

## Up Front

### Let's Respond to FDA's Questions Regarding Its Regulation of Social Media

On April 1, 2009, my "April Fool's" fake press release announcing that the FDA issued the first-ever draft guidance on pharma's use of social media created quite a stir among pharmaceutical industry pundits and executives.

Later that month, I drafted a petition calling upon the FDA to convene a public hearing on the issue. The petition stated:

"...it is necessary for the FDA to convene a PUBLIC HEARING

where ALL stakeholders can participate in a discussion of the issues and provide the FDA with a good understanding of the Internet as it exists today and tomorrow. That understanding and knowledge can then be the basis for issuing guidance that will allow the pharmaceutical industry to contribute to the conversation online" (see "FDA, Tear Down This Wall! A Draft Petition Calling for a Public Hearing"; <http://bit.ly/Q7jzA>).

#### They Said It Wouldn't Happen!

At the time, many experts pooh-poohed my call for a public hearing and said it would never happen. Richard Meyer, for example, wrote a DTC Marketing Blog post entitled "Why the FDA will not conduct a public hearing on social media" (see <http://bit.ly/Er0Or>).

"If the FDA opened hearings to the public they would get an earful of what they don't want to hear or acknowledge: that patients are becoming empowered because they don't trust drug companies and that they prefer older approved medications or generics to new branded drugs," said Meyer.

#### Pigs Can Fly!

Well, the FDA has now actually submitted a notice to the Federal Register (published Monday, September 21, 2009) calling for a public hearing on the "Promotion of Food and Drug Adminis-



tration-Regulated Medical Products Using the Internet and Social Media Tools" (see <http://bit.ly/DGEiE>).

Here's the short version of the notice:

Docket No. FDA-2009-N-0441, CDER 200994. Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools; Notice of Public Hearing (Notice of public hearing; request for comments). Public Hearing on November 12, 2009 And November 13, 2009.

Support for such a hearing was documented in a *Pharma Marketing News* article (see <http://bit.ly/86cQX>), which summarized results of a reader survey.

#### Submit Your Comments

The FDA is also seeking comments before and after the hearing (until February 28, 2010). You can submit a comment for inclusion in the docket at [www.regulations.gov](http://www.regulations.gov).

Either before or after you submit your comments to the FDA, you may want to take a look at the survey I created (see <http://bit.ly/s7tuw>). It includes all the 19 questions for which the FDA is seeking comments (aka, "earfuls of what they don't want to hear").

This survey includes these main sections (pages):

1. Introduction
2. Questions About You (affiliation, support of industry, etc.)
3. Issue 1: Accountability
4. Issue 2: Fulfilling Regulatory Requirements
5. Issue 3: Posting Corrective Information
6. Issue 4: Links
7. Issue 5: Adverse Event Reporting
8. Opt In Choice (if you'd like attribution in a future PMN article)

*Continues...*

## 9. Thank You and Summary of Results

Many questions are pre-programmed with answers that you can select. As the survey progresses, other choices may be added to the list of answers. These additional choices will come from reviewing comments made to each question. It is important, therefore, that you include comments with any additional choices.

After you complete the survey, you will be able to see a summary of responses, not including comments or other identifiable information about respondents.

Your comments are confidential (anonymous) unless you specifically provide your contact information at the end of the survey and allow us to attribute comments to you personally.

It is hoped that by participating in this survey you will learn more about the issues and use what you learn to submit an official comment to the FDA.



**John Mack, Editor**



**Follow me and my friends on Twitter.**  
[www.twitter.com/pharmaguy](http://www.twitter.com/pharmaguy)

A banner with a green top section containing the text "FDA's Regulation of Rx Promotion via the Internet &amp; Social Media". Below this is a yellow section with a graphic on the left showing a hand holding a pen over a document with the text "Pharma Marketing News Questionnaire &amp; Survey". To the right of the graphic, the text reads: "FDA is seeking answers to 19 specific questions. Do you have the answers? Take this survey and tell us, then copy the FDA." The banner also includes small icons for YouTube, Facebook, and Twitter.

Many questions are pre-programmed with answers that you can select. As the survey progresses, other choices may be added to the list of answers. These additional choices will come from reviewing comments made to each question. It is important, therefore, that you include comments with any additional choices. It is hoped that by participating in this survey you will learn more about the issues and use what you learn to submit official comments to the FDA.

Please take 2 minutes to answer this questionnaire regarding FDA's regulation of Rx promotion via the Internet and social media.

**TAKE THE SURVEY HERE: <http://bit.ly/s7tuw>**