



Food, Drug & Device/FDA ADVISORY ■

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Dietary Supplement Manufacturer “Likes” Post on Facebook; FDA Does Not

FDA Issues Warning Letter for Facebook and More

On February 26, 2013, the U.S. Food & Drug Administration (FDA) published a Warning Letter¹ issued to a dietary supplement manufacturer because, among other violations, the company “liked”—a function unique to Facebook that is utilized by a user simply clicking the  button underneath the post—a post on its Facebook wall that was posted by a consumer. FDA warned AMARC Enterprises (AMARC) that numerous cancer treatment claims made on the company website, including the company’s Facebook page, violated the Federal Food, Drug and Cosmetic Act (FDCA). According to FDA, the company’s promotional activities suggesting that its Poly-MVA supplement could cure or treat cancer established that the product is a drug intended for use in the cure, mitigation, treatment or prevention of disease. FDA also cited the following consumer Facebook post, which was “liked” by Poly MVA (the site administrator):

“PolyMVA has done wonders for me. I take it intravenously 2x a week and it has helped me tremendously. It enabled me to keep cancer at bay without the use of chemo and radiation...Thank you AMARC”

FDA’s Warning Letter to AMARC is the most recent development in FDA’s activity related to social media.

FDA takes the position that a company website constitutes product labeling,² but has declined to issue formal guidance on the promotion of FDA-regulated products on the Internet. The uncertainty within industry due to the lack of guidance has been complicated by rapid changes in Internet-based communications, including the growth of, and consumers’ reliance on, social media.

In 2011, FDA issued its only Draft Guidance addressing social media (“2011 Draft Guidance”).³ However, the 2011 Draft Guidance focused narrowly on how FDA-regulated entities should respond to unsolicited consumer requests for off-label use information. Despite the fact that the preamble suggested that it would address “emerging electronic media,” the 2011 Draft Guidance provided no specific guidelines for *any* social media outlet and did not even mention Facebook.

¹ FDA Warning Letter to AMARC Enterprises (December 11, 2012), available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm340266.htm>.

² See FDA Letter to Washington Legal Foundation (November 1, 2001), available at http://www.fda.gov/ohrms/dockets/dailys/01/Nov01/110901/01p-0187_pdn0001.pdf (denying the citizen petition’s request for the Agency to formally adopt a policy that a company’s Internet website did not constitute labeling).

³ FDA’s Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Medical Devices (December 2011), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf>.

The Draft Guidance did provide one bedrock principle: manufacturers are generally responsible and accountable for any website or social media content that “they maintain and over which they have full control.”⁴ Far short of the comprehensive recommendations the industry had hoped for, the 2011 Draft Guidance left many questions unanswered. These lingering questions have only been magnified by social media outlets such as Facebook, with its constantly changing interface and added features and complexities. With current guidance limited to unsolicited requests for off-label information, and future guidance unlikely before the congressionally mandated deadline of July 9, 2014,⁵ FDA’s enforcement activity provides the only guidance for determining FDA’s policy.

With over 1 billion users worldwide, Facebook is the most popular social media service on the planet. Today, Facebook is a powerful tool for companies to utilize for marketing and product promotion. Since 2011, FDA has issued over a dozen Warning Letters that cite promotional violations by activity on a company’s Facebook page. These Warning Letters collectively evidence a clear trend of subjecting this social media space to scrutiny as labeling under the FDCA. Specifically, FDA has warned companies for claims made using the following Facebook features:

- the “Info”/“About” section of the Facebook page;⁶
- a reference/link to the company website on the Facebook page (where the company’s website included improper drug claims for a dietary supplement);⁷
- a reference/link to third-party articles posted to the Facebook page;⁸
- a video posted to the Facebook wall;⁹
- a wall post by the company/site administrator;¹⁰
- company “comments” to wall posts by consumers;¹¹
- testimonials posted to the Facebook wall by the company;¹² and
- the company “liking” a consumer post.¹³

⁴ 2011 Draft Guidance at 10.

⁵ See 21 USC 379d-5. This little-known provision was passed as part of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012.

⁶ FDA Warning Letter to AloeElite (March 30, 2011), available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm253987.htm>.

⁷ FDA Warning Letter to From Fatigued to Fantastic, LLC (April 18, 2012), available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm301795.htm>.

⁸ FDA Warning Letter to Vitality Distributing, Inc. (April 24, 2012), available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm301669.htm>.

⁹ FDA Warning Letter to Quincy Bioscience Manufacturing (October 16, 2012), available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm324557.htm>.

¹⁰ FDA Warning Letter to Nature’s Rite (September 19, 2011), available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm273464.htm>; FDA Warning Letter to For Earth, Inc. (August 19, 2011), available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm271386.htm>.

¹¹ FDA Warning Letter to Trinity Sports Group (August 28, 2012), available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm318392.htm>.

¹² FDA Warning Letter to Cellular Rx (May 25, 2011), available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm256922.htm>.

¹³ FDA Warning Letter to AMARC Enterprises (December 11, 2012), available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm340266.htm>.

These Warning Letters demonstrate that not only are a company's explicit, affirmative postings on its Facebook page regulated as product labeling, but a company's implicit statements are as well. By including customer testimonial posts on the Facebook page or by merely "liking" a customer post, a company can violate the FDCA. As AMARC recently learned, FDA considered the company's affirmative act of "liking" the *consumer post* as evidence that AMARC was promoting Poly-MVA for use in the treatment of cancer. And because Poly-MVA has not been approved by FDA as a drug, the claims are illegal under the FDCA.

These Warning Letters also provide remarkable insight into FDA's sophistication in the social media arena. It is evident from FDA's issuance of numerous Warning Letters regarding Facebook content that the Agency reviews and considers the content of a company's Facebook wall in the same way that it does a company website—both are firm-controlled websites. However, applying this principle to Facebook poses difficulties. Differing from a company website (over which the company has complete control) and third-party websites (over which the company generally has no control), Facebook provides an interactive forum. On Facebook, a company may set up its own page where a site administrator has control over what the *company* posts to its Facebook page, allows for *consumer* posts to the Facebook page and provides the site administrator control to respond to, limit or remove posts.

While FDA has not issued explicit guidance regarding the use of Facebook, it is clear that FDA holds firms *accountable* for what appears on their Facebook page and considers any *affirmative actions* by the company to constitute promotional activities. FDA will hold companies accountable for any off-label information (in the case of drugs) or any claims that establish that the product is a drug (for example, in the case of dietary supplements or cosmetics) if the company takes an affirmative action with respect to the claim (posting, commenting, "liking").

In order to avoid a Warning Letter related to the use of social media, companies should carefully review their advertising and promotional materials, including the information and materials available on the Internet and through social media such as Facebook. We recommend a review of your company policies and procedures to ensure that:

- Your company understands the need for processes designed to comply with the principles and guidance that FDA may apply to your company's social media activity, keeping in mind that:
 - a Facebook page, much like a company website, constitutes labeling, not advertising, and is subject to FDA's jurisdiction; and
 - although FDA has never clearly articulated its policy with regard to specific social media outlets such as Facebook, FDA will still issue Warning Letters to companies for improper claims found on a company's Facebook page;
- you have a robust policy in place for product promotion on the Internet and through social media, including specific guidelines for Facebook pages and other company controlled websites;
- you have procedures governing employee use of social media, including Facebook; and
- you have a site administrator with responsibility for actively overseeing the company's social media outlets.

When developing a social media policy, be aware that FDA is reviewing your company's Facebook page, but does not want to be your Facebook "friend."

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