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September 16, 2014

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

Submitted via http://www.regulations.gov

Re: Docket No. FDA-2014-D-0397 – Draft Guidance on Internet / Social Media Platforms with Character Space Limitations - Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices

To Whom It May Concern:

The Interactive Advertising Bureau (IAB) appreciates the opportunity to submit these comments on the Food and Drug Administration's ("FDA") Draft Guidance entitled "Internet / Social Media Platforms with Character Space Limitations – Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices" (the "Draft Guidance"). The IAB is encouraged that the FDA recognizes the value of Internet and social media advertising for public health. However, as explained below, we are concerned that the Draft Guidance will not improve the quality of information available to consumers and, in fact, could diminish the opportunity to get valuable information to consumers and patients. We strongly encourage the FDA to work directly with social media and Internet platforms to evolve guidance that supports the FDA's mission of ensuring that consumers are provided with drug and device-related information that is reliable and balanced, while also ensuring that the guidance reflects an accurate understanding of both platforms' current functionalities and accommodates their future evolution.

Background on the Interactive Advertising Bureau

Founded in 1996 and headquartered in New York City, the IAB (www.iab.net) represents over 600 leading companies that actively engage in and support the sale of interactive advertising, including leading search engines and online publishers. Collectively, our members are responsible for selling nearly 90% of online advertising in the United States. The IAB educates policymakers, consumers, marketers, agencies, media companies and the wider business community about the value of interactive advertising. Working with its member companies, the IAB evaluates and recommends standards and practices and fields critical research on interactive advertising.

Comments on the Draft Guidance

The IAB and our members share the FDA's goal of promoting fair, balanced, and reliable online advertising for prescription drugs and medical devices. Healthcare professionals, patients

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and caregivers are increasingly using the Internet as a core resource for health; 72% of internet users say they looked online for health information within the past year.[1] Moreover, about one out of every three cell phone owners (31%) have used their phones to look for health information, including 52% of smartphone owners.[2]

To that end, the IAB welcomes the FDA's efforts to provide guidance on the appropriate use of platforms with character space limitations. The IAB is concerned, however, that the Draft Guidance misrepresents the functionalities of specific platforms identified in the examples that are intended to illustrate how the Draft Guidance can be implemented. Even in the limited time since the Draft Guidance was issued, our member companies report that these examples are already creating confusion in the marketplace. While the products discussed in the Draft Guidance are hypothetical, the examples purport to illustrate how companies can use specific, existing platforms that are available in the marketplace. However, the Draft Guidance does not describe the platforms' functionalities correctly or comprehensively, leaving regulated companies unable to implement the FDA's recommendations. Moreover, the FDA's use of highly specific examples based on today's services may limit the ability of platforms to innovate in the future.

To promote adoption of the FDA's recommendations, the IAB respectfully asks the FDA to work with stakeholders to issue an updated Draft Guidance (or Final Guidance) as soon as possible, that allows for the differentiation of platforms and, in cases where examples are given, accurately describes each identified platform's functionalities while offering companies flexible alternatives to meet the FDA's requirements.

Twitter

The Twitter platform enables users to share and interact in real time via brief public updates, called "Tweets." The Draft Guidance states that Tweets are "limited to 140 character spaces per message or Tweet." When Twitter was founded in 2006, the platform only supported Tweets of 140 characters. Over the last eight years, Twitter has enhanced the capabilities of what content can appear with a Tweet. Today, Tweets can include photos, videos, and links. These technological enhancements allow for an increased amount of information to be presented to consumers including patients, consumers, healthcare providers, caregivers, and advocates.

Google Sitelinks

Similarly, the Draft Guidance does not accurately describe Google's sitelinks extension offered on the AdWords platform. As explained by Google in its public customer support explanatory page, "The sitelinks ad extension shows links to specific pages on your website beneath the text of your ads (and in addition to the main landing page)….You can add sitelinks when you create your campaign. You can edit your link text and URLs, and see how ads that

[1] Susannah Fox & Maeve Duggan, Pew Research Center, "Health Online 2013" 3 (2013).

[2] Susannah Fox & Maeve Duggan, Pew Research Center, "Mobile Health 2012" (Nov. 8, 2012), available at http://www.pewinternet.org/2012/11/08/mobile-health-2012/.

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contain sitelinks perform in the Ad extensions tab." The FDA's examples in the Draft Guidance imply that when advertisers use sitelinks, those sitelinks will always appear with the advertiser's ads. This is not the case, however.

As Google alerts advertisers, "ads won't always show sitelinks…. [and] the format that appears could vary. For instance, anywhere from two to six sitelinks may appear on desktop ads. We consider several factors when determining what types of sitelinks we'll display with your ad, and whether we'll display sitelinks at all." AdWords shows sitelinks depending on a number of factors, some of which are outside an advertiser's full control. These factors include the position of the advertiser's ad on the search results page and the relevance of other ads on the page. Google's algorithms are designed to provide the most useful mix of information in response to user queries. Sometimes, that mix of information will include all of an advertiser's sitelinks, but sometimes it will not.

Policy Considerations

The IAB appreciates the FDA's effort to provide clear guidance through the use of examples featuring hypothetical products. As described above, these hypothetical examples reference actual platforms in a manner that is inaccurate and thus confusing to regulated companies. This confusion – if left uncorrected – will inhibit the flow of information about medical and device products to consumers by creating overly restrictive boundaries that hinder advertisers' ability to get their message to consumers, making the medium less desirable to marketers relative to other platforms.[3] Further, the use of specific examples may have the unintended effect of directing companies toward the platforms described, to the exclusion of other options for presenting online information to consumers.

The IAB therefore encourages the FDA to offer further flexibility on how additional features of character-space-limited platforms can be used to appropriately communicate all necessary information related to prescription drugs and medical products. Just as the FDA has made accommodations to ensure that direct-to-consumer ads are feasible in broadcast media,[4] the IAB asks the FDA to recognize and accommodate the unique characteristics of Internet advertising.

Specifically, the IAB suggests that the FDA consider a range of options that reflect the evolving nature of social media and Internet platforms, as well as provide consumers with easy access to relevant information. This flexible approach would take into consideration each platform's unique interface with the consumer. By providing companies with wider options to

[3] A recent article stated: "By restricting the transmission of information, the FDA is increasing costs and reducing productivity. Consumers could greatly benefit from increased access to truthful and non-misleading healthcare information, but pharmaceutical companies need flexibility in how they can communicate." Diana G. Carew & Michael Mandel, Progressive Policy Institute, "The Data-Driven Economy and the FDA" (Sept. 9, 2014), available at http://www.progressivepolicy.org/issues/economy/fda-guidelines-ignore-data-driven-economy/.

[4] Food and Drug Administration, "Guidance for Industry: Consumer-Directed Broadcast Advertisements" (Aug. 1999).

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communicate reliable and balanced information, the FDA can help expand consumers' access to important information and helpful products. The IAB and its members stand ready to engage with the FDA and medical community in a dialogue about possible options.

For example, the FDA could consider the option of allowing regulated companies, in certain circumstances, to present risk information for their products "one click in" from an underlying advertisement, or something equivalent to "one click in," provided that the underlying advertisement is accurate and non-misleading. By just clicking on a link, the consumer could access substantial additional information about a product. This approach would be similar to the "adequate provision" requirement in broadcast advertising, with which consumers are very familiar, where patients are directed to find the prescribing information in another medium more conducive to a thorough consideration of the risks and benefits.[5]

Further, in character-space-limited formats, "one click" access to risk and benefit information could be part of the advertising execution, and help fulfill the fair balance need of the promotional piece. Companies could then provide comprehensive risk information by including a clearly-labeled link to any website that otherwise complies with applicable FDA labeling regulations when using social media/Internet platforms with character limits. This approach would facilitate the free flow of information to consumers about prescription drugs and medical devices, leading to improved public health outcomes and encouraging innovation in the healthcare space.

* * *

The IAB applauds and shares the FDA's commitment to promoting consumer access to reliable, balanced, and timely online information about regulated medical products. As Internet and social media technologies evolve, we hope that the FDA will continue its efforts to offer industry guidance that ensures that health information can be obtained online in a variety of formats. As we've offered in the past, we would welcome the opportunity to work with the FDA and other relevant stakeholders to ensure that such information is appropriately communicated across platforms.

Sincerely,

Mike Zaneis
Executive Vice President and General Counsel
Interactive Advertising Bureau

[5] *Id.*