

FDA-2009-N-0441-0001

Request to make an oral presentation at November 12 and 13, 2009, Public Hearing on Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools

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Since September 20, 2009, Pharma Marketing News (www.news.pharma-mkting.com) has been hosting an online survey/questionnaire that asks respondents to answer all 19 questions posed by FDA in its public notice. The survey can be found here: <http://bit.ly/zPR1f>

The survey includes the following sections:

1. Introduction
2. Questions About Respondent (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
9. Thank You and Summary of Results

Sections 3 through 7 include the 19 questions FDA included in its public notice. Many of these questions, however, are pre-programmed with answers that respondents may select. Respondents may also insert comments and supply their own answers. As the survey progresses, other the pre-programmed choices were updated to include answers submitted in comments.

The goal of this survey is to obtain both quantitative and qualitative answers to the questions posed by the FDA. As the survey progresses, results will be (and have been) summarized on Pharma Marketing Blog and in Pharma marketing News. Below is one such summary posted to Pharma Marketing Blog:

-----BEGIN PHARMA MARKETING BLOG POST-----

[What Techniques are Used by Pharma to Monitor Adverse Events on Social Media Sites? Survey says...](#)

In preparation for FDA's public hearing on the Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools, the agency is asking for comments on 19 specific questions (see "[Let's Respond to FDA's Questions Regarding Its Regulation of Social Media](#)"). These questions are included in my ongoing online survey/questionnaire, which you can access [here](#).

I am following the results of this survey closely and will provide updates. Here, I focus on this question:

How are entities with postmarketing reporting responsibilities and other stakeholders using the Internet and social media tools with regard to *monitoring adverse event information about their products??*

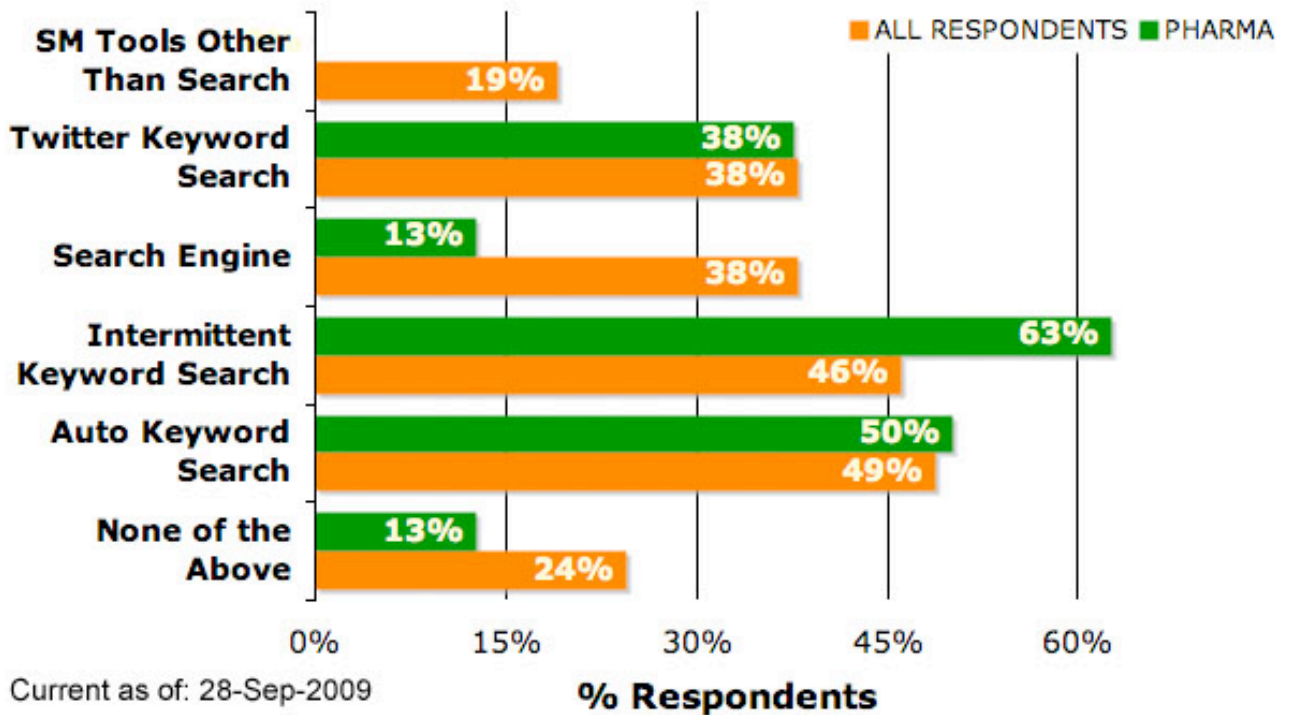
The survey asks respondents to choose one or more of the following responses (and/or add additional comments):

- Use of automated keyword searches of selected social media sites by specialized agencies and/or professionals
- Intermittent searches of selected social media sites performed by company personnel or agents
- Intermittent searches of SEARCH ENGINES performed by company personnel or agents
- Routine and automated keyword searches of TWITTER (eg, performed by SocialOomph or other services)
- Use of social media monitoring tools that do not include keywords.
- None of the above
- Don't Know

Of course, this question is most appropriate to be answered by someone within a pharmaceutical company. Some outside vendors/consultants may also know from their own experience working for pharmaceutical companies.

The image below shows how respondents answered this question (ALL respondents vs. PHARMA respondents). The image will be updated frequently. See the date stamp on the image for when it was last updated. To see the most up-to-date results, please take the survey yourself and you will be able to see a summary at the end.

Techniques Used to Monitor AEs on Social Media Sites



A Pharma Marketing News chart. (c) 2009. All rights reserved.

Also see:

- [How is Adverse Event Information from Social Media Sources Processed by Pharmacos? Survey says...](#)
- [Challenges Handling Adverse Events Found on SM Sites. Survey Says...](#)
- [Uncertainties Regarding Reporting Adverse Events Found on Social Media Sites: Survey Says...](#)

-----END PHARMA MARKETING BLOG POST-----

Pharma Marketing News would like to present the up-to-date findings of this survey at the November public hearing as per the sample Pharma Marketing Blog post. The results, however, will be presented in a PowerPoint slide deck, which will include charts like the one shown.

NOTE: Not all questions will have these kind of data charts because some questions required were open-ended answers and respondents were not given a list of possible answers to choose from. In this case, a few key findings may be presented.

Allowing for 30-45 seconds per question, it is estimated that this presentation will require 15 to 20 minutes.

It is hoped that by presenting results of this survey at the November hearing, more people will participate in answering the questions. The entire survey responses database, including open-ended comments, will be submitted into the docket when the survey is completed just prior to the February, 2010 comment submission deadline.