



Abbott Quality & Regulatory

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Division of Dockets Management (HFA –305)
Food and Drug Administration
5630 Fishers Lane - Room 1061
Rockville, MD 20852

RE: Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools [Docket FDA-2009-N-0441]

Dear Sir or Madam:

Abbott Laboratories is a global, broad-based health care company devoted to discovering new medicines, new technologies and new ways to manage health. Our products span the continuum of care, from nutritional products and laboratory diagnostics through medical devices and pharmaceutical therapies.

As a diversified healthcare company, Abbott is pleased to provide input intended to help guide FDA in making policy decisions on the promotion of human prescription drugs, biologics, and medical devices using the Internet (IN) and social media (SM) (collectively "IN/SM"). Our comments recommend procedural steps to continue the communication and dialogue between FDA and its stakeholders. Abbott is also interested in sharing pertinent information relating to how regulated industry should operate in IN/SM spaces as a basis upon which to apply existing regulations to product-related information and to elucidate the areas that warrant FDA guidance, reflective of the IN/SM's unique ability to present information in novel formats.

Many healthcare companies are beginning their entry into the IN/SM environment with pilot programs, which will yield additional data and experiences related to the use of IN/SM tools in the FDA-regulated environment. We recommend FDA maintain an open docket on the topic of IN/SM to allow companies to further share with the agency the results of their pilots, as it relates to FDA policy in this area.

Due to the fluid nature of IN/SM technology, we recommend a more flexible approach to communicating FDA-thinking in this evolving area. For example, the electronic publication of concept paper(s) on an FDA webpage dedicated to the topic of IN/SM. As with other FDA sites, we recommend inclusion of a list-serve for interested stakeholders to register and receive notification of FDA updates to the page. It is recognized that



such concept papers would not serve as guidance, which is subject to FDA's Good Guidance Practices at 21 C.F.R § 10.115, but rather would provide a means to continue the dialogue on this important, evolving topic.

The unique aspect of SM is the ability for individuals to interact together and express views and opinions in a two-way communication. This is very different from merely using the IN to push out product-related content to readers in one-direction. With two-way communication comes the need for standards to be put into place by regulated industry. Regulated industry should expect personnel who participate in SM on behalf of the company to be trained, to understand, and to follow corporate and FDA guidelines with regard to acceptable behaviors. Company employees and agents of a company, whose job is to engage/comment within a SM community, must be held accountable for identifying themselves (name and affiliation) and making clear when the views expressed are representative of the company or theirs alone.

A company that engages in SM regarding its products must establish SM policy (ies), processes, and tools, particularly around such topics as:

- (1) level of sponsorship and accountability,
- (2) monitoring, and
- (3) handling of information, such as reports of adverse events.

We recommend the development of an FDA guidance that addresses these topics and provide the following comments to assist in its development.

Level of Sponsorship/Ownership and Accountability

Ownership should be defined by the **amount of control** the manufacturer has to influence content. The amount of control should serve as the basis for determining accountability and responsibility related to content. The amount of control the manufacturer has to influence content varies from: (1) 100% manufacturer-created/built content, to (2) content co-owned by the manufacturer with a third party, also considered manufacturer controlled, to (3) content where the manufacturer has responsibility for some portion of content that appears on a site that is not wholly owned by the manufacturer. For items one and two, as the owner, the manufacturer is accountable for the material because of the level of control that exists. For item three, the manufacturer should only be held accountable for the portion that is manufacturer controlled.

Ownership should also be defined by the **type of media** in which content appears. Media types span the spectrum from: (1) *earned* where the manufacturer provides information (e.g. to a reporter), but does not control the resulting message, to (2) *paid* advertising and *shared* social media where the manufacturer controls the original message, but may not be able to protect the message from being later manipulated independent of the company, to (3) *owned* where the manufacturer controls the content and distribution (e.g. e-mail, brochures, websites) exclusively. Manufacturers should be held accountable for content that appears on *owned* media at all times. As well, manufacturers should be accountable for content appearing on *paid* and *shared* media, but only when the content is within manufacturer control initially, not if the content is modified independent of the company a later date. Manufacturers should not be held accountable for content in *earned* media.



Defining company responsibility for “ownership” in this manner is consistent with the position articulated by the Federal Trade Commission (FTC) in its “Guides Concerning the Use of Endorsements and Testimonials in Advertising,” effective December 1, 2009 at 16 CFR Part 255. The FTC guide focuses on whether “viewed objectively” the relationship between advertiser and the speaker is such that the speaker’s statement can be considered “sponsored” by the advertiser, and thus an “advertising message.” When this same concept is applied to IN/SM “content” ownership, clear levels of accountability can be established in guidance.

Monitoring

Company monitoring of IN/SM includes processes for listening, evaluating, and timely response to issues with an ultimate goal of encouraging the safe use of company products. Thus, companies should develop a monitoring framework/plan to monitor the IN/SM for mentions of their company and their products, which would include, for example, information related to product adverse events and complaints.

The monitoring plan should define the media types that the manufacturer intends to monitor, which would include those areas in which the manufacturer has control over the messaging and resulting online behavior. An important element of agency guidance is recognition that with any monitoring plan the IN/SM environment changes rapidly and can not be effectively monitored in its entirety. Additional elements of the plan should include how to conduct the monitoring and mechanisms for processing, handling, and responding to information identified via monitoring.

Handling of Information

In the event that IN/SM monitoring by a company reveals adverse events (AE) potentially associated with its own products, the manufacturer is responsible for triaging the information per existing business procedures governing compliance with FDA AE reporting obligations to the extent that a reasonable effort can be made to find the required information.

To encourage the most effective AE reporting to FDA, FDA should make available a user-friendly system through which web users may report events directly to FDA as was suggested by speakers at the November 12-13, 2009 Part 15 hearing on this topic.

When correcting erroneous information, facts, such as the package insert and data sources, should be used and the information should be corrected in a manner that is transparent with respect for the audience, without interrupting ongoing third-party exchanges.

Conclusion

We support further elucidation of these important elements in FDA guidance. Thank you for the opportunity to provide these comments.



Should you have any questions, please contact me at (847) 937-8197 or via e-mail at april.veoukas@abbott.com or Lauren Hetrick at (301) 255-0080 or lauren.hetrick@abbott.com.

Sincerely,

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