''at the time of initial publication of the advertisement for a prescription drug product''); *id.* § 602.12(f)(4) (making 21 C.F.R. § 341.81(b)(3)(i) applicable to biological product promotional labeling).

[13] Postmarketing Submission Guidance, *supra* note 11, at 2.

[14] The Draft Guidance only applies to websites with interactive content, such as social media sites, blogs or forums, not to static websites. *See id.* at 1.

[15] *See id.* at 3.

[16] *See id.* at 4.

[17] *See id.* at 4-5.

[18] Form FDA 2253 is used for promotional labeling for prescription drugs and biologics for human use, and Form FDA 2301 for drugs intended for use in animals.

Table 1. Examples of Submissions for Certain Website Types[19]

Type of Website	Suggested Action
Static websites with interactive or real-time components (e.g., comments, discussion forum)	Submit entire website, including static and interactive elements, with annotations describing interactive/real-time portions
Independent third-party websites on which company contributes using interactive or real-time elements	Submit home page and the interactive portion of the website showing the company's first communication
Non-restricted sites including interactive portions on which company actively participates	Every month, submit a list of all such sites on which the company participated in that month, including site name, URL, date range of participation, and date of most recent contribution
Restricted access sites	Submit all website content relevant to company's contribution, including screenshots of the website and screenshots or transcripts of all communications related to company's contribution

[19] *See* Postmarketing Submission Guidance, *supra* note 11, at 6-7.

This draft guidance simplifies OPDP's task of monitoring companies' online promotion activities and telegraphs FDA's intention to continue such proactive scrutiny. While it is not yet clear whether the submission methods described in the Draft Guidance will be adequate to cover the range of social media and interactive websites, FDA's proposed standards will certainly require regulated entities to create new procedures for such submissions, and perhaps even appoint individuals to oversee all online activities.

B. Social Media Platforms with Character Space Limitations

On June 17, 2014, FDA published draft guidance on standards for drug and device advertising on social media websites that impose character limitations on posted content (e.g., Twitter, Google Sitelinks).[20] This is, perhaps, the guidance the drug and device industry had been most anticipating because it explains how companies must structure social media promotions to comply with FDA labeling regulations. Although FDA grants minimal leeway to drug and device companies seeking to advertise using such platforms, the Agency still demands strict adherence to traditional requirements: (1) no false or misleading statements, (2) fair balance, and (3) substantiation of any claims. Indeed, the Draft Guidance includes list of provisions that apply in equal measure to Internet/social media promotions and advertising in traditional media.[21]

The Draft Guidance sets forth the following factors drug and device companies should consider when developing promotional statements for social media websites with character limitations:

- Each individual communication should contain accurate benefit information and material facts and should be non-misleading (truthful and non-misleading)[22]
- Each individual communication should contain risk information along with benefit information (fair balance)[23]
- The content of risk information should, at a minimum, include the most serious risks associated with the product[24]:
  - o ''Most serious risks'' include boxed warnings, risks known to be life-threatening, and contraindications. However, if a prescription drug has none of these, the most significant warnings should be included.
- A direct link to comprehensive risk information about the product should be included in each communication[25]:
  - o The linked page should be entirely devoted to risk information and should not display any promotional content
  - o Manufacturers may use URL shortening services to reduce the character count of the hyperlink
- The prominence of risk information should be comparable to the benefit information, taking into consideration any formatting capabilities available on the specific social media platform (e.g., the use of dashes)[26]
- Both the brand name and the generic name of the product should appear within each character-space-limited communication and the linked risk information page[27]

As with traditional media, however, the requirements for fair balance do not apply to social media reminder advertisements, which simply name the product without mentioning any suggested uses or benefits.[28]

FDA also includes specific examples of Twitter and Google sitelinks promotions that would comply with the draft guidance.[29] Recent information about sitelinks' capabilities from Google, however, has thrown into doubt the relevant example from FDA. Google's advertising policies state that sponsored advertisements on its search engine will not always generate the accompanying sitelinks, which in the case of drug and device companies would provide access to complete risk information for the promoted product.[30] This revelation will likely ensure that all regulated companies will avoid promotional statements in sponsored links unless Google can provide an option whereby the sitelinks consistently appear with the primary promotional link.

Ultimately, however, FDA recommends that manufacturers consider carefully whether all of the required information can be adequately conveyed in a character-space-limited communication.[31] If it cannot, manufacturers must consider whether social media is an appropriate promotional tool for that product. Realistically, in light of the stringent requirements for risk and other information that must be included in each single tweet or Facebook post, it is likely that only a few products with very limited risk profiles will be suitable for product-related social media posts that also comply with the guidance document. In fact, reminder advertisements may be the least risky and most impactful use of social media platforms to call attention to regulated drugs and devices since manufacturers need not include risk in-

[20] The guidance applies to manufacturers, packers, and distributors of prescription human and animal drugs and medical devices for human use. U.S. Food & Drug Admin., Draft Guidance: Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices at 1 (2014) (hereinafter ''Space-Limited Communications Guidance''), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401087.pdf.

[21] *See id.* at 2-5.

[22] *See id.* at 6.

[23] *See id.* at 6-7.

[24] *See id.* at 9.

[25] *See id.* at 10.

[26] *See id.* at 10-11.

[27] *See id.* at 13.

[28] *See id.* at 4 & n.10.

[29] *See id.* at 11-12.

[30] *Sitelink Extensions*, Google, https://support.google.com/adwordspolicy/answer/1054210?hl=en (last visited Sept. 10, 2014) (''After you create your sitelinks, they might appear with your ads for a few weeks and then stop appearing. This change might occur because there could be a delay in the review process that we do to make sure your sitelinks meet our policies.'').

[31] *See* Space-Limited Communications Guidance, *supra* note 20, at 7.

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formation that would threaten to exceed the character count.

C. Correcting Independent Third-Party Misinformation

Published simultaneously with the guidance document on character-space-limited communications, this draft guidance applies to independent user-generated content (''UGC''), information posted on third-party websites by individuals unaffiliated with and not sponsored by the manufacturer.[32] FDA expressly provides that manufacturers are not obligated to scour the entire Internet to ferret out every iota of product misinformation on third-party websites.[33] Manufacturers have long questioned FDA's authority to hold manufacturers responsible for communications by third parties who are not subject to the manufacturer's influence or control.[34] This draft guidance confirms that companies addressing third-party misinformation is, in fact, voluntary, if the UGC is free of *any* influence from the manufacturer.

In the context of third-party misinformation, FDA makes a limited concession to traditional advertising and labeling requirements by allowing manufacturers to post corrective statements without regard to fair balance of benefit and risk as long as the information:

- Is relevant and responsive to the misinformation the manufacturer seeks to correct;
- Is limited and tailored to the misinformation;
- Is not promotional in any way;
- Is not false or misleading;
- Is consistent with the FDA-required labeling for the product;
- Is supported by sufficient evidence;
- Either is posted with the misinformation in the same area or forum, or references the misinformation with the intention of being posted with the misinformation; and
- Discloses that the person providing the corrective information is affiliated with the company.[35]

Even though risk information is not required as part of the corrective posting itself, the draft guidance recommends including a direct link to a non-promotional webpage with the complete FDA-approved labeling for the product.[36]

While FDA does not require a manufacturer to seek out all product misinformation in a single forum, choosing to correct multiple posts may obligate the manufacturer to address all misinformation contained within the portion of the forum defined by the selected posts (e.g., all communications posted in a specific date range).[37] Also, once a company chooses to provide corrective information, it may not discriminate between beneficial and detrimental misinformation in independent UGC.[38] For example, a manufacturer may not correct misinformation that overstates product risk while ignoring exaggerated efficacy claims in the same post. The guidance document draws specific lines between corrections and promotional information, highlighting when the guidance will or will not apply, and companies must be sure that corrections do not cross over the line into ''promotions.'' If they do, all promotional requirements, including fair balance, will apply to those communications.

Since the process of correcting misinformation in the UGC context is completely voluntary, there is no clear advantage for drug and device companies to seek out misinformation proactively. In fact, choosing to do so places a significantly greater regulatory burden on a company. Companies will need to develop specific policies and training programs addressing employee conduct on the Internet both at work and during nonworking hours to avoid the additional liability and to prevent employees from independently responding to misinformation in their capacity as employees.

IV. Missed Opportunities and Additional Considerations

While the three draft guidance documents clarified FDA's stance on social media promotion of drugs and devices in some respects, they also highlighted, through FDA's omissions, key issues that still require clarification.

A. Social Media ''Endorsements''

One of the most prominent and popular aspects of social media outlets is the integrated functionality allowing users to share articles, links, posts, videos, and other forms of information with other users. Such tools include the ''like'' function on Facebook and the ''retweet'' function on Twitter. Even though a large portion of social media activity is based on these user ''endorsements,'' FDA did not address this functionality at all in the recent draft guidance. FDA Warning Letters have addressed companies' use of the ''like'' function,[39] indicating that the Agency considers such use a promotional activity. FDA should elaborate on these limited statements and inform the drug and device industries how these functions apply to the already articulated standards for social media promotions. For instance, in deciding whether a company has ''control or influence'' over a third-party site—keeping in mind that the influence may be limited in scope—will FDA consider

[32] The guidance applies to manufacturers, packers, and distributors of prescription human and animal drugs and medical devices for human use. U.S. Food & Drug Admin., Draft Guidance: Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices at 1 (2014) (hereinafter ''Third-Party Misinformation Guidance''), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401079.pdf.

[33] *See id.* at 4.

[34] *See, e.g.*, Letter from Jeffrey K. Francer, Vice President & Senior Counsel, Pharmaceutical Research Mfrs. of Am., to Div. of Dockets Mgmt. (HFA-305), U.S. Food & Drug Admin. at 2 (Apr. 11, 2014) (''[T]hird-party statements not caused or controlled by a manufacturer do not fall within the statutory or regulatory scope of FDA's authority to regulate promotional labeling or advertising.'').

[35] *See* Third-Party Misinformation Guidance, *supra* note 32, at 5-6.

[36] *See id.* at 6.

[37] *See id.* at 6-7.

[38] *See id.*

[39] U.S. Food & Drug Admin. Warning Letter to AMARC Enterprises, Inc. (Dec. 11, 2012), *available at* http://www.fda.gov/iceci/enforcementactions/warningletters/2012/ucm340266.htm.

whether the company liked or retweeted information posted on the site?

It seems apparent that a company's direct endorsement of independent UGC would make the company responsible for that statement under drug and device promotion and labeling regulations. Opting to like or retweet a third-party post that exaggerates the efficacy of a prescription drug, which attaches the company's official name as an endorsement, would likely impose just as much responsibility on the company as if it had created the post itself. However, if an employee likes or retweets the same post from a personal account, the result is less clear. Until FDA provides clearer guidance on user endorsement functions of social media platforms, companies may limit the use of such tools through internal policies, training programs and by participating in only restricted access sites.

B. Control over Display of Promotional Information

FDA's draft guidance is written with the assumption that drug and device companies have complete control over the promotional information that is visible to users. However, as the Google sitelinks issue has made perfectly clear, while companies may include all required information when posting promotional material to a social media platform, the platform itself may alter the information when presenting it to other users. As another example, when compiling lists of links to information in which a specific user may be interested, social media and other websites (e.g., search engines, news databases) often truncate posted materials to give the user a sense of the content. The poster has no control over the portion of the post which is displayed or that which is excised. Thus, while the full display of a social media promotion of a prescription drug may comply with FDA expectations, users may at times see only a partial display of the promotional information which would not comply with applicable guidance. This issue exemplifies the significant differences between online promotions and traditional media advertising, where all of the promotional information is immediately visible to the viewer.

C. Return of the One-Click Rule?

Prior to issuing the draft social media guidance, FDA had soundly rejected the so-called ''one-click'' rule as a solution for including risk information in character-space-limited communications.[40] In the recent guidance, however, FDA appeared to retreat from this position formerly communicated in Untitled Letters by allowing companies to include links to full risk information as part of promotional communications on social media websites. Although ''serious warnings'' associated with drugs and devices must appear in such communications, the new standard indicates that Internet advertisements for regulated products need not constitute a completely self-contained unit separate from the body of information available within the simple click of a mouse.

The limited concession may embolden certain drug and device companies to test the limits of this modified one-click rule by including less and less risk information and relying more on the included link. This is especially true because the draft guidance only mandates inclusion of the ''most serious risks'' associated with a product, which may comprise only the ''most significant warnings'' if a product does not have a boxed warning or contraindications. The character-space-limited communication guidance does not specify how a company should determine whether certain risks or warnings are significant, and even states that FDA does not expect companies to disclose certain warnings in such promotional statements.[41] FDA will likely need to tailor its expectations further in supplemental guidance or even through Untitled Letters or Warning Letters, if need be.

V. Conclusion

Despite the release of the three guidance documents that defined many aspects of social media use, some social media actions taken by drug and device companies still require further instruction or guidance from FDA (e.g. liking, retweeting and sharing). Comments to FDA on the Space-Limited Communications Guidance and the Third-Party Misinformation Guidance were due by September 16. The draft guidance documents require manufacturers, packers, and distributors participating in non-restricted social media activities to be transparent and regularly submit multiple documents regarding their site to FDA, which will require companies to develop new policies and procedures for social media use. Coupled with ongoing OPDP surveillance, the new interactive content submission requirements will allow FDA to review company websites more thoroughly and consistently, which may lead to an increase in the number of Warning Letters and Untitled letters sent to regulated entities.

The regulatory landscape regarding participating in social media is still in its infancy and practical applications of these policies by FDA will most likely provide ample opportunity for continued evolution. Hopefully, FDA maintains the momentum it has generated and continues to develop and release proactive industry guidance rather than return to reactive, enforcement-based policies.

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[40] See FDA's fourteen Untitled Letters referencing companies' use of Google sponsored links, *supra* note 5.

[41] Space-Limited Communications Guidance, *supra* note 20, at 9 n.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 . . . .'').

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