

VIA ELECTRONIC DELIVERY

February 28, 2010

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: **Comment Request; Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools; Docket No. FDA-2009-N-0441; 74 Fed. Reg. 48083 (September 21, 2009)**

Dear Sir or Madam:

Johnson & Johnson, on behalf of its Family of Companies, respectfully submits the following written comments in response to the September 21, 2009 Federal Register Notice announcing the Public Hearing on the Promotion of Food and Drug Administration-Regulated Medical Products using the Internet and Social Media Tools. We appreciate the opportunity to contribute to the development of guidelines regarding the promotion of Food and Drug Administration (FDA) regulated medical products using the Internet and social media tools, particularly to the extent such tools promote health literacy and support the public health. We would like to thank the FDA for both the opportunity to participate in the public hearing held on November 12-13, 2009, and to submit the enclosed written comments. Our general comments appear first, and are followed by our comments in response to FDA's questions included in the September 21, 2009 Federal Register Notice (FDA's questions appear in bold below).<sup>1</sup>

#### General Comments

It was clear during the public hearing that social media and the Internet represent a unique and evolving platform for not only communicating important health information to the public, but also providing a means for people to discuss and seek out information about their health, diseases and treatments. There is an obvious need to differentiate Internet and social media from traditional forms of labeling or advertising because, unlike traditional promotional labeling and print or broadcast advertisements, Internet and social media users have a greater ability to control, alter and respond to the promotional messages and other product information they receive. It was also clear during the meeting that there was a need for individuals to have access to accurate and responsible information. The Internet and social media present an enormous opportunity to help promote public health and health literacy. Through responsible policies and practices companies can help advance these goals by encouraging the safe use of their products and providing accurate, balanced and credible product information. Finally, flexibility in the regulatory approach to online content is very important so that companies can participate more fully, and add their voices to the online conversations while complying with regulatory responsibilities.

1. **For what online communications are manufacturers, packers, or distributors accountable?**

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<sup>1</sup> 74 Fed. Reg. 48,083 (September 21, 2009).

- a. What parameters or criteria should be applied to determine when third-party communications occurring on the Internet and through social media technologies are subject to substantive influence by companies that market products related to the communication or discussion?
- b. When should third-Party discussions be treated as being performed by, or on behalf of, the companies that market the product, as opposed to being performed independent of the influence of the companies marketing the products?
- c. How should companies disclose their involvement or influence over discussions or materials, particularly discussions or material on third-party sites?
- d. Are there different considerations that should be weighed depending on the specific social media platform that is used or based on the intended audience? If so, what are these considerations?
- e. With regard to the potential for company communications to be altered by third parties, what is the experience to date with respect to the unauthorized dissemination of modified product information (originally created by a company) by non-company users of the Internet?

To enable engagement in social media in a responsible fashion, companies should consider developing internal guidelines for the use of social media tools. Compared to traditional communication vehicles like print, radio or television, certain forms of online communications (e.g. blogs, chat rooms, message boards and other social media platforms or services) afford companies much less control over content. This reality requires that a distinction be made between company-created, sponsored or controlled online content and third-party-created and controlled content.

Companies should be responsible for any company-created content (including content created on behalf of the company) posted by or on behalf of the company, whether it is posted on a company site or on a third-party site. Companies should also be responsible and transparent in disclosing material connections<sup>2</sup> between the company and third-party content that they sponsor, create and/or control. Disclosure should also be required for any third party content provider who receives compensation from a company for posting content.

Companies cannot police all of the Internet to ensure that third party statements are correct, however. Similarly companies should not be held responsible for correcting content that is superimposed on their sites without permission<sup>3</sup>, or for any other content that they do not and cannot control. Indeed, like content published by an unaffiliated third party in traditional media, user generated content (UGC) is, by definition, third party content. Just as would be true of the many pages of a journal in which a company places a product advertisement, where a company is a mere advertiser on a third party's blog or site the content of such a blog or site should be viewed as being performed independent of the influence of the company. Further, there is no regulatory basis, to hold a company responsible for statements of an unaffiliated third party. As established by statute and regulation, only a company's labeling and, for prescription drugs and restricted medical devices, advertising, is subject to FDA jurisdiction. While the term "advertising" is not defined in the Act, "labeling" is defined as "labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers,

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<sup>2</sup> For example, online participant's material connections (e.g., payments or free products) to a product manufacturer that is not reasonably expected by consumers should be disclosed. See Federal Trade Commission Guides Concerning the Use of Endorsements and Testimonials in Advertising, 16 CFR Part 255 (2009).

<sup>3</sup> For example, Google SideWiki allows consumers to post comments on a panel Google superimposes on websites. See <http://www.google.com/sidewiki/intl/en/learnmore.html> for additional information.

or (2) accompanying such article.”<sup>4</sup> Whether certain materials are “accompanying” a particular product or otherwise deemed to be “labeling,” the FDA cannot impose requirements on conduct that is in no way controlled by the company.<sup>5</sup> UGC is by definition third-party content and not subject to a company’s control. It therefore cannot be considered a company’s promotional labeling or advertising under the law and is outside the FDA’s jurisdiction.

Despite the fact that UGC does not constitute promotional labeling or advertising, a company may nonetheless have responsibility for UGC in certain circumstances. For example, if a company-owned or controlled site includes a chat room, message board or other area designated for online conversation related to a regulated product, then that company should also as a prudential matter be responsible for monitoring and if necessary responding to UGC posted to that site.

While a company may actively monitor its own product specific sites, and be proactive in responding to and correcting UGC that contains inaccurate or otherwise inappropriate product information, the degree of company responsibility to correct UGC will vary depending on the nature of the site and its stated purpose. There are different considerations that should be weighed for example with sites that are available only to the medical community and for non-product related sites. There should be no requirement, for example, where a drug manufacturer hosts a site as a forum for consumers to learn about and discuss the symptoms of a particular disease and that may include posts by users regarding various treatment options that are not specific to, but may include, the company’s own products. In such cases the company should prominently indicate the site’s intended use in the Terms of Use for that site and take appropriate actions when those terms are violated. The UGC on such sites should not, however, be treated as company speech for regulatory purposes.

2. **How can manufacturers, packers, or distributors fulfill regulatory requirements (e.g., fair balance, disclosure of indication and risk information, post-marketing submission requirements) in their Internet and social media promotion, particularly when using tools that are associated with space limitations and tools that allow for real-time communications (e.g., microblogs, mobile technology)?**
  - a. **How should product information be presented using various social media tools to ensure that the user has access to a balanced presentation of both risks and benefits of medical products?**
  - b. **Are there data to support conclusions about whether different types or formats of presentations have a positive or negative impact on the public health?**
  - c. **Are there proposed solutions that may help address regulatory concerns when using social media tools associated with space limitations or tools that allow for real-time communications to present product information?**
  - d. **How should companies address the potential volume of information shared on various social media sites with regard to real-time information that is continuously posted and regulatory requirements to submit promotional materials to FDA as applicable?**

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<sup>4</sup> 21 U.S.C. §321(m).

<sup>5</sup> Kordel v. United States, 335 U.S. 345 (1948). In Kordel, the Supreme Court concluded that materials were “labeling” if (1) they have a “textual relationship” to the drug; and (2) they were sent as part of an “integrated . . . transaction” with the drug. Id. at 348–50. See, also, 21 CFR §201.100(d), which describes the requirements for “any labeling...*distributed by or on behalf of* the manufacturer, packer or distributor of the drug...” (Emphasis added).

Flexibility in regulatory approach is crucial in the evolving digital world. The Internet presents an unprecedented opportunity to provide important health information and information about regulated products in formats and locations that meet the expectations and needs of consumers searching for such information. Technology can help companies provide information about products in convenient and easily accessible ways, particularly for applications with limited space options. In such cases, links, rollover and scrolling functions can enable direct connections to safety and efficacy information about regulated products, and are consistent with online expectations and habits.<sup>6</sup> In fact, the FTC has specifically noted that hyperlinked disclosures are not only permissible but are also “particularly useful if the disclosure is lengthy.”<sup>7</sup> Such practices are also consistent with (and are more immediate and convenient than) some currently acceptable methods of fulfilling regulatory requirements such as directing people in a television advertisement to obtain additional information from an advertisement in a magazine.<sup>8</sup> The Internet provides the ability and flexibility to reach people with information where they are and when they need it.

Sponsored Internet Search Results: During the FDA public hearing in November 2009, Google stated that drug companies’ search advertisements were “more relevant, transparent and informative” before the FDA enforcement letters on search advertising in April 2009. Yahoo! provided similar comments and data. Both Google and Yahoo! reported that click-through rates on such advertisements plummeted after the Agency sent out enforcement letters about the sponsored search results. This is not surprising in light of the fact that in response to those letters many companies revised their sponsored search results so that product names no longer appeared in URLs. According to Google and Yahoo!, the overall result is decreased transparency for the consumer. Google and Yahoo! provided potential solutions during the public hearing that the FDA should consider<sup>9</sup>, and we submit that FDA should endorse a range of options, including:

- Product Claim Sponsored Links: The headline is the official site including the product name along with a link to a landing page such as the official product site home page. There is a brief statement regarding the benefits of the product (e.g., “Learn about seasonal allergy treatment”), balanced by a brief safety statement regarding a product warning (e.g., “Warning: Avoid if you have liver problems. Not indicated for children under 18.”). There is a “More Info” link which directs the user to the full risk information;

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<sup>6</sup> See, e.g., FTC, Dot Com Disclosures: Information About Online Advertising (2000), available at <http://www.ftc.gov/bcp/edu/pubs/business/ecommerce/bus41.pdf>, wherein the FTC notes that “websites are interactive and have a certain depth—with multiple pages linked together and pop-up screens, for example—that may affect how proximity [of required disclosures] is evaluated.” Therefore, “[a]dvertisers have the flexibility to be creative in designing their ads, so long as necessary disclosures are communicated effectively and the overall message conveyed to consumers is not misleading” given that “[i]n reviewing their online ads, advertisers should adopt the perspective of a reasonable consumer.”

<sup>7</sup> *Id.*

<sup>8</sup> See FDA DDMAC, Guidance for Industry Consumer-Directed Broadcast Advertisements (1999) (“Sponsors of broadcast advertisements are also required to present a brief summary or, alternatively, may make ‘adequate provision ... for dissemination of the approved or permitted package labeling in connection with the broadcast presentation’” (quoting 21 CFR 202.1(e)(1))), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070065.pdf>.

<sup>9</sup> See, e.g., Presentation by Mary Ann Belliveau, Director, Health; and Amy Cowan, Head of Industry, Health; Google, November 12, 2009 FDA Public Hearing.

- **Product Name Sponsored Links:** The headline is the same as above. There is no benefit statement. A “More Info” link or roll-over function directs the user to the indication and/or full prescribing/product information as needed and appropriate.
- **Sponsored Links for Products with Boxed Warning:** The headline is the same as above. There is no benefit statement. There is a “safety and prescribing statement” such as, “Click to see full safety and prescribing information, including boxed warning,” and a “More Info” link that will direct the user to the risk information.

These proposals are excellent examples of how the promotional regulatory requirements can be met using technology solutions. The industry trade group, PhRMA, has made similar suggestions that we also support. Such solutions could be easily adapted in other applications with limited space options, including tools that allow for real-time communications.

3. **What parameters should apply to the posting of corrective information on websites controlled by third parties?**
  - a. **Are there any parameters or criteria that could be used to determine the appropriateness of correcting misinformation and/or scope of information a company can provide when trying to correct misinformation on a website outside a company’s control?**
  - b. **Should the parameters differentiate with regard to the prominence of the third-party site (i.e., readership), its intended audience (e.g., general public, healthcare professionals, patients), its intended purpose (e.g., personal diary, encyclopedia-type reference), and/or the author of the information on the site?**

In general, the information a company may provide to correct information on third party websites should not be considered promotional labeling or advertising<sup>10</sup>, as long as the corrective information is tailored to respond to an inappropriate, false or inaccurate representation about a company’s product and incorporates no additional or otherwise promotional information. While the company is under no regulatory obligation to correct such third-party content, the company may wish to set the record straight where appropriate. For example, the company could choose to address inaccurate third-party statements by providing a link to the full prescribing/product information, or may prefer to utilize a standard statement such as “the company has assessed this information and has determined that these statements are inaccurate/incomplete and the company encourages readers to access the full product information at (URL).”

As with traditional media, the FDA should allow companies to determine whether and when to participate in or to correct information on third party sites. Content on the Internet is so broadly distributed and changes so frequently that any requirement to monitor third-party content would be impossible to meet. Companies may decide to participate or correct misinformation on third-party sites, when it comes to the company’s attention, but such participation should not be mandated. A number of factors may come into play, including the willingness of those communities to take information provided by companies into consideration when making editorial decisions. Indeed, there are many third party sites where companies have little or no editorial control (e.g., [www.Wikipedia.org](http://www.Wikipedia.org) has a

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<sup>10</sup> As discussed above, non-promotional corrections are not labeling or advertising subject to the FDA’s jurisdiction. Rather, such corrections should be made at a company’s discretion to assist in the dissemination of the most accurate and useful information to consumers and patients.

clearly defined editorial policy that prevents companies from making edits directly to the wiki). Participation in a blog or a chat room would of course have to be consistent with product labeling, but such participation should not be deemed to be an endorsement of all the content on that site, or of any later content posted on the site.

Recognition that companies should not be responsible for UGC merely because they have participated in the online discussion would be consistent with Congressional policy regarding Internet content generally, as reflected in Section 230 of the Communications Decency Act, which provides online publishers broad immunity from content they do not create.<sup>11</sup> As codified in the Communications Decency Act (CDA), it was Congress's intent to promote the continued development of interactive media with minimal government regulation or intervention.<sup>12</sup> By granting broad immunity from a myriad of claims arising from third party content, Congress ensured that the Internet would flourish as a marketplace for ideas and commerce. As reflected in judicial decisions interpreting the CDA, this broad immunity is available even to online publishers that monitor and correct the UGC posted to their websites as long as such corrections do not materially alter the meaning of the original content. Like Congress, the FDA should ensure that its guidance in this area does not chill robust public online discussions by imposing overwhelming or cost-prohibitive obligations and liabilities for content which a company does not control.

#### 4. When is the use of links appropriate?

- a. **The Internet allows users to move easily between websites or sources that provide information on many related topics. Under the act, companies are prohibited from promoting approved human and animal drugs, biologics and medical devices for unapproved uses. However, sponsors sometimes provide links from their branded (e.g., mentions a product) websites to other informational sources about diseases, such as support groups, some of which may contain information about unapproved disease conditions or unapproved uses of approved products.**
- b. **Furthermore, some companies are using unbranded (e.g., does not mention a product) uniform resource locators (URLs) that, when clicked on, take users directly to branded information.**
- c. **The agency is interested in any comments about the appropriateness of various techniques regarding the use of links and data or research about whether or not users find these approaches to be misleading.**
- d. **Should parameters be established for links to and from websites?**
- e. **In addition, the agency is interested in any data or research concerning the frequency with which users actually click on different categories of links (e.g., banner ads, links**

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<sup>11</sup> 47 U.S.C. § 230(c)(1) (2000) ("No provider . . . of an interactive computer service shall be treated as the publisher or speaker of any information provided by another information content provider.").

<sup>12</sup> The policy codified in the preamble to 47 U.S.C. § 230, the safe harbor provision to the Communications Decency Act, is as follows:

(b) Policy. It is the policy of the United States-- (1) to promote the continued development of the Internet and other interactive computer services and other interactive media; (2) to preserve the vibrant and competitive free market that presently exists for the Internet and other interactive computer services, unfettered by Federal or State regulation; (3) to encourage the development of technologies which maximize user control over what information is received by individuals, families, and schools who use the Internet and other interactive computer services . . .

**within websites, sponsored links, organic search result links) to get additional information about products.**

Providing links from branded websites to other general information sources about diseases, support groups, etc. is wholly consistent with the promotional regulations. We believe such links are appropriate and frequently provide useful information for people seeking health or disease information. Companies should employ appropriate discretion in the use of links, considering for example whether such links are to credible sources of information. In some instances it may be more appropriate to link to the home page only, but this should not be mandatory.

Similarly, the use of unbranded URLs should not be problematic if they provide links to branded information, as long as the unbranded information is compliant, and the landing page for the branded information provides appropriate information regarding the product's risks and benefits (including approved uses).

**5. Questions specific to Internet adverse event reporting:**

- a. How are entities with post-marketing reporting responsibilities and other stakeholders using the Internet and social media tools with regard to monitoring adverse event information about their products?**
- b. How is adverse event information from these sources being received, reviewed, and processed?**
- c. What challenges are presented in handling adverse event information from these sources?**
- d. What uncertainties are there regarding what should be reported from these sources to meet FDA adverse event reporting obligations?**

For the reasons stated earlier and during the public hearing, companies should not bear the burden of monitoring the entire Internet for adverse events. The rule should be as it is with other media and interactions with health care practitioners: if a company representative becomes aware of an adverse event on a non-company related Internet site, that information must be evaluated for potential reporting to FDA. This is consistent with the current regulations and guidelines for adverse event reporting. Companies should have policies in place addressing how to evaluate their own websites for potential adverse events, and apply the same reporting criteria used for any other interactions.

FDA should also acknowledge the additional difficulty in following up on adverse event reports in the online space. Even if a potential adverse event is identified, given the anonymity prevalent in online interactions, there will often not be enough information to meet the four required elements for reporting. In addition, there will likely be no reliable means to follow up to obtain additional information where, for example, privacy laws and the open nature of online conversations may hinder the ability to seek follow up information.

In view of the nature of online communications, FDA should consider endorsing an alternative, and potentially more effective, approach for company-owned sites that would use the technology of the Internet to greater advantage. One solution on a company site might be to direct adverse event reporting to an appropriate place, for example, by providing a prominent link for reporting adverse events that will provide reporting forms and/or appropriate contact information for direct communication.

Conclusion

In closing, we respectfully request that, as FDA considers issuing regulatory guidance in the promotion of FDA-regulated medical products using the Internet and social media tools, the Agency keep its approach as simple and flexible as possible.

We appreciate the opportunity to participate in the public hearing and to submit these written comments. We welcome any future opportunities to discuss this topic.

Very truly yours,



Elizabeth Forminard  
Senior Counsel  
Johnson & Johnson



Philomena McArthur  
Sr. Director Regulatory Advertising & Promotion  
Pharmaceutical Group Health Care Compliance  
Johnson & Johnson Pharmaceutical Research &  
Development, LLC