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Docket No. FDA-2009-N-0441

Promotion of FDA-Regulated Medical Products
Using the Internet and Social Media Tools

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Introduction

On September 21, 2009, the U.S. Food and Drug Administration (“FDA”) announced that it is seeking public input to guide the agency in making policy decisions on the promotion of FDA-regulated medical products using the Internet and social media tools.¹ In addition to soliciting written comments, the FDA held a two-day public hearing on November 12-13, 2009, that featured oral presentations from a range of interested parties, including Google. Google welcomes this opportunity to respond to the FDA’s request for comments on issues related to the promotion and discussion of FDA-regulated medical products using the Internet and social media.

The FDA’s Notice of Public Hearing and Request for Comments (“FDA Notice”) noted that new Internet tools and technologies have proliferated since the previous hearing in 1996. Among the new “Web 2.0” tools and technologies identified by the FDA are blogs, microblogs, podcasts, online social networks, video sharing websites, widgets, and wiki technology. Online search engines are another tool that has revolutionized the Internet experience since 1996, by allowing consumers to filter the most relevant websites out of a vast and exploding array of competing online sources.

These Comments provide background to aid the FDA in evaluating the implications of Web 2.0 technology for regulating the promotion of medical products, as well as proposals for applying the FDA’s existing regulatory requirements in the contexts of search engine sponsored links and new social media tools such as the YouTube video sharing website and Google’s Sidewiki product.²

¹ 74 Fed. Reg. 48,083 (Sept. 21, 2009).

² Mobile devices are not a focus of the FDA’s current inquiry as we understand it. Nevertheless, it is important to note that the rise of mobile devices may make additional policy adjustments appropriate in the future. In comparison to desktop computing, mobile devices involve different technological capabilities and limitations related to Internet use, and thus may require different policy responses from those recommended herein.

Overview of Comments

Google encourages the FDA to adopt standards to ensure that sponsored search engine links can be used to promote FDA-regulated medical products in a manner that complies with FDA requirements. Google proposes specific standard formats for links that include product claims and for pharmaceuticals required to display “black box” warnings. These proposed formats utilize the interactive features of the online medium to provide risk information to consumers within the space limitations of search engine results.

In addition, these Comments discuss the YouTube video sharing website and promotional tools available through that website. Google believes that YouTube webpages, including Brand Channels, should not be viewed as “sponsored by” companies for the purpose of adverse event reporting because such outlets are owned, hosted, and supervised by a third party. Further, Google believes that the basic commenting controls provided for YouTube Brand Channels do not constitute substantive influence over online communications by independent parties.

Finally, Google addresses the FDA’s questions regarding corrective information on third party websites (Question 3) and adverse event reporting (Question 5) in the context of the Sidewiki service, an opt-in feature of Google Toolbar that allows Internet users to view and offer independent commentary alongside any website. The Sidewiki window appears alongside the underlying websites but is separately owned and hosted by Google and not by any pharmaceutical manufacturer. Consistent with the FDA’s prior guidance in the area of adverse event reporting, Google believes that the FDA should not require regulated entities to monitor or respond to adverse event information, misinformation, or misconceptions on third party websites or services, such as Sidewiki, that are not sponsored by and are outside the control of pharmaceutical manufacturers.

Formatting Standards for Sponsored Links to FDA-Regulated Medical Products Would Benefit Consumers and Industry

Search engines are an important and growing means for consumers to seek health information. In response to the FDA’s Notice, Google recommends that the FDA set standards for sponsored links that promote regulated medical products, including a standard format for links that include product claims and a special standard format for drugs that carry “black box” warnings. Our recommendation responds to the FDA’s Question 2 regarding compliance with regulatory requirements for Internet promotions using tools with space limitations and Question 4 regarding the use of links. We believe that such standards for sponsored links would benefit consumers by providing effective notice of product risks and benefits within the space constraints of search engine results. In addition, such standards would provide clear guidance to the medical industry and to Internet search companies by specifying a means to comply with existing FDA regulatory requirements in these contexts.

Search Engines Facilitate Consumer Access to Online Health Information

Numerous websites exist to provide consumers with immediate access to health information. Google and other search engines are a common starting point for consumers’ online

research using these sources. Search engines allow consumers to type in a word or words resulting in an Internet search for relevant results. Search engines allow consumers to identify, quickly and easily, the most relevant websites among the wealth of sources on the Internet.

Typically, search engines return both sponsored and non-sponsored links in response to a consumer's search query. While both types of links are responsive to the search query, non-sponsored links are identified through a search algorithm while sponsored links are presented based on a search engine's arrangements with advertisers. Google clearly distinguishes sponsored links from non-sponsored links,³ but both types of link employ the same basic format: a heading that links to the website search result, followed by two lines of text capturing the website content, followed by the Uniform Resource Locator for the website in question. This format is typical for both Google and other leading online search engines.

Consumers' use of search engines to find health information is significant and growing fast. Google research estimates that 111 million individuals conducted 4.6 billion health-related online searches, across all search engines, during the last three months of 2007. That figure is equivalent to 50 million searches per day, or nearly 35,000 searches every minute. Indeed, consumers' use of search engines to find health information has become so prevalent that the number of searches makes it possible to use online search trends as an indicator of health trends. For example, Google created a dedicated Flu Trends website after finding that certain search terms, in the aggregate, tend to be indicators of higher flu activity in a geographic area.⁴

Consumers' reliance on search functions to obtain health information is rising. On Google's search engine, queries about health conditions increased approximately threefold between 2006 and 2009, with the biggest part of that increase occurring since 2008. This measure does not include queries for "swine flu" and "H1N1" terms, which have been so frequently searched in recent months that they would create even higher figures. The spike in queries related to swine flu provides further evidence of consumers increasingly turning to search engines and the Internet for pertinent and timely information on their health concerns.

Information gathered through online search queries affects consumer behavior, and therefore public health. A research study conducted by Google and Harris Interactive found that 36% of people who gathered information online about a health condition went on to speak to their doctors as a result of their search. In addition, 21% of searchers made a change to their lifestyles based on the information they found online.

Consumers' growing reliance on online sources that provide health information and influence health choices presents tremendous opportunities for public health benefits. Consumers' use of search engines to locate online health information makes it critical to

³ For a Google search, sponsored results may appear above and/or to the right of the links to non-sponsored results. They are clearly labeled as "Sponsored Links." Sponsored links that appear above the non-sponsored results are also set off using a colored background.

⁴ Google's Flu Trends website is available at <http://www.google.org/flutrends/>.

ensure that search results are relevant, transparent, and informative in light of consumers' search queries.

The FDA Can Ensure That Consumers Receive Balanced Information by Setting Formatting Standards for Sponsored Links to Regulated Medical Products

As the FDA acknowledges in its Notice, its regulations on medical product promotion do not specifically address disclosures for the Internet and new media. The FDA points out that some online tools offer “novel presentation and content features” that are distinct and different from traditional media and that affect how promotional materials are or can be presented.⁵

Online search engines are novel and different from other media in that search results are both abbreviated and interactive. Search results are most effective and useful when presented in a brief format that consumers can quickly review in order to select the most relevant results. Search results need not contain full information because consumers always have the option of clicking a link for more information. Consumers are familiar with how search results function and have become accustomed to interacting with such results in order to find the information they seek. Providing voluminous details within search results would overwhelm consumers and render search engines less helpful. As the FDA evaluates search and other new media tools, it is critical to ensure that while sponsored links delivered through search engines meet regulatory requirements and provide balanced information to consumers, that the standards allow this essential tool to remain relevant and useful for the increasing numbers of consumers who are seeking health information online. To this end, Google requests that the FDA set clear standards as described below for the use of sponsored search engine links to promote FDA-regulated medical products.

In the absence of specific standards, there exists uncertainty regarding how FDA regulations on medical product advertising apply to the search engine context. In 2009, the FDA sent Notice of Violation (“NOV”) letters to several pharmaceutical companies regarding their sponsored links on Internet search engines. In these letters, the FDA asserted that numerous drugs were illegally misbranded in sponsored links. As a primary concern, the FDA indicated that certain sponsored links made representations and/or suggestions about drug efficacy without including in the same content any of the risk information, did not adequately communicate the drugs' indications, and did not use the established names of the drugs.⁶

Unfortunately, the NOV letters have hindered search engines' ability to be a platform for conveying useful prescription drug information to consumers. Prior to the NOV letters, as the FDA noted, sponsored links for prescription drugs commonly contained some use indication. Since the NOV letters were issued, sponsored links now generally include both branded and unbranded advertisements. Branded sponsored links now generally include the name of a prescription drug, but no product claims or indication of the drug's purpose – even if the consumer has searched for that drug by name. As a result, consumers are left

⁵ 74 Fed. Reg. at 48,085.

⁶ *See, e.g.*, Shefali Doshi, FDA Division of Drug Marketing, Advertising, and Communications, Letter to Fadwa Almanaky, Bayer Healthcare Pharmaceuticals, Inc. (undated).

guessing about whether or how a specific drug may be relevant to them. The same search will often yield an unbranded sponsored link that refers to a use indication but does not mention a prescription drug by name. This format omits facts about the sponsorship of the link that are important to consumers. Both the branded and unbranded advertisements typically lead to a prescription drug company website. But from consumers' perspective, the search results are less useful, informative, and transparent.

New FDA standards on the use of sponsored links would reduce costs and improve consumer protection by providing clear guidance for complying with FDA requirements in the online search engine setting. Any such standards should recognize the interactive nature of the Internet in general and search engine results specifically, as described above. Television, radio, and print media sources lack the sophisticated interactive capabilities of the Internet. More than in other media, consumers online are constantly and actively involved in sorting and selecting information sources. Standards for sponsored link advertising should take advantage of the Internet's interactive capabilities, requiring information to be presented in a manner that is most useful to consumers online and recognizing that links are an effective way to provide information within space limitations.

Proposed Standards for Sponsored Links

Google proposes formatting standards for sponsored links that include product claims and for sponsored links that promote "black box" prescription drugs. We believe that the proposed standards would effectively communicate important information to consumers and meet FDA regulatory requirements within the space limitations of such links, while ensuring that links include sufficient information to be relevant and responsive to consumer search queries.

Promotional communications that make claims about medical products must include certain disclosures, such as indicated use and associated risks. Prescription drug advertising must likewise present a "true statement" of information on side effects, contraindications, and effectiveness.⁷ To satisfy this standard, prescription drug advertising is required to provide a "fair balance" of information on risks and benefits.⁸ The FDA's regulations require that the risk information must be comparable in prominence and readability to the benefits claims.⁹ Risk information must be included in each part of an advertisement as necessary to qualify representations about the drug.¹⁰ FDA regulations specify that the pertinent information "may be concise if it is supplemented by a prominent reference on each page to the presence and location elsewhere in the advertisement of a more complete discussion" of the qualifying information.¹¹

In its Notice, the FDA solicited input regarding how the above and other regulatory requirements can be satisfied in the context of Internet and social media promotion,

⁷ 21 C.F.R. § 202.1(e)(1).

⁸ 21 C.F.R. § 202.1(e)(5)(ii).

⁹ 21 C.F.R. § 202.1(e)(7)(viii).

¹⁰ 21 C.F.R. § 202.1(e)(3)(i).

¹¹ *Id.*

particularly when using tools associated with space limitations.¹² The FDA also solicited public views on the appropriate use of links.¹³ Google suggests that the FDA adopt standard formats for sponsored search engine links that meet the FDA's existing requirements.

Proposed Standard for Sponsored Links Containing Product Claims

To meet the “fair balance” standard, Google proposes that sponsored links containing product claims include one line of text which may make a claim about the product, followed by one line of risk information. As with all sponsored links, each line of text should be limited to 62 characters. We recommend that the product claim line should include the brand and generic names of the drug and a short description of the indicated use or benefit.

Below the product claim line, the risk information line should be preceded by a standard label (“Risks”) that cannot be changed by the sponsoring company.¹⁴ We suggest that the FDA may require that the risk information presented in this brief format consist of the most important or urgent contraindications or side effects associated with a specific prescription drug. In such a scenario, the brief risk statement in the text advertisement would be closely followed by a “More Info” link that leads directly to additional details on side effects and contraindications. Google’s proposed format translates into the online context the FDA’s existing requirement that a part of an advertisement may contain a concise statement of risk if it is supplemented by a prominent reference to additional information.¹⁵

Proposed Standard for Sponsored Links for “Black Box” Prescription Drugs

The FDA requires certain drugs to be labeled with a “black box” warning of serious contraindications or adverse effects.¹⁶ The boxed warning must briefly describe the risk and refer the reader to more detailed information. “Reminder” advertisements, which contain the product name without any claims or use indication, generally may not be used for a prescription drug that is required to be labeled with a boxed warning.¹⁷

Google proposes a separate standard format, different from that described above, for black box sponsored links. Google puts forward for consideration that sponsored links for boxed warning drugs should include the brand and generic names of the drug only and not include product claims. In this proposed format, the first line of the link, set by the advertiser, would state generically that the website contains product information, but would not contain any product claims or use indications for the drug. The second line of the link would contain permanent text stating: “Click to see full safety and prescribing information,

¹² 74 Fed. Reg. at 48,086.

¹³ *Id.* at 48,087.

¹⁴ Although the early prototype presented at the FDA workshop proposed a “Warning” label, this could be confusing to consumers because the format is intended for pharmaceuticals that do not have boxed warnings. Google therefore withdraws its initial proposal in favor of the model presented here.

¹⁵ 21 C.F.R. § 202.1(e)(3)(i).

¹⁶ 21 C.F.R. § 201.57(c)(1).

¹⁷ 21 C.F.R. § 202.1(e)(2)(i). Reminder advertisements include the name of the product, but do not include indications or dosage, nor may such advertisements make representations or suggestions related to the product. Reminder advertisements are not subject to the usual “true statement” requirements, described above, for prescription drug advertising.

including boxed warning.” A “More Info” link following this standard text would link directly to a webpage with the boxed warning and other risk information.

The proposed format would contain enough information to make consumers aware that the link is sponsored by a specific product, thus helping them to make an informed decision about whether the result is relevant to them and should be clicked for more information. At the same time, the proposed format would highlight the existence of warning information about the product. Consumers would immediately be informed that there are risks associated with the product, before seeing any product claim or use information. Google believes that the proposed format strikes an appropriate balance by warning consumers of the existence of product risks while keeping search engine results useful and informative.

YouTube Promotional and Social Media Features

YouTube is a Google website that permits users to upload video content to the Internet and to view and comment on content posted by other users. Videos are available through “watch pages” that may also display user comments on the video, links to other YouTube videos, and other content determined by YouTube. In order to help the FDA answer the questions posed in its Notice, Google offers the below descriptions of the promotional opportunities available to companies on YouTube.

As discussed in the final subsection, these descriptions of YouTube’s services show that YouTube watch pages and Brand Channels are not “sponsored by” companies for the purpose of postmarketing reporting obligations because they can only be customized within limits set by Google. In addition, we believe that companies should not be required to post and review user comments on their YouTube videos, because this might discourage companies from posting videos and thereby limit the health information available to consumers. These descriptions help to put YouTube’s promotional opportunities into context with respect to the FDA’s questions regarding Internet adverse event reporting and demonstrate why the companies whose products and services are offered should not be responsible for monitoring or reporting on user content.

Promotional Opportunities on YouTube

Companies, including medical products companies, may offer a wide variety of video content on YouTube, including advertising. YouTube offers several different ways for companies to promote their video content and draw a wider audience of YouTube viewers. In addition to these video advertising features, there are multiple locations on the YouTube website that accommodate display or interactive advertising similar to what is found on many websites.

Video Advertisements

YouTube provides another avenue to reach the public with video advertisements such as would be played during television programming. Such advertisements may run before, after, or during “premium content” YouTube videos, which are clips or full-length content from television or online production companies. These advertisements are similar to television advertisements in length, but delivered through a different medium. Video advertisements

can also be targeted based on broad categories of information such as a viewer's gender or general location.

Sponsored Links

Sponsored video links are a way for companies to draw attention to their promotional videos posted on YouTube. Sponsored video links function in much the same way as sponsored links through the Google search engine. Sponsored links from advertising partners are returned in response to a user's search query, when the sponsored link is related to the query terms. Clicking on the thumbnail for the sponsored link takes the user to a YouTube watch page that shows the sponsored video. It is also possible for companies to promote their videos through text links that appear at the bottom of YouTube videos.

Promoted Videos

In addition to using sponsored links, companies can attract viewers to their advertising videos by making them "Promoted Videos." Promoted Videos are uploaded by YouTube advertising partners and curated by the YouTube editorial team. They are labeled so that viewers are aware when content is a Promoted Video.

There are several ways for viewers to reach Promoted Videos. Promoted Video links may appear on the search results page if a user has entered a relevant search query. Links to Promoted Videos may also be delivered through the YouTube home page or on a watch page, based on contextual targeting. Promoted Videos are different from "Related Videos," which are identified through an algorithm.

Brand Channels

Many companies choose to display their video content on a dedicated watch page called a "Brand Channel." Brand Channels are similar to the channels that all registered YouTube users may operate, but Brand Channels offer enhanced functionalities. Brand Channels are available to any company that either purchases a certain amount of advertising on YouTube or is a YouTube revenue-sharing partner.

Like user channels, Brand Channels are set within a fixed template that is set by Google. A generic framework for this template is included as Appendix A. The enhanced features of Brand Channels include a greater ability to customize the watch page, expanded editing powers within the template set by YouTube, and automatic play for featured content (the viewer need not click to initiate playback). Although a Brand Channel page can be customized with a company's logo, motto, or other details, Google hosts all Brand Channel content and retains the ability to remove content that does not satisfy our Terms of Service or other policies. Companies can only modify or customize the Brand Channels within the limits set by Google.

On Brand Channels, like other user channels, the uploader of the video content has some ability to regulate user comments, as discussed below. Brand Channel operators may also disable Related Videos and enable only Promoted Videos to appear on a watch page. Facebook or Twitter gadgets may be embedded.

Social Media Response Features of YouTube

Watch pages for user videos and Promoted Videos can display text comments or response videos from other YouTube users. Users may also post videos in response to a user video or Promoted Video. The person or entity that uploads the video content has control over the commenting feature. The uploader may choose to allow all comments, disallow all comments, or review the comments and selectively decide which ones are posted to the watch page.

Brand Channels offer companies somewhat more control over the commenting feature. As with other types of user channels, companies may allow all comments, disallow all comments, or allow selected and approved comments. In addition, companies with Brand Channels may identify certain YouTube users as “Friends.” A Brand Channel may allow only Friends to comment and exclude all other comments, or may allow Friend comments to be posted without review while other comments are subject to review and approval before being posted.

If comments are disallowed on a user or Brand Channel watch page, then they are not written to that page and are not seen by the person or entity that uploaded the content.

Application of FDA Regulations to YouTube

Question 1 in the FDA Notice asks when regulated entities should be accountable for online communications.¹⁸ Among other questions, the FDA inquires when third party communications online are subject to substantive influence by companies that market products related to the communications.¹⁹ Google does not believe that the basic commenting controls provided for YouTube Brand Channels constitute substantive influence over such communications. Although companies may use the features to control the rate or flow of comments on a Brand Channel watch page, or to remove comments that may be offensive or otherwise unacceptable, the controls are not intended for companies to exercise editorial control, nor do they provide companies with any way to verify or substantiate the commenter’s assertions.

Moreover, although Brand Channels are customizable for companies, Google does not believe that a Brand Channel qualifies as a website “sponsored by” the Brand Channel operator for the purpose of postmarketing reporting obligations. Entities with such reporting obligations should review websites that they sponsor for adverse experience information to determine if such events should be reported to the FDA.²⁰ Google believes that a Brand Channel should not be considered to be sponsored by an outside company because YouTube owns, operates, hosts, and imposes significant controls on all Brand Channels. Although Brand Channels can be customized to suit a company’s needs, they can only be altered within the limits set by YouTube.

¹⁸ 74 Fed. Reg. at 48,086.

¹⁹ *Id.*

²⁰ U.S. Food and Drug Administration, *Draft Guidance for Industry: Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines* 21 (March 2001) (*hereinafter* “Draft Guidance”).

It is important to preserve companies' ability to decide whether commenting should be permitted on a Brand Channel watch page. An obligation to permit commenting could discourage medical product companies from establishing Brand Channels, which would reduce the health information available to consumers through the innovative YouTube medium. Moreover, it is not necessary for companies to permit comments in order to track adverse events because individuals can and do use other established channels to report any adverse experiences to the appropriate companies. Companies should retain discretion over whether to allow commenting on a Brand Channel, just as companies may decide whether to place social media features on their own websites.

Google's Sidewiki Service for Independent Website Commentary

Sidewiki Enables Increased Public Commentary and Participation

Launched in September 2009, Sidewiki is a service that users may choose to enable as part of the Google Toolbar. The Sidewiki service allows users who have opted-in to create independent commentary related to almost any website on the Internet and allows other Sidewiki users to view that commentary at the same time they view the underlying website. Sidewiki presents its users with a vertical window on the left side of the web browser window, next to the relevant website, in which they can write and read this commentary. The service uses an algorithm to identify the best comments, based in part on user ratings, and seeks to display only comments that are judged to be of high quality. An example of a web browser displaying the Sidewiki window appears as Appendix B.

Sidewiki allows the public to participate in the Internet and provides a unique form of interactivity that does not exist in traditional media. For example, users can praise excellent websites, offer additional information, provide an independent critique, or expose scams, all in a way that is easily viewable by other Sidewiki users but which does not affect the underlying website's operation in any way.²¹ And while website operators cannot directly control or edit Sidewiki content created by users, they can choose to enter "site owner" Sidewiki comments about their own websites, which will then appear at the top of the Sidewiki window when users visit that specific website. In this way, the website owner is guaranteed a voice in the discussion of their site, but not in a way that allows them to control content other users may wish to contribute to the discussion. Simply put, Sidewiki enables increased public commentary and open participation on the Internet, without interference with the underlying websites.

Sidewiki Is Independent of Underlying Websites

Given the novelty of the Sidewiki service, Google believes that it is important to emphasize that the Sidewiki service is wholly owned and operated by Google. The content created by Sidewiki authors is hosted on Google infrastructure and served to Sidewiki readers from that infrastructure. Further, the Sidewiki user interface is rendered by accessing the standard

²¹ See, e.g., Noam Cohen, *Twitter and a Newspaper Untie a Gag Order*, N.Y. TIMES, Oct. 18, 2009, available at <http://www.nytimes.com/2009/10/19/technology/internet/19link.html> (setting forth how users of social media tools, including Sidewiki, exposed the illegal dumping activities of a shipping company).

tools exposed by the web browser application. The underlying website is not affected or changed in any way by the operation of the Sidewiki tool. The website operator in no way controls how or what content is posted on Sidewiki. Ultimately, Sidewiki is an optional extension of the user's Internet browsing experience, conceptually similar to opening a reference book while reading a newspaper article.

Application of FDA Regulations to Sidewiki

Question 3 in the FDA Notice asks what parameters should apply to the posting of corrective information on web sites controlled by third parties.²² Question 5 asks how regulated entities should approach adverse event reporting in the Internet context.²³ Both of these questions explore whether a business regulated by the FDA should be responsible for monitoring and responding to content posted online by persons or entities other than the regulated business.

Google respectfully encourages the FDA to avoid any regulation that would undermine the independent, participatory, and democratic nature of Sidewiki and other innovative social media services. In particular, Google is concerned that requiring regulated businesses to monitor or respond to comments on Sidewiki and other services would create an incentive for such businesses to attempt to control or eliminate these forums, thereby preventing consumers from enjoying the benefits of these services. Given the free speech and participatory citizenship values enhanced and fostered by such services, Google believes that the FDA should clearly state that regulated entities are not required to monitor or respond to commentary on such websites and services that they do not sponsor.

Requiring Businesses to Monitor or Respond to Sidewiki Commentary Would Be a Departure from the FDA's Existing Position

As the description above shows, Sidewiki is not controlled or sponsored by the websites that are commented upon, but is wholly owned and operated by Google. Thus, Sidewiki constitutes an independent online forum even though the Sidewiki window appears next to the website that is commented upon by virtue of the Google Toolbar's use of web browser "add-on" infrastructure. Applying the FDA's established position, companies should not be required to monitor Sidewiki for adverse event experiences or for misinformation about FDA-regulated medical products.

The FDA's *Draft Guidance for Industry: Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines*, issued in March 2001 ("Draft Guidance"), explains that entities with postmarketing reporting obligations should review websites that *they sponsor* for adverse experience information, but are not responsible for reviewing websites that they do not sponsor for such information.²⁴ Because the owners of the underlying websites have no control over Sidewiki or its content, Sidewiki is clearly not "sponsored by" these regulated entities, but rather by Google. Indeed, website visitors who have not affirmatively chosen to activate the Sidewiki service cannot even see the Sidewiki window or comments. Thus,

²² 74 Fed. Reg. at 48,087.

²³ *Id.*

²⁴ Draft Guidance, *supra* note 20.

applying the FDA's existing guidance, we believe that businesses should not be responsible for proactively reviewing comments on Sidewiki, just as they are not responsible for reviewing information on other sites that they do not sponsor.

Question 3 in the FDA Notice introduces the possibility of companies posting corrective information on websites controlled by third parties. In order to post corrective information, a regulated company would need to become aware of misinformation or misconceptions on a website outside of that company's control. Although some companies may wish to undertake such research voluntarily, Google suggests that the FDA not impose any requirement for companies to monitor websites that they do not sponsor. In the context of adverse events, the FDA's Draft Guidance drew a reasonable distinction between websites sponsored by a regulated business, which involve a finite and easily-located universe of online content, and third party websites, which generate an unworkable monitoring task. Google believes that this distinction is equally reasonable in the context of online misinformation, and therefore that it would be inconsistent for the FDA to require regulated entities to monitor or correct misconceptions or misinformation that may appear on third party websites.

Requiring Businesses to Monitor and Respond to Sidewiki Commentary Would Be Contrary to Public Policy

There are compelling public policy justifications for maintaining the existing distinction between websites sponsored by regulated companies and outside websites and services. Altering the FDA's established position would place an undue and unworkable burden on regulated businesses by requiring them to search an infinite number of webpages and thereby forcing them to search for the proverbial "needles in a haystack." Given the vast and exploding number of online resources, it is not feasible for businesses to review every website that they do not sponsor for adverse event information or incorrect information. In addition, unscrupulous competitors or pranksters could take advantage of the anonymity of the Internet to publish false information on adverse events or any other matter. Due to these challenges, businesses would face an unfair and unworkable high risk of error and liability. Google is not aware of any precedent for compelling businesses to monitor and respond to the virtually unlimited amounts of information available through unrelated online sources.

Google is also concerned that imposing these risks and burdens on regulated entities would create an incentive for those entities to apply business and/or legal pressures to shut down third party websites and services, such as Sidewiki, that could give rise to monitoring obligations. Google strongly believes that such outside websites and services contribute to the vitality and free information structure of the Internet, and play an important role in helping consumers to understand and use online resources, especially as the amount of information online continues to increase exponentially. It is critical for regulation to avoid stifling the public participation and exchange of ideas that Sidewiki and similar innovations are intended to promote.

Moreover, such significant effort is unlikely to advance consumer protection. Consumers generally recognize that online information sources, like other sources, differ in their trustworthiness. A consumer who finds information about a commercial product on a third

party website is therefore likely to seek confirmation and/or additional information from the website of the commercial producer itself. As a result, misinformation on a third party website is unlikely to confuse consumers as long as the commercial website includes correct information. Likewise, a consumer is most likely to report adverse information directly to the company concerned, and thus the compliance burden of compulsory monitoring of third party websites is not justified by the low probability of discovering additional reporting information.²⁵

In sum, the FDA's existing distinction between websites sponsored by a regulated entity and third party websites is reasonable, workable, and should be maintained. Although the FDA established this distinction in the context of adverse events reporting, it is equally applicable to the tasks of monitoring and correcting misinformation raised by Question 3 in the FDA Notice. To provide clarity for the regulated community, Google urges the FDA to take the explicit position that regulated entities are not required to monitor or respond to commentary on third party websites and services such as Sidewiki.

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Google appreciates the opportunity to provide these Comments to the FDA as it considers the important issue of online promotion of regulated medical products. Please do not hesitate to contact Pablo Chavez, Managing Policy Counsel, at 202.346.1237 with any questions.

²⁵ A white paper written by Nielsen Online surveyed 500 healthcare-related messages across several disease categories online and found only one message that contained all four of the elements required to trigger an adverse event reporting obligation. See Melissa Davies, *Listening to Consumers in a Highly Regulated Environment: How Pharmaceutical Manufacturers Can Leverage Consumer-Generated Media*, Nielsen Online (August 2008).

APPENDIX A

Generic Framework for YouTube Brand Channel



APPENDIX B

Example of Web Browser Displaying Sidewiki Window

In this example, a Google employee warns visitors about a scam website.

