

PHARMACEUTICAL AND BIOTECHNOLOGY UPDATE

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FDA Announces Public Hearing on the Internet and Social Media in Drug Advertising and Promotion

On September 21, 2009, the U.S. Food and Drug Administration (FDA) announced plans to hold a public hearing on November 12 and 13, 2009, to discuss issues surrounding the use of Internet and social media in the promotion of FDA-regulated products, including prescription drugs, prescription biologics, medical devices, and prescription animal drugs.

The FDA has opened [Docket No. FDA-2009-N-0441](#) at www.regulations.gov for comments and registration for parties wishing to attend or to speak at the meeting. Comments will be accepted until February 28, 2010.

In its announcement, the FDA specifically invites input on five broad issues that it describes as the most frequently raised by regulated companies and other interested parties. The FDA also seeks available data and research on the use of social media tools in promotion, including data from companies about their experience. Below, we summarize the topics FDA has identified as important going forward, and encourage companies to consider participating in the hearing.

In addition, the agency welcomes other relevant comments and input on Internet-based promotion. We believe there are other important issues that companies should consider when engaging the agency through its hearing or docket, or establishing corporate policies on this important subject, including:

- The use of viral marketing that incorporates social media tools;
- Whether and how the agency may limit social media promotion of a product with a high risk profile or associated safety issues; and
- Whether promotion using the Internet and social media tools constitutes advertising or labeling.

The topics for discussion at the public hearing will pose significant challenges for FDA and regulated industry going forward. The FDA will have to balance its statutory mandate with a fast-changing media environment to develop a “living” regulatory structure that can be applied to many different communication tools. This challenge has stymied the development of useful guidance to date, and may ultimately doom the current effort. Regardless, companies should participate in and observe the FDA’s regulatory efforts closely, adopt corporate policies to govern their own actions, and take steps to assure truthful and non-misleading promotion through the myriad of available media choices.



Questions FDA Has Identified for Discussion at the Hearing

1) For what online communications are manufacturers accountable?

- In what situations can manufacturers be held responsible for third-party communications?
- Does this analysis vary depending on the specific social media platform used?

2) How can manufacturers fulfill regulatory 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?

- What types or formats of presentations ensure that promotion using social media tools contains a fair balance between risk and benefit information?

3) What parameters should apply to the posting of corrective information on Web sites controlled by third parties?

- Does the audience of the site (general public, health care professionals) affect this analysis?

4) When are links appropriate?

- Is it appropriate to link from branded to unbranded sites or other sites outside the control of the manufacturer?
- Is there data or research that shows how users actually use different links to access more information about a product?

5) Adverse Event Reporting.

- The FDA's current interpretation is that manufacturers are responsible for reporting adverse event information obtained through Internet sites that they sponsor. How are companies monitoring the Internet and social media for possible adverse events?
- What methods do companies use to review and process adverse event information found on disparate Internet sources?

Conclusion

The FDA has so far elected to treat the Internet just as it does traditional media. Its policies for Internet and social media tools have been developed ad hoc, in individual enforcement actions. In announcing a public hearing on these topics, the FDA is taking a meaningful step forward in addressing these important issues, and we welcome these efforts.

Please contact any of the attorneys listed below to further discuss these issues or for assistance in monitoring the hearing or fashioning comments.



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