

Questions for the FDA Regarding “Next Steps” for Guidance Related to the Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools

These questions were collected over the course of 3 weeks following the public hearings. Input was provided by over 50 individuals representing a broad range of industry stakeholders, including marketing/PR agencies, manufacturers, search companies, health portals, and individual consumers. We understand that the FDA may not be able to answer any or all of these questions.

In an attempt to make this document as clear as possible, we have organized the questions into 5 main categories. Although we have tried to consolidate questions to limit redundancy, you might still find some overlap. Please note this document uses the term “guidelines” and “guidance” interchangeably when referring to what we believe will be the final output of this process. In addition, the term “pharma” is used to refer to any manufacturer of an FDA-regulated product.

The questions that are answered will be made publicly available on www.fdasm.com, and shared with the community at large via a various blogs and Twitter networks.

Thank you very much for your time.

Sincerely,

Fabio Gratton,

On behalf of the FDASM Community

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Dear Fabio and the FDASM Community,

Thank you for submitting your questions. We found them to be useful in identifying general issues for policy development. However, please note that we are unable to provide additional comments on some of the questions in this forum as we need to adhere to FDA’s Good Guidance Practices (GGP’s).

FDA welcomes research, data, and comments from its stakeholders and the public on any current issues related to Internet and social media promotion and adverse event reporting of FDA-regulated medical products and encourages the submission of written and electronic comments to this docket, which closes on February 28, 2010. We are committed to getting the best information as possible in helping inform our policy. Once the docket closes and we review all the comments, we will be able to determine next steps.

Again, we appreciate your continued support of this important endeavor, which we believe will aid FDA in achieving its objective of ensuring that consumers and healthcare professionals have access to accurate, balanced, and timely information about medical products.

Kind regards,

Thomas Abrams, Director, Division of Drug Marketing, Advertising, and Communications (DDMAC)

Kristin Davis, Deputy Director, DDMAC

Mark Askine, Associate Director, DDMAC

Jean-Ah Kang, Special Assistant to the Director, DDMAC

1. TRANSPARENCY, INFORMATION SHARING, AND COMMUNICATION

- Will all the written comments that are submitted to the docket be made available to the public for viewing?

Yes, all written comments submitted to this docket will be made available for public viewing at www.regulations.gov by opening the docket folder, searchable by "FDA-2009-N-0441-0001."

- Is the FDA considering creating something similar to the "Open Government" Blog (<http://www.whitehouse.gov/Open/Blog/>) or HSS' recently-launched "Health IT Buzz" Blog (<http://healthit.hhs.gov/blog/onc/>) to keep various stakeholders apprised and involved in the guideline development process?

FDA is committed to keeping its stakeholders apprised and involved with our policy development regarding promotion of medical products on the Internet and social media. We are exploring the best ways to accomplish this.

- Prior to FDA issuing guidance, will there be a public communication about what the agency is working on, how they are working, what they are concerned about, what their goals are, and what they are considering?

FDA is committed to keeping its stakeholders apprised about our policy development. However, there is a limit to what we can disclose at certain points as we need to comply with FDA's Good Guidance Practices (GGP's). FDA must adhere to GGP's with regard to developing, issuing, and using potential guidance documents.

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<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=10.115>

2. TIMING-RELATED QUESTIONS

- Will the FDA publish a detailed timeline for this whole process? If so, when?

We are unable to comment on timeframes for potentially issuing any draft guidance documents. At this time, we are currently accepting written and electronic comments to this docket until February 28, 2010. Once the docket closes and we review all the comments, we will be able to determine next steps. FDA must adhere to Good Guidance Practices (GGP's) with regard to developing, issuing, and using potential guidance documents.

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- In what timeframe might we expect the the first (draft) guidance be issued after the close of written comments? (3-6 months, 6-9 months, 9-12 months, or further out?)

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- Will there be another comment period after the first (draft) guidance is issued? (If so, how long can we expect that to last?)

In general, there is opportunity for public comment from all interested stakeholders after any draft guidance is issued by FDA. Comments and suggestions regarding a draft guidance document should be submitted within the specified timeframe listed in the Federal Register notice announcing the availability of the draft guidance. The specified timeframe is usually 90 days.

3. STAKEHOLDER COLLABORATION

- Does the FDA plan to proactively reach out to more stakeholders -- patients, public, and physicians in particular -- during the comment period? If so, how does it do that? What can we do to help?

FDA welcomes research, data, and comments from its stakeholders and the public on any current issues related to Internet and social media promotion and adverse event reporting of FDA-regulated medical products and encourages the submission of comments to this docket, which closes on February 28, 2010. We are committed to getting the best information as possible in helping inform our policy. Should we have questions about a particular submission to the docket, we may reach out to the submitter for clarification; however, we are unable to comment further as to the specific details of our future outreach and information gathering at this time.

- Does the FDA plan to reach out to any of the presenters, especially those that presented data, to either request more details or to have the data looked at / analyzed in a different way?

FDA appreciated the testimony of the presenters at the recent public hearing. In addition, FDA welcomes research, data, and comments from its stakeholders and the public on any current issues related to Internet and social media promotion and adverse event reporting of FDA-regulated medical products and encourages the submission of comments to this docket, which closes on February 28, 2010. We are committed to getting the best information as possible in helping inform our policy. Should we have questions about a particular submission to the docket, we may reach out to the submitter for clarification; however, we are unable to comment further as to the specific details of our future outreach and information gathering this at this time.

- Is the FDA considering a "taskforce/workgroup" -- consisting of various stakeholders -- to help shape guidance, AS WELL as future post-guidance activities (e.g. like an ongoing advisory board)?

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- Will there be a consultation with "experts" and/or other industries to review the potential possible negative effects of guidance rules?

FDA will seek out any expertise that is needed in our policy development in this area. However, we are unable to comment on any specifics involved in our internal deliberations.

- How will FDA collaborate with the FDA advisory board on patient risk communications?

Government agencies often collaborate on important issues. At this time, we cannot comment specifically on any potential work with other government agencies or with an FDA advisory board.

- How will FDA collaborate with the FTC?

Government agencies often collaborate on important issues. At this time, we cannot comment specifically on any potential work with other government agencies.

- How will you choose who to engage with industry and beyond for further input to development of guidelines for social media and web marketing?

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4. STEPS / APPROACH TO CREATING GUIDANCE/GUIDELINES

- Will the first guidance the FDA issues be considered "draft"?

Any potential guidance on Internet and social media promotion of FDA-regulated medical products would be considered a "Level 1 guidance document" that would be issued as a draft guidance document. Level 1 guidance documents set forth initial interpretations of statutory or regulatory requirements; set forth changes in interpretation or policy that are of more than a minor nature; include complex scientific issues; or cover highly controversial issues.

Please refer to the following link for more information about guidance documents, as outlined in the Code of Federal Regulations:

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- Will the FDA be compiling a summary (not just transcripts) of the hearing presentations and what some of their key takeaways were and how those takeaways will help to shape the guidelines?

We plan to provide a brief overview of the 77 presentations made at the public hearing at upcoming public speaking engagements in 2010 and will make the summary as informative as possible. However, there are limits to what we discuss as we need to comply with FDA's Good Guidance Practices (GGP's).

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- Does the FDA plan to pull in any outside consultants, or hire additional experts internally, to help craft the guidelines?

FDA will seek out any expertise that is needed in our policy development in this area. However, we are unable to comment on any specifics involved in our internal deliberations.

- Does the FDA plan to conduct any of its own primary research to further assess the benefits-and-risks of various approaches for online communications prior to issuing guidance?

DDMAC has an active research program designed to investigate applied and theoretical issues in the communication of risk and benefit information in direct-to-consumer (DTC) and professional promotional prescription drug materials. This research program utilizes a number of different research methodologies, including survey and experimental research as well as qualitative research for development purposes. DDMAC's research supports FDA's goal of science-based policy while maintaining its commitment to protect the public health.

Please refer to the following link for more information about DDMAC's past or ongoing research projects:

<http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090276.htm>

DDMAC also encourages other groups that may be doing or have completed research in this area to submit data to the docket to make the information publicly available. FDA is a data-driven agency and appreciates the submission of robust data to help inform our policy development.

- Will the draft be shared for comments by industry, consumers, healthcare professionals and bloggers?

In general, there is opportunity for public comment from all interested stakeholders after any draft guidance is issued by FDA. Comments and suggestions regarding a draft guidance document should be submitted within the specified timeframe listed in the Federal Register notice announcing the availability of the draft guidance. The specified timeframe is usually 90 days.

- Given that so many of the ideas shared at the presentations require ongoing studies and experimentation, what kind of resources does the FDA have at its disposal to carry out studies and how much of the work will be given to pharmaceutical companies or agencies so that experiments about AE reporting, correction models, terms of service examples, patient language PIs, patient language adverse event reporting forms, and the like can be done?

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- Does the FDA intend to work in collaboration with the FTC? Will they actively work with the FTC as opposed to follow the existing FTC guidance, as opposed to no consideration given?

Government agencies often collaborate on important issues. At this time, we cannot comment specifically on any potential work with other government agencies.

- Knowing the speed at which media changes, is the FDA considering a more regular timeline for reviewing and revising guidance?

We are unable to comment on timeframes for potentially issuing or revising any draft guidance documents. At this time, we are currently accepting written and electronic comments to this docket until February 28, 2010. Once we review all the comments, we will be able to determine next steps. FDA must adhere to Good Guidance Practices (GGP's) with regard to developing, issuing, and using potential guidance documents.

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- What does the FDA intend to do to demonstrate that they truly understand the new nature of this emerging media and the impact it has on people and businesses?

FDA will continue to engage with its stakeholders and seek out expertise in this evolving area. FDA welcomes research, data, and other input from its stakeholders and the public on any current issues related to Internet and social media promotion as well as the emerging technology and its impact on and potential benefits for public health.

5. QUESTIONS ABOUT SPECIFIC GUIDANCE/GUIDELINES CONTENT

- Is the current plan to organize guidance by topics similar to how the docket was structured?

This is a policy-related question that we are unable to answer at this time as we need to comply with FDA's Good Guidance Practices (GGP's). FDA must adhere to GGP's with regard to developing, issuing, and using potential guidance documents.

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- Will the guidance from the FDA take into account the difference between Pharmaceutical and Medical Device companies interacting with current patients whom use products of their manufacture (e.g. patient has pacemaker; patient takes Rx for depression) versus possible patients whom might be appropriate for their specific product.

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- Will the FDA consider the purpose of messaging (pre scrip vs. post script targeted to adherence and focus on health outcome) in the guidelines?

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- What will disclosure rules look like for bloggers and 'tweets' who are paid by pharmaceutical clients to tweet? How must they disclose this relationship?

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- Will the FDA consider creating AE "safe harbor," pending future guidance, that will allow manufacturers to view online conversations about their brands without fear of legal action or warning letters?

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- During the time the FDA is creating its guidance document, will the agency pre-approve search engine ads, especially those using Google's new format?

Pharmaceutical companies can submit a draft promotional piece as a request for advisory comments to ensure that the promotional piece is in compliance with the regulations. Please note that while FDA provides advisory comments on draft promotional pieces that are voluntarily submitted for comment, FDA does not "pre-approve" these promotional pieces.

- Are we responsible as the manufacturer for the content created by a 3rd party that's generated at a later date from when we initially linked to their website?

This is a policy-related question that we are unable to answer at this time as we need to comply with FDA's Good Guidance Practices (GGP's). FDA must adhere to GGP's with regard to developing, issuing, and using potential guidance documents.

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- What regulatory process is necessary internally to keep up with FDA concerns and how do you recommend we reorganize our internal resources to properly accommodate the massive new social media task of patrolling information; or are we responsible for patrolling 3rd party postings?

We believe that it is a good idea for companies to have robust policies in place for any type of promotion about their products, including social media promotion. We would advise them to carefully review their materials and processes to ensure that their promotion is compliant with the regulations. Consumers and healthcare professionals deserve an accurate and balanced picture of a drug product when it is promoted.

The question of 3rd party postings is a policy-related question that we are unable to specifically answer at this time as we need to comply with FDA's Good Guidance Practices (GGP's). FDA must adhere to GGP's with regard to developing, issuing, and using potential guidance documents.

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- In Social Media crisis situations, what role would the FDA play in reorganizing the madness so that proper health information is disseminated (versus falsified claims?)

FDA has various methods to help it achieve its mission of protecting the public health, including various surveillance, enforcement, and education programs. We are unable to comment on the broad question of FDA's role in a "social media crisis situation" as this would depend on the specific issue at hand.

However, in any given situation, FDA strives to achieve its mission to protect the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

- How will the FDA apply DTC advertising regulations for pharma to social media?

FDA's objective is for consumers and healthcare professionals to have access to accurate, balanced, and timely information about medical products. To this end, DDMAC provides oversight of prescription drug promotion to help ensure compliance with FDA's laws and regulations, which require that all promotional communications about prescription drugs that are disseminated by or on behalf of a manufacturer be truthful, non-misleading, and balanced. These rules apply regardless of the medium used for dissemination. Therefore, any positions that we take or guidance that is developed on prescription drug promotion will be based on FDA's laws and regulations.

- How can Pharma find out in a timely way about potential solutions to issues of risk-vs-benefit (for example, YAZ trying new Google paid search format)? Can others proceed? Can /will the FDA provide a statement about this so we can make some decisions prior to guidelines being issued?

We do not comment on our internal policy deliberations, including those specific to a particular proposal submitted by a company for one of its products under our advisory comment process. Pharmaceutical companies can submit a draft promotional piece as a request for advisory comments to ensure that the promotional piece is in compliance with the regulations, but any comments provided by FDA on a draft promotional piece are not publicly releasable by the Agency. However, when FDA issues any guidance document, the availability of that document will be publicly announced in the Federal Register.

- What kind of on-going metrics or actions will be put in place to monitor actions to be sure that any new guidelines put in place aren't having a different affect than anticipated? For example, the loss of one click rule was showed to have a negative impact on public health not originally planned with the sending of the 14 letters.

FDA will seek out any expertise that is needed in our policy development in this area and welcomes comments from any of its stakeholders on any guidances or actions issued. However, we are unable to comment on any specifics involved in our internal deliberations.

In reference to the untitled letters issued for violative sponsor links by pharmaceutical companies, it should be noted that FDA never had what some are referring to as a "one click rule."

- There has been a lot of discussion concerning "significant websites" that we might be required monitor/corrected and from which manufacturers might be expected to track and report adverse events. Will the FDA take responsibility for defining what "significant" might mean, or will this definition be created by some external advisory panel?

This is a policy-related question that we are unable to answer at this time as we need to comply with FDA's Good Guidance Practices (GGP's). FDA must adhere to GGP's with regard to developing, issuing, and using potential guidance documents.

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- In a web that has no (US-) borders, how will the FDA define what platforms, information, participants will be governed by FDA regulation versus non-US regulators? Also, given that AEs can come from people living in different countries, how would manufacturers know where to report the information?

This is a policy-related question that we are unable to answer at this time as we need to comply with FDA's Good Guidance Practices (GGP's). FDA must adhere to GGP's with regard to developing, issuing, and using potential guidance documents.

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