

THE FOOD AND DRUG ADMINISTRATION'S FOCUS ON ONLINE MARKETING OF PHARMACEUTICAL PRODUCTS

On March 26, 2009, the US Food and Drug Administration's (FDA's) Division of Drug Marketing, Advertising, and Communications (DDMAC) sent Untitled Letters to 14 pharmaceutical companies addressing their use of "sponsored links" on internet search engines,¹ i.e., links (with product-related content) from which a user can access the official product websites. FDA's position, as explained in the Untitled Letters, is that a sponsored link violates the Federal Food, Drug, and Cosmetic Act's (FDCA's) misbranding provisions where the product-related content associated with the link contains inadequate or misleading information related to a drug product's risks or indications.

Notably, FDA has yet to issue specific regulations or guidance addressing online promotional practices, and, in fact, FDA has never stated an official policy on how online promotion fits within the current drug labeling and advertising regulatory scheme. Nonetheless, FDA is actively monitoring companies' practices on the Internet, and companies are required to submit promotional materials disseminated on the Internet to FDA for review at the time of first use (or as otherwise required).² For the time being, DDMAC's issuance of Warning Letters and Untitled Letters continues to best reflect its views regarding the dissemination of product-related information on the Internet.

Since 2000, DDMAC has issued approximately 40 letters asserting Internet-related violative practices, most of which address promotional practices on official product websites. In 2008, however, DDMAC sent two letters addressing use of videos posted on third-party websites (such as YouTube), and one letter addressing use of "online banners." Thus, it is clear that FDA continues to monitor and respond to industry's evolving practices on the Internet, and such practices will likely to be a continuing enforcement focus for FDA.

"SPONSORED LINK" UNTITLED LETTERS

FDA sent the Untitled Letters to 14 pharmaceutical companies, and 11 of the letters assert violations related to multiple products (for a total of 48 products addressed among the 14 letters). As discussed in this client advisory, FDA asserts similar violative practices across the 14 letters—specifically that a sponsored link misbrands a drug

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¹ The Untitled Letters were sent to the following companies (in alphabetical order): Bayer Healthcare Pharmaceuticals, Inc.; Biogen Idec; Boehringer Ingelheim Pharmaceuticals, Inc.; Cephalon, Inc.; Eli Lilly and Co.; Forest Laboratories Inc.; Genentech Inc.; GlaxoSmithKline; Hoffman-La Roche Inc.; Johnson & Johnson Pharmaceutical Services, L.L.C.; Merck & Co., Inc.; Novartis Pharmaceuticals Corp.; Pfizer Inc.; and sanofi-aventis U.S. LLC. FDA posted the letters on its website on April 3, and they are available for viewing (along with images of the promotional materials at issue) at <http://www.fda.gov/cder/warn/warn2009.htm>.

² 21 C.F.R. § 314.81(b)(3)(i).

product where the link-associated content: (i) inadequately communicates a product's risk information; (ii) inadequately communicates a product's indication(s); or (iii) fails to use a product's required established name.

The letters are styled as Untitled Letters, which according to FDA's Regulatory Procedures Manual means that the letters "cite[] violations that do not meet the threshold of regulatory significance for a Warning Letter."³ FDA has explained that a violation of "regulatory significance" means that the violation "may lead to enforcement action if not promptly and adequately corrected."⁴ This distinction has relevance in that a Warning Letter represents a stronger form of notice that FDA views a particular practice as violative of the FDCA. Nonetheless, the simultaneous issuance of these Untitled Letters to multiple companies reflects a desire to stake out an Agency position on this issue and then consider the responses and alternatives offered up by industry. Although a significant debate will likely ensue over whether such links are appropriately subject to the standard requirements for promotional materials, it is unlikely FDA will afford industry significant flexibility.

FDA generally addresses, across the 14 Untitled Letters, the following issues related to use of sponsored links:

- **Omission of Risk Information:** In all 14 letters, FDA asserts that the sponsored links make "representations and/or suggestions" about the efficacy of specific products (i.e., the sponsored links make product claims) without communicating any risk information associated with use of the products. FDA asserts that omission of the most serious and frequently occurring risks from the sponsored-link content misleadingly suggests that the products are safer than demonstrated. FDA expresses specific concern in the letters regarding the omission of risk information for products that have "Boxed Warnings" or restricted distribution programs. Notably, FDA acknowledges in the letters that the sponsored links contain links to the respective product websites; however, according to FDA, this does mitigate "the misleading omission of risk information" from the sponsored link itself.

- **Inadequate Communication (and Broadening) of Indication:** In 13 of the 14 letters, FDA asserts that the sponsored links contain "brief statements" explaining "what

the [products] are used for" (i.e., the products' indication(s)), but that the statements are "incomplete and misleading, suggesting that [the products] are useful in a broader range of conditions or patients than has been demonstrated by substantial evidence or substantial clinical experience."

- **Failure to Use Required Established Name:** FDA asserts that many of the sponsored links do not present the products' full established names in accordance with FDA regulations.⁵ In other words, the sponsored links refer to the products' proprietary names without also providing their established names (also known as "generic names"). FDA asserts this violation in each of the 14 letters (with respect to 41 of the 48 drug products addressed across the letters).

Each letter concludes by stating that, for the reasons discussed (and previously summarized), the sponsored links misbrand the drug products in violation of the FDCA and FDA regulations. FDA requests that each company "immediately cease the dissemination" of the violative promotional materials (i.e., the sponsored links). FDA requests that the companies submit written responses, which should state whether they intend to comply with the request to cease dissemination. FDA also requests that the written responses list all promotional materials currently in use (with associated Form 2253 submission dates)⁶ with respect to the products identified in the Untitled Letters, and identify whether any other promotional materials in use contain "violations such as those described" in the letters.

RELATED "NEW MEDIA" ISSUES AND IMPLICATIONS

On October 16-17, 1996, FDA held a public meeting entitled "Promotion of FDA-Regulated Products on the Internet." In the Federal Register notice announcing that meeting, FDA explained that it was evaluating:

[H]ow the statutory provisions, regulations, and policies concerning advertising and labeling should be applied to product-related information on the Internet and whether any additional regulations, policies, or guidances are needed. Although

3 FDA, Regulatory Procedures Manual at 4-2-1 (Mar. 2009).

4 *Id.* at 4-1-1.

5 21 C.F.R. §§ 201.10(g)(1), 202.1(b)(1).

6 FDA Form 2253 is the form for submission of advertisements and promotional materials for DDMAC review.

the agency believes that many issues can be addressed through existing FDA regulations, special characteristics of the Internet may require the agency to provide guidance to the industry on how the regulations should be applied.⁷

As noted above, however, FDA has yet to issue specific regulations or guidance addressing Internet promotional practices, and, in fact, FDA has never stated a definitive policy on how Internet promotion fits within the current drug labeling and advertising regulatory scheme.⁸ With the continued advancement of online technologies, we expect that FDA will ultimately issue a draft guidance, and we note that the FDA website currently states that “DDMAC is developing an agency-wide policy to address how advertising and promotion of FDA-regulated products will be regulated on the Internet.”⁹ However, FDA’s timeframe for issuing such guidance—and the scope of any guidance—is as yet unclear. Thus, until FDA issues specific regulations or guidance on Internet promotional activities, Untitled Letters and Warning Letters continue to be the primary source of FDA’s current views regarding the dissemination of product-related information on the Internet.

The relevant letters issued by FDA over the last several years have focused on companies’ practices on official product websites. As previously noted, however, in 2008 FDA issued two Warning Letters addressing use of videos posted on third-party websites,¹⁰ and one Untitled Letter addressing use of “online banners.”¹¹ In particular, in the Warning Letter to Shire Development Inc. (Shire), FDA asserts that Shire posted a “video testimonial” on YouTube.com featuring celebrity Ty Pennington discussing his experiences using Adderall XR® Capsules. According to FDA, the video testimonial overstates the product’s efficacy and omits important risk-

related information, and in addition, the video testimonial was not submitted to FDA for review (under a Form 2253).¹² Although arguably this letter is a straightforward application of FDA’s drug labeling and advertising regulations, it is likely a signal that FDA is actively reviewing other modes of Internet communication, and may turn to enforcement in the “Web 2.0” context, in which companies may play a role in fostering interactivity between users (e.g., patient networking sites). Such enforcement will present significant difficulties for FDA in terms of how such Web 2.0 activities fit within the current regulatory framework, and the extent to which such communications are protected under the First Amendment.

Along with the 14 Untitled Letters addressing use of sponsored links, these recent letters indicate that FDA continues to respond to companies’ evolving practices on the Internet, and we expect that this trend will continue going forward. Companies active in online marketing of pharmaceutical products and medical devices should carefully monitor these developments and consider creative strategies for achieving compliance in an ambiguous and dynamic regulatory environment.

We hope that you have found this client advisory useful. If you have additional questions, please contact your Arnold & Porter attorney or:

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⁷ 61 Fed. Reg. 48,707 (Sept. 16, 1996).

⁸ Letter from Margaret M. Dotzel, Associate Commissioner for Policy, FDA, Responding to Citizen Petition from Daniel J. Popeo and Paul D. Kamenar, Washington Legal Foundation, Docket No. 2001P-0187 (Nov. 1, 2001).

⁹ FDA DDMAC, “Policy Development and Guidance to Industry,” available at http://www.fda.gov/cder/handbook/pol_guid.htm (last visited Apr. 13, 2009).

¹⁰ Warning Letter from Thomas Abram, Director, DDMAC, FDA to Angus Russell, CEO, Shire Development, Inc. (Sept. 25, 2008); Warning Letter from Thomas Abram, Director, DDMAC, FDA to Jeffrey B. Kindler, Chairman and CEO, Pfizer, Inc. (Apr. 16, 2008).

¹¹ Untitled Letter from Sangeeta Vaswani, Acting Group Leader, DDMAC, FDA to Graydon A. Elliot, Director, Drug Regulatory Affairs, Novartis Pharmaceuticals Corp. (Aug. 28, 2008).

¹² Warning Letter to Shire, at 4-5.