Biotechnology Industry Organization

April 14, 2014

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA–2013–N–1430: Draft Guidance for Industry on Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments on the FDA Draft Guidance on "Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics" (Draft Guidance).

BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

I. General Comments

Social media and the internet represent a unique and rapidly evolving platform for not only communicating significant health information to the public, but also providing an important resource for people to discuss and seek out information about their health, diseases and treatments. Social media and the internet provide users with a greater ability to control, alter, and respond to promotional messages and other information, often in the form of user generated content (UGC) that frequently occurs in real-time.

As FDA acknowledged in the Draft Guidance, "although some interactive promotional media are substantially similar in presentation and content to certain traditional promotional media, such as print media, FDA recognizes that in other cases they possess certain unique technological features and offer novel presentation and content features."[1] Because of the uniqueness and rapid evolution of this media, it is important to apply flexibility in the regulatory approach to enable companies to participate more fully and develop responsible policies and practices to help advance and encourage the safe use of their products.

[1] Draft Guidance, lines 25-27.

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We welcome FDA's acknowledgement of the unique characteristics and logistical considerations presented by content available through the internet and social media. In addition, BIO appreciates the FDA's general proposition in this Draft Guidance that companies are "not responsible for UGC that is truly independent of the firm;"[2,3] and also FDA's flexibility in proposing practical approaches to fulfilling the regulatory requirements, such as how to meet post-marketing reporting requirements.[4]

We look forward to FDA's planned release of additional guidance concerning internet promotion, including guidance on the use of links and the correction of third-party misinformation on internet and social media platforms.[5] It is important for firms to have the regulatory clarity needed not only to accurately and responsibly fulfill their regulatory reporting requirements, but also to be able to appropriately utilize all available media platforms on which medical professionals and the public seek and receive health information.

II. Specific Comments to the Draft Guidance

We provide below specific comments regarding certain aspects of the Draft Guidance. We also append a chart detailing several additional issues and proposed changes by page and line number.

A. The Draft Guidance's Discussion of "Labeling" Needs to Align More Closely to Labeling and Advertising Requirements

Under the Federal Food, Drug and Cosmetic Act (FFDCA), FDA has the authority to regulate "labeling" and "advertising."[6] These are often referred to collectively by FDA and the regulated community as "promotion." The FFDCA defines "labeling" to mean "written, printed or graphic matter" upon the article or "any of its containers or wrappers," or "accompanying such article."[7] FDA notes in the Draft Guidance that *Kordel v. United States* supports the notion that "…the language 'accompanying such article' in the 'labeling' definition is interpreted broadly, to include materials that supplement or

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[2] Draft Guidance, line 189.

[3] FDA's recognition that companies are not responsible for UGC that is truly independent of the firm is consistent with Section 230 of the Communications Decency Act, also cited in the Draft Guidance, which is helpful for a consistent governmental approach to regulation of internet content and fulfillment of Congressional intent regarding responsibility for third-party content. *See*, Draft Guidance footnote 5 ("cf. 47 U.S.C. 230(c)(1) ("no provider or user of an interactive computer service shall be treated as the publisher or speaker of any information provided by another information content provider")). The Communications Decency Act further defines "information content provider" as someone "responsible, in whole or in part, for the creation or development of information provided through the Internet or any other interactive computer service." 47 U.S.C. 230(f)(3).

[4] 21 CFR 314.81(b)(3)(i); 21 CFR 601.12(f)(4); and 21 CFR 514.80(b)(5)(ii); Draft Guidance, lines 30-34.

[5] *See*, CDER 2014 Guidance Agenda available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM314767.pdf.

[6] *See*, 21 U.S.C. §§ 352(a) & (n).

[7] 21 U.S.C. §321(m).

explain an article. No physical attachment between the materials and the article is necessary; rather, it is the textual relationship between the items that is significant."[8] However, the Supreme Court's holding was more specific, in that it held that written materials comprise "labeling" when they: (1) have the same origin as the drug; (2) have the same destination; (3) are designed for use in the sale and distribution of the drug; and (4) have a "textual relationship" or "constitute[] an essential supplement" to the label.[9] The discussion of labeling in *Kordel* has subsequently been interpreted at the Federal Circuit Court level to mean, "labeling does not include every writing which bears some relation to the product. There is a line to be drawn, and, if the statutory purpose is to be served, it must be drawn in terms of the function served by the writing."[10]

However, the Draft Guidance discussion of the "Legal Overview of Statutory and Regulatory Requirements for Labeling and Advertising" may cause confusion concerning the scope of FDA's authority over promotional labeling. The Draft Guidance states that "promotional labeling is generally any labeling, other than the FDA-required labeling, that is devised for promotion of the product. Examples of promotional labeling pieces are described at 21 CFR §202.1(l)(2)."[11]

The citation to 21 CFR §201.1(l)(2) in the Draft Guidance as "examples of promotional labeling" is inconsistent with prior agency acknowledgement that the regulation operates to exclude certain forms of manufacturer communication from the scope of the advertising provisions of the FFDCA and associated regulation.[12] Accordingly, as a predicate matter, when FDA considers the final guidance and future guidances, the Agency should clarify that the appropriate definition of "labeling" is found in 21 U.S.C. § 321(m), the general regulatory definition of labeling in 21 C.F.R. 1.3(a), and relevant case law.

B. The "Influence Test"

The Draft Guidance discusses the Agency's approach to determining a firm's responsibility for submitting interactive promotional media as required by postmarketing submission requirements. In doing so, the Agency, by way of example, puts forth an "influence test." Under the influence test, the "Agency considers whether the firm, or anyone acting on its behalf, is influencing or controlling the promotional activity or communication in whole or in part." The Draft Guidance further notes that a "firm is responsible if it exerts influence over a site in any particular, even if the influence is limited in scope. For example, if the firm collaborates on or has editorial, preview, or review privilege over the content provided, then it is responsible for that content." [13]

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[8] *Kordel v. United States*, 335 U.S. 345, 350 (1948).

[9] *Kordel* at 348, 350.

[10] *United States v. An Undetermined Number of Cases..."Sterling Vinegar and Honey...*," 338 F.2d 157, 158-59 (2d Cir. 1964).

[11] Draft Guidance, lines 90-92.

[12] Def.'s Summ. J. Reply at 22-23, *Allergan v. United States*, No. 09-1879 (D.D.C. filed Mar. 29, 2010).

[13] Draft Guidance, lines 120-123.

We believe that this position is overly broad and subject to misinterpretation regarding the scope of FDA's regulatory authority over labeling and advertising. As explained in more detail below, we are particularly concerned that the Draft Guidance fails to recognize that not all content controlled or influenced by a firm or its employees is labeling or advertising.

In addition, we also address below our concerns with the Agency's proposed views on what constitutes a firm's influence on UGC such that the firm would be responsible for the content. Despite providing limited examples concerning UGC, third-party controlled sites, and employee- or agent-provided content, the Draft Guidance does not discuss the concept of influence in detail. Therefore, the Draft Guidance raises additional questions and causes some confusion regarding what FDA may view as content that is "independent" of the firm. As discussed in more detail below, we have questions concerning the Agency's proposed views on content created by limited agents of a firm, the correction of a third party's misinformation, the impact of mere preview or review rights, and the overall impact of this Draft Guidance on the principle of scientific exchange.

1. *Not All Content Controlled or Influenced by a Firm or Its Employees Is Labeling or Advertising*

BIO requests that the Draft Guidance be revised to clarify that not all communications or information by a firm or its employees are labeling or advertising. Although the Draft Guidance does implicitly recognize that not all manufacturer content is promotional through its discussion of accountability,[14] certain provisions in the Draft Guidance lead to confusion over this point.

For example, the Draft Guidance provides that:

- "FDA's regulation of prescription drug product promotion extends both to promotional activities that are carried out by the firm itself, and to promotion conducted on the firm's behalf," and that in "determining whether the firm is accountable for a communication about its product(s), the Agency considers whether the firm or anyone acting on its behalf ***is influencing or controlling the product promotional activity or communication in***

[14] *See*, *e.g.*, Draft Guidance, lines 51-57, which distinguishes between a "communication" and "product promotional activity" ("FDA's regulation of prescription drug product promotion extends both to promotional activities that are carried out by the firm itself, and to promotion conducted on the firm's behalf. In determining whether the firm is accountable for a *communication* about its product(s), the Agency considers whether the firm or anyone acting on its behalf is influencing or controlling the product *promotional* activity or *communication* in whole or part. Firms may have a variety of options for how much control they exert over activities that utilize interactive promotional media, regardless of whether the *promotional* activity occurs on firm-sponsored or third-party venues." (emphases added)).

whole or part…regardless of whether their promotional activity occurs on firm-sponsored or third-party venues"[15] (emphasis added).

- "…a firm is responsible if it ***exerts influence over a site in any particular, even if the influence is limited in scope***," and provides an example that "if the firm collaborates on or has editorial, preview, or review privilege over the content provided, then it is responsible for that content"[16] (emphasis added).

- "if a firm provides only financial support (*e.g.*, through an unrestricted educational grant) and has no other control or influence on that site, then the firm is *not* responsible for information on a third-party site and has no obligation to submit the content to FDA."[17]

- "Regardless of financial support, if a firm has any control of, or influence on, the third-party site, even if limited in scope, it is responsible for submission to FDA to meet the post-marketing submission requirements."[18]

In each of these instances, the Draft Guidance omits the first step of analyzing whether a communication is, in fact, labeling or advertising. Thus, the Draft Guidance could be misinterpreted to mean that it covers firm or employee/agent communications that are not in fact labeling or advertising. In other words, the above views could potentially be misinterpreted to mean that any communication influenced or controlled by a firm is promotional labeling. This misinterpretation is particularly likely since the idea that a firm is responsible for such communications, even if its "influence is limited in scope," is repeated throughout the Draft Guidance.

In addition, the Draft Guidance should be revised to acknowledge situations where a firm can provide more than just "financial support" and yet the firm's influence is so limited in scope that it should not be viewed as accountable for the content such that the communication or information might be considered labeling or advertising. For example, a firm may provide general guidelines to a third party for its appropriate content development within the third party contract, or maintain some rights to review (but not alter) the content and should therefore *not* have the information or communication be considered labeling or advertising. Additional examples of firm activities that should not be viewed as labeling or advertising include providing a forum for the scientific exchange of UGC, informing a third party of inaccurate medical or scientific information about a product, or preventing the posting of inaccurate information. We discuss several of these specific situations in more detail below.

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[15] Draft Guidance, lines 51-57.

[16] Draft Guidance Section IV. Factors Considered in Determining Postmarketing Submission Requirements for Interactive Promotional Media, pg. 3, lines 120-123.

[17] Draft Guidance, lines 136-139.

[18] Draft Guidance, lines 156-158.

2. *Correction of Third-Party Misinformation*

We note that FDA plans guidance in 2014 on the issue of firms correcting third-party information about prescription drugs on internet/social media platforms.[19] Nonetheless, we point out the issue of correcting third-party misinformation as an example of the potential overreaching in this Draft Guidance's position that interactive promotional media content would be viewed by FDA as advertising or labeling if the firm has "any control or influence, even if that influence is limited in scope."

Specifically, activities by a firm or its employees that are not viewed as labeling or advertising should include situations where a firm merely corrects a third party's inaccurate information about the firm's products, or prevents such inaccurate information from being posted in the first instance.[20] Although firms are not (and should not be) required to monitor or seek to correct internet content not created or controlled by them, there may be instances in which a firm may seek to correct inaccurate information on interactive promotional media of which the firm becomes aware. This should not be viewed as "influence" over the content that would subject that content to labeling or advertising requirements.

3. *"Preview" or "Review" Rights*

In the Draft Guidance, FDA proposes that a firm is responsible for promotion on a third-party site "if the firm has any control or influence on the third-party site, even if that influence is limited in scope. For example, if a firm collaborates, or has editorial, preview, or review privilege, then it is responsible for its promotion on the site, and such, that site is subject to submission to FDA to meet postmarketing submission requirements."[25] We believe that FDA is overreaching in its inclusion of preview and review privileges among these examples. Firms should not be responsible for promotional labeling when they merely have the ability to "preview" or "review" content on a third-party site. The mere fact of having preview or review privileges does not necessarily equate to influence over content. This is particularly (but not exclusively) true if the firm does not provide any suggestions for content modification, but rather merely receives an advance or courtesy preview copy of the content. Other examples include a firm's review of content for scientific accuracy and/or review for ensuring proper transparency in funding or sponsorship.

The same principle should apply when a third-party site provides a firm with a courtesy preview and/or requests a firm to review for accuracy, when a firm provides content and input without any editorial control, or when a firm requests its promotional content to

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[19] *See*, CDER 2014 Guidance Agenda, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM314767.pdf.

[20] Companies legally cannot control all communications by their employees. *See*, *e.g.*, National Labor Relations Act ("NLRA") restrictions regarding "protected activity," 29 USC §157, and generally First Amendment case law.

[25] Draft Guidance, lines 133-136.

appear prominently on a third-party site. In these examples, the firm also should not be responsible for other third-party content appearing in proximity to its promotional content when the firm has no control over the substance of such nearby content. In addition, and equally important, such third-party content adjacent to firm promotional content should not be treated as labeling, and therefore the firm should not be viewed as responsible for the adjacent third-party content.

4. User Generated Content and "Independent of the Firm"

There is no regulatory basis to hold a firm responsible for statements that are not made by or on behalf of the firm. This includes a firm merely providing a forum or the availability of a platform in which UGC can be requested or shared. In addition to the definition of "labeling" discussed above, recognition that firms should not be responsible for UGC that is not actually made on behalf of the firm would be consistent with Section 230 of the Communications Decency Act, also cited by FDA in the Draft Guidance.[21, 22] Accordingly, in order to better align with statutory authority, FDA guidances addressing responsibility for UGC should more closely adhere to labeling and advertising requirements stating that such communications actually be, by, or on behalf of the firm.

The FDA cannot impose requirements on content that is not distributed by or on behalf of the firm.[23] Therefore, the definition of "independent of the firm" should be consistent with the existing legal framework – otherwise the Draft Guidance could appear to inappropriately broaden the scope of labeling or advertising to content that is not actually distributed by or on behalf of the firm.

Although BIO agrees with FDA's position that "…a firm generally is not responsible for UGC that is truly independent of the firm," and that FDA will not ordinarily view [such] UGC on firm-owned or firm-controlled venues such as blogs, message boards, and chat rooms as promotional content on behalf of the firm." However, we disagree with FDA's all-encompassing position that "the firm [should have] had no influence on the UGC," or that the UGC was not "prompted" by the firm.[24]

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[21] 47 U.S.C. §230 (c) (1) (2000) ("No provider…of an interactive computer service shall be treated as the publisher or speaker of any information provided by another information content provider.").

[22] As codified in the Communications Decency Act, it was Congress' intent to promote the continued development of interactive media with minimal government regulation or intervention. The policy codified in the preamble to 47 U.S.C. §230, the safe harbor provision to the Communications Decency Act, is as follows: (b) Policy. It is the policy of the United States – (1) to promote the continued development of the internet and other interactive computer services and other interactive media; (2) to preserve the vibrant and competitive free market that presently exists for the internet and other interactive computer services, unfettered by Federal or State regulation; (3) to encourage the development of technologies which maximize user control over what information is received by individuals, families, and schools who use the internet and other interactive computer services…

[23] See, *e.g.*, 21 CFR §201.100(d), which describes the requirements for "any labeling…distributed ***by or on behalf of*** the manufacturer, packer or distributor of the drug…" (emphasis added).

[24] Draft Guidance, lines 189-193.

The Agency should clarify that UGC resulting from a two-way dialogue with an independent user, even if on a firm-controlled or firm-owned venue, is not "prompted" UGC, or UGC "influenced" by the firm, and therefore should not be viewed as promotional communication on behalf of the firm. In addition, FDA should clarify that if a firm serves as a forum moderator, and in particular as moderator removes offensive or inappropriate UCG, this should not serve to make the UCG "influenced" by the firm.

Furthermore, we believe it would be helpful if the Agency clarified that the mere fact of providing the ability to comment on a firm-controlled or owned venue does *not* constitute "prompting."

5. Scientific Exchange

The Draft Guidance does not address the interplay of the "influence test" with long-standing scientific exchange principles that separate unregulated "scientific exchange" from more extensively regulated promotion. BIO is concerned that the Agency is inadvertently proposing that statements previously thought to be scientific exchange will now be subject to a different test merely because they are provided on a social media platform. The Draft Guidance should clarify that the principles of scientific exchange apply regardless of how the exchange is conducted.

6. Acting on Behalf of the Firm

In addition, the Draft Guidance states that "[a] firm is responsible for the content generated by an employee or agent who is acting on behalf of the firm to promote the firm's product."[25] Although it is helpful that the Agency's examples speak to when an agent is acting on the firm's behalf, the Agency should acknowledge that there may be many instances in which an individual with a relationship with a firm (whether an employment relationship or contractual) may generate content outside the scope of his or her delineated duties or the parameters of the contractual relationship with the firm, and thus is not acting on behalf of the firm.

We note that a health care professional who has a specific service arrangement with a firm (such as a paid promotional speaker) may not be acting on behalf of a firm when he or she generates content at his or her own initiation outside the scope of the contracted services. In such an instance, the health care professional is representing his or her opinion as a medical professional and engaging in medical or scientific dialogue, not within the limited scope of his or her arrangement with the firm, and thus not acting on a firm's behalf. As an additional example, a health care professional who receives research funds from a firm should be free to comment on interactive social media about disease states and products as an independent individual without such interactive activities being attributed to the firm.

[25] Draft Guidance, lines 160-161.

C. The Draft Guidance Should Allow Companies to Determine Periodic Submission Time Frames for Interactive Digital Promotion based on Actual Activity and Internal Process Considerations

The Draft Guidance recommends that, instead of submitting examples of the materials at the time of initial dissemination, as is currently required under the FFDCA, firms may submit a periodic "updated listing of all non-restricted sites for which it is responsible or in which it remains an active participant and that include interactive or real-time communications" once every month.[26] We appreciate FDA's recognition of the challenges of submitting digital promotional materials that display real-time information, and resulting flexibility in recommending a practical approach for submitting them periodically.[27] While this represents a practical and flexible approach, we would recommend revising it to allow firms to determine the periodic submission schedule based on the actual activity of the site, which may be less frequent than once per month, and on internal company process considerations. However, if FDA believes that a specific timeframe should be included, we would suggest that it be no less frequently than once a quarter.

Additionally, FDA states that "the firm should include annotations to describe the parts that are interactive and allow for real-time communications," and that "any subsequent changes should be annotated and resubmitted…."[28] We ask FDA to clarify expectations for the timing of submission of a site where the firm controls all the content, but not necessarily the native functionality of the interactive promotional space. For example, a firm controls all the content on a Facebook page, but does not control functionality that is native to Facebook. Unless notified of the functionality changes ahead of time by Facebook, it would be impossible for the firm to submit at the time of initial display. It also is important for FDA to recognize that social media platforms are subject to formatting changes that are outside of the firm's control. It would be helpful for FDA to recognize this point in any final guidance and provide direction on how to resubmit in such instances.

Furthermore, it would be helpful if FDA provided an example of best practices for how to annotate the interactive functionality on a submission, given that most submissions only require providing static content. With regard to the required components of the periodic Form FDA 2253 submission for human drugs and biologics, it would be very useful if FDA provided a sample submission either as an Appendix to the Draft Guidance or on the OPDP website. Further explanation of the 'corresponding documents' referred to in line 253 of the Draft Guidance also would be helpful.

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[26] Draft Guidance, lines 246-248.

[27] "…for some interactive promotional media, submission 'at the time of initial dissemination' may pose a challenge for firms, particularly when these media communicate information that is displayed in real time. While 'at the time of initial dissemination' does not refer to submissions on a weekly, monthly or other routine schedule, FDA intends to exercise its enforcement discretion under certain circumstances due to the high volume of information that may be posted within short periods of time using interactive promotional media that allow for real-time communications." Draft Guidance, lines 63-71.

[28] Draft Guidance, lines 222-224.

Finally, in the Draft Guidance, FDA states that, for sites with restricted access, "[s]creenshots or other visual representations of the actual site, including the interactive or real-time communications, should be submitted monthly on Form FDA 2253…." We assume that FDA would require that these screenshots be taken on or near the date of the submission, but seek clarification in this regard.

D. Submission of Surrounding Pages on Third-Party Sites

The Draft Guidance states the Agency's view that "because the firm influenced the placement of its promotion within the third-party site, the firm is responsible for submitting to FDA the promotion, along with the surrounding pages, to adequately provide context to facilitate the review of the third-party site, in order to fulfill the postmarketing submission requirements."[29] We note that FDA's approach to submission requirements in this regard for promotional messages in interactive media appears to differ from that of more static media (*e.g.*, print ads), and it is unclear under what authority the FDA may subject such surrounding third-party context (not generated or disseminated by the firm) to postmarketing submission requirements.

However, should the Agency go forward with its recommendation that firms submit the surrounding pages on independent sites if the firm has influenced placement of the content, we appreciate the Agency's acknowledgement of the fluid nature of such surrounding pages in interactive media, where content and context may change rapidly and frequently. We note that submission of surrounding content at the time of initial dissemination may not be feasible, as the promotional media would need to be physically placed and "live" in order to capture the promotional content in the surrounding context. Development environments for sites hosted by third parties may not be available to sponsors until made available to the public. Firms should be permitted to submit surrounding context shortly after it goes on public display. We also note that FDA must have reasonable expectations with regard to firm monitoring of these sites and the submission of updated materials.

Additionally, the same interactive promotional media can be placed on many webpages, where the firm influences the placement but does not control the surrounding content. We suggest FDA clarify that sponsors should submit the surrounding content only with the first use, rather than the surrounding content of every webpage where the promotion appears. This point is particularly relevant in the context of dynamic platforms, such as Facebook. Dynamic platforms are designed to give each individual user a unique view that is based on the other content the user has "liked" or interacted with previously. In such contexts, it is important to note that there is no one universal "page," and therefore it is impossible to submit to FDA what the promotion looks like or will look like to all users in context. FDA should advise and clarify submission requirements in such contexts.

[29] Draft Guidance, lines 150-154.

III. Conclusion

In closing, we appreciate FDA's practical and flexible approach in issuing regulatory guidance documents in the promotion of FDA-regulated medical products using the internet and social media, and greatly welcome the opportunity to participate in their development. BIO appreciates this opportunity to comment on the FDA Draft Guidance on "Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics." We would be pleased to provide further input or clarification of our comments, as needed.

Respectfully submitted,

/s/
Jeffrey Peters
Deputy General Counsel, Healthcare

SPECIFIC COMMENTS

SECTION	ISSUE	PROPOSED CHANGE
I. INTRODUCTION		
Lines: 22-24	"For the purposes of this guidance, the phrase *interactive promotional media* includes modern tools and technologies that allow for real-time communications and interactions (*e.g.*, blogs, microblogs, social networking sites, online communities, and live podcasts) that firms use to promote their drugs."	We request that the scope of the modalities included in this Draft Guidance be defined. We request that the word "includes" be replaced with "defined", and the entire phase that follows be worded as "…, defined as modern tools and technologies that allow for two-way communication between the user and industry (*e.g.*, blogs, microblogs, social networking sites, online communities, and live podcasts), that firms use to promote their drugs."
IV. FACTORS CONSIDERED IN DETERMINING POSTMARKETING SUBMISSION REQUIREMENTS FOR INTERACTIVE PROMOTIONAL MEDIA		
Lines: 134-136	"For example, if a firm collaborates, or has editorial, preview, or review privilege, then it is responsible for its promotion on the site, and, as such, that site is subject to submission to the FDA to meet postmarketing submission requirements."	We request that "review" and "preview" be deleted, and the sentence be changed to "For example, if a firm collaborates, or has editorial or review privilege with intent to promote, then it is responsible …" As discussed above, firms may find medical and/or scientific inaccuracies on a site that may benefit from correction.
Lines: 139-141	"Furthermore, if a firm is merely providing promotional materials to a third-party site but does not direct the placement of the promotion within the site and has no other control or influence on that site, the firm is responsible only for the content it places	We request deleting "does not direct the placement of the promotion within the site", as there may be cases where promotional placement is requested to target on-label patients only.

SECTION	ISSUE	PROPOSED CHANGE
	there….”	
Lines: 166-168	“For example, if an employee or agent of a firm, such as a medical science liaison or paid speaker (*e.g.*, a key opinion leader) acting on the firms behalf, comments on a third party site about the firm’s product, the firm is responsible for the content its employee or agent provides.”	We request deleting “medical science liaison” and adding clarifying language by adding “promotional” after “paid” speaker to make clear that the Draft Guidance relates to promotional content and not scientific exchange. We also request deleting “key opinion leader” to make clear that key opinion leaders are not necessarily speakers for the firm (paid or otherwise), and do not necessarily have contractual or financial relationships with firms. A firm’s possible internal designation of an individual as a “key opinion leader” does not mean that the individual is or has been providing services on behalf of the firm.