

FDA Accepting Comments on Drug and Device Advertising Using the Internet and Social Media Tools

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The Food and Drug Administration (“FDA”) held a public hearing on November 12 – 13, 2009, titled *Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools* (“Public Hearing”).¹ In addition to the Public Hearing, the FDA is accepting written comments from interested parties.² Interested parties, including pharmaceutical, medical device, and biologics manufacturers, should consider reviewing the available materials from the Public Hearing and submitting written comments to the open docket. **Comments must be submitted by February 28, 2010. Information regarding submission of comments on the Public Hearing can be found at <http://www.regulations.gov>.**

During the Public Hearing, interested parties made presentations and answered questions from the FDA panelists.³ The Public Hearing was significant because it provided the public, including consumers, patient advocacy groups, Internet vendors, advertising agencies, and industry, the opportunity to provide the FDA with information regarding the development and use of social media that could impact any future guidance document or regulation developed by the FDA.

The FDA stated in its Notice of Public Hearing that the purpose of the Public Hearing was to “provide an opportunity for broad public participation and comment concerning Internet promotion of FDA-regulated medical products . . . FDA is particularly interested in hearing views from the public as to how expanding Web 2.0 technologies

¹ Information regarding the Public Hearing, including transcripts and an archived webcast, is available at <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm184250.htm>.

² See, Notice of Public Hearing; Request for Comments, 74 Fed. Reg. 48,083 (Sept. 21, 2009), available at: <http://edocket.access.gpo.gov/2009/pdf/E9-22618.pdf> (“Notice of Public Hearing”).

³ The FDA panelists included representatives from the FDA’s Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Center for Veterinary Medicine, and Center for Devices and Radiological Health.

may be used to promote medical products to both health care professionals and consumers in a truthful, nonmisleading, and balanced manner.”⁴ The FDA further stated in the Notice of Public Hearing and reiterated at the Public Hearing that it is particularly interested in data and research on the use of social media tools in promotion to health care professionals and consumers.⁵

Specifically, the FDA asked the presenters to focus on five specific questions:

1. For what online communications are manufacturers, packers, or distributors accountable?
2. How can manufacturers, packers, or distributors fulfill regulatory requirements (e.g., fair balance, disclosure of indication and risk information, postmarketing 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)?
3. What parameters should apply to the posting of corrective information on Web sites controlled by third parties?
4. When is the use of links appropriate?
5. Questions specific to Internet adverse event reporting.⁶

EpsteinBeckerGreen strongly encourages interested parties to submit written comments responsive to the questions outlined by the FDA and, if available, provide any data or research related to social media tools. EpsteinBeckerGreen is available to assist with drafting and submitting comments to the FDA.

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This Client Alert was authored by [Wendy C. Goldstein](#), [Sarah K. Giesting](#) and [Lee H. Rosebush](#). For additional information about the issues discussed in this Client Alert, please contact one of the authors or the EpsteinBeckerGreen attorney who regularly handles your legal matters.

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⁴ 74 Fed. Reg. 48,085.

⁵ 74 Fed. Reg. 48,086.

⁶ 74 Fed. Reg. 48,086 - 48,088.

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