September 16, 2014

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

Re: Docket No. FDA–201-D-0397: Draft Guidance for Industry on Internet/Social Media Platforms With Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments on the “Draft Guidance for Industry on Internet/Social Media Platforms With Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices.”

BIO represents more than 1,100 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.

GENERAL COMMENTS:

In general, we find the Draft Guidance imposes broad speaker based restrictions on manufacturer communications made via Internet and social media platforms associated with character-space and formatting limitations. As BIO has commented previously,¹ the provision by a manufacturer of truthful and not misleading information about a manufacturer’s products has constitutional protection under the First Amendment.² A manufacturer should have flexibility to participate in the scientific and medical dialogue that is occurring constantly via Internet and social media platforms, and to share information about its products on these platforms, so long as it does so in a manner that is truthful and not misleading, even if the precise content may be inconsistent with the FDA recommendations contained in this Draft Guidance.

² Sorrell v. IMS Health, Inc. 113 S.Ct. 2653, 2659 (2011) (“[s]peech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment”).
As BIO has commented previously to FDA, the Internet and social media 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. Because of the uniqueness and rapid evolution of this platform, it is important to apply a practical, flexible 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. BIO is concerned that the Draft Guidance does not fully provide such flexibility, and therefore encourages the Agency to take a more practical approach when issuing any final guidance.

1. FDA is Applying Stricter Standards in Character Limited Space

In lines 289-293 the Draft Guidance accurately concludes that “a concise disclosure of specific risk information may be presented together with benefit information within the confines of character-space limited internet/social media platforms if supplemented by a prominent reference to the presence and location elsewhere of a more complete discussion of the risks associated with the product...”

However, we are concerned that FDA is proposing unnecessarily strict standards in character limited space than apply in non-character limited space. For example, the Draft Guidance requires that the “most serious risks” associated with the product must be presented with the benefit information when using media with character space constraints. The Draft Guidance further states in lines 134-137 that if “an accurate and balanced presentation of both risks and benefits of a specific product is not possible within the constraints of the platform, then the firm should reconsider using that platform for the intended promotional message (other than for permitted reminder promotion).”

These interpretations are not found anywhere in the laws or regulations cited. The regulations only require that “prescription drug advertisements must present a fair balance between information relating to risk and information relating to benefit,” and that “risk information must be presented with a prominence and readability reasonably comparable to claims about drug benefits.” Importantly, the regulations acknowledge that “…for prescription drug advertisements to be truthful and non-misleading, they must contain risk information in each part, as necessary, to qualify any representations and/or suggestions made in that part about the drug,” and allow the risk information to be “concise if supplemented by a prominent reference to the presence and location elsewhere in the advertisement of a more complete discussion.”

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Therefore, we believe that FDA here proposes a stricter standard than what is intended by regulation by requiring the character limited space risk information to include all boxed warning risk concepts, all risks known to be fatal or life-threatening, and all contraindications.

In light of the above, FDA should revise its Draft Guidance to suggest its proposal as merely one possible approach, rather than as a requirement of law or regulation, and should also recognize that this may not be feasible for many products. Therefore, in the interest of public health, the Draft Guidance should also provide for alternative approaches which allow for the provision of detailed safety information through common social media applications such as links with directional statements to safety information. Providing such information by way of links with directional statements can be consistent with a truthful and not misleading standard.

In particular, FDA should consider adopting more flexibility consistent with other governmental agencies approach to addressing speech. FTC, for example, demonstrated flexibility in understanding the limitations of technology and the ability of consumers to use hyperlinks to obtain additional information in their updated Dot Com Guidance (March 2013). For example, the Dot Com Guidance states, "When a space-constrained ad requires a disclosure, incorporate the disclosure into the ad whenever possible. However, when it is not possible to make a disclosure in a space-constrained ad, it may, under some circumstances, be acceptable to make the disclosure clearly and conspicuously on the page to which the ad links."  

Flexibility in approach would assure a firm’s ability to share truthful and non-misleading information about their product, no matter what platform is utilized, as appropriate.

2. Exceptions for Crisis Communications and Public-Health Related Concerns

In this Draft Guidance, FDA states that advertising and promotional labeling posted on social media platforms with character-space limitations must present a fair balance between information relating to risks and information relating to benefits. Without conceding with this point, BIO recommends that should FDA maintain this perspective in any final guidance, FDA should acknowledge that crisis communications and public health–related concerns that require quick reaction by the manufacturer are neither advertising nor promotional labeling and should clarify that the Draft Guidance does not apply. For example, a manufacturer may need to inform the public of counterfeit medications, product recalls, or information about drug shortages. FDA should explicitly acknowledge that in these situations, and in other communications that do not constitute advertising or promotional labeling, the use of the proprietary name and indication on character space–limited platforms without fair-balance information is wholly permissible.

3. Use of Graphics

FDA proposes that companies provide a direct hyperlink to a destination that is devoted exclusively to the communication of risk information (line 326). The Draft Guidance goes on to state that “An example that the Agency would not consider to provide direct and exclusive access to risk information would include a hyperlink only to a product’s home page that also includes benefit information and other claims or graphics.” FDA provides no rationale for these limitations.

We recommend that the Agency reconsider the omission of graphics. Creative elements, including format options that otherwise exist in promotion, could enhance the understanding of risk information. The use of graphics is acceptable when communicating fair balance, and is mentioned in FDA’s 2009 Draft Guidance for Industry, “Presenting Risk Information in Prescription Drug and Medical Device Promotion.” We propose that the Agency delete the phrase “or graphics” in line 336, so that firms have the flexibility to format the risk information in a way that is easily read and comprehended by consumers. We further request that FDA revise its proposal that the link be devoted exclusively to risk information. Instead, in any final guidance, FDA should acknowledge a manufacturer’s ability to structure the information in a manner that is not false and misleading and that meets any applicable regulatory requirement.

4. Alternative Approach

We suggest as an alternative approach that FDA revise the “requirements” of the Draft Guidance to be recommendations where feasible, but be flexible in allowing even more concise summaries when “all serious risks” and benefits would exceed the character-space-limitation. In such an approach, Sponsors can effectively make a truthful and non-misleading statement in a character space-constrained digital platform using a more concise summary of benefit and safety information, as long as they include clear and conspicuous links to where the additional, more detailed information can be found.

5. Technical Accuracy

We note that based on the Agency’s understanding of how Google SiteLinks works in the Draft Guidance, companies may unintentionally not follow the recommendations in the Draft Guidance by following its approach for SiteLinks. Google controls the algorithm for how many and which SiteLinks appear, not the company. SiteLinks may not actually appear as intended by the company under Google’s algorithm. As such, we ask FDA to provide a comparable example of communicating more complex risk information in a manner that will work using existing technology.

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In the Draft Guidance, FDA encourages the use of unshortened URLs that include a reference to risk for links to risk information. However, on some platforms such as Twitter, links are generally automatically shortened and thus the reference to risk would not be visible to the consumer. As such, we ask FDA to acknowledge that use of unshortened URLs may not be under a company’s control and use of platforms that automatically shorten links would not be in violation of the guidance.

6. Scope

Finally, the Draft Guidance limits its application to character limited spaces and expressly declines to address space limited platforms, and cites paid search and Twitter as the only two examples of character space limited platforms. However, we note that other platforms have character-space limitations and should be included.

These include:

- Pinterest: 500 character limit for a caption on a pin
- LinkedIn: 700 characters
- Facebook and Twitter profile pages: Although specifically excluded from the Draft Guidance, for example, Twitter user bios have a limit of 160 characters.

BIO also notes that some platforms are space-limited, but not character limited, and should be eligible for similar treatment. Some platforms, such as Facebook and YouTube, have long character limits for posts (63,000 characters) or video descriptions (5,000) characters. However, these platforms usually display only the first 150-500 characters and require the user to click on a “See More” link to display the rest of the content. With this in mind, and as these platforms typically impose formatting restrictions that limit readability of long text blocks, the Agency should consider such spaces as effectively character limited.

7. Tweeting or Retweeting of FDA Approval

We note that FDA’s recommendations on manufacturer product communication in the Draft Guidance appear to be inconsistent with how the Agency itself has communicated about product approvals until mid-August 2014. Therefore, BIO suggests this Draft Guidance does not preclude, and any future recommendations should not limit, manufacturers from retweeting prior or current messages from FDA, including “now approved” announcements that include the proprietary drug name and public-health announcement, or a manufacturer tweeting its own messages including such information. If FDA has formally changed its practice or policy regarding such announcements to avoid mention of a product name, we would suggest such change is misplaced and does not advance the interests of public health. Moreover, whether or not FDA continues this

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practice, we would assume and agree that FDA’s prior practice was neither false nor misleading, and as such manufacturers should have flexibility to utilize or communicate such messages.

**CONCLUSION:**

BIO appreciates this opportunity to comment on the “Draft Guidance for Industry on Internet/Social Media Platforms With Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices.” We would be pleased to provide further input or clarification of our comments, as needed.

Respectfully submitted,

/s/
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