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**COMMENTS OF PFIZER INC ON THE USE OF THE INTERNET AND SOCIAL MEDIA IN  
PROMOTING FDA-REGULATED MEDICAL PRODUCTS  
(DOCKET NO. FDA-2009-N-0441)**

Pfizer Inc (Pfizer) submits these comments to FDA on the Use of the Internet and Social Media in Promotion of FDA-Regulated Medical Products. Pfizer presented testimony at the hearing on November 12 and 13, 2009 on this important topic. These comments supplement our testimony, and are submitted pursuant to the notice announcing the public hearing, 74 Fed. Reg. 48,083 (Sept. 21, 2009). They are also intended to complement the comments submitted by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Organization (BIO), which Pfizer fully supports.

Clear, enforceable, evidence-based regulatory requirements that reflect real-world user expectations in the Internet and social media context are necessary to encourage manufacturers to provide truthful and non-misleading product information, subject to FDA regulatory oversight, to improve the overall quality of health information available to users online. Pfizer's comments therefore focus on the following points: (1) Because of the First Amendment values involved in FDA regulation of Internet and social media communications, rulemaking is the appropriate procedural mechanism for FDA to invoke in this area; (2) The public health would benefit from rulemaking because rulemaking results in legal norms that are binding and therefore enforceable through regulatory action; (3) The lack of a clear regulatory framework for manufacturer participation in new media will proliferate the largely unregulated conversations currently taking place online; and (4) The new requirements that FDA establishes through rulemaking should recognize the specific user expectations that exist in the Internet and social media contexts, and should not assume that the techniques FDA has developed to assure that conventional promotion is truthful and non-misleading are necessary to achieve that same objective in the new media context.<sup>1</sup>

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<sup>1</sup> Although Pfizer believes that regulations are ultimately required, Pfizer also believes that guidance is an appropriate interim step to provide some standards to regulated industry while the rulemaking process proceeds, as discussed below. Pfizer thus joins PhRMA in requesting timely guidance to facilitate industry in providing important health information through the Internet and social media. Pfizer further agrees with BIO that FDA could supplement its ultimate regulations with guidance as technological and other developments warrant.

**I. FDA SHOULD DEVELOP NEW REGULATIONS SPECIFICALLY APPLICABLE TO THE INTERNET AND SOCIAL MEDIA**

FDA should not try to fit the square peg of Internet and social media communications into the round hole of the Agency’s existing rules developed for conventional media. Rather, FDA should develop comprehensive new rules describing the actions manufacturers must take in order for their online communications to be truthful and non-misleading in the specific context of the online environment. The Agency should ultimately establish these new rules not in guidance—which by definition cannot change existing rules but can merely provide an interpretive gloss on those rules—but rather in new regulations. As discussed below, the public health would be benefitted by the establishment of binding, legally enforceable new rules that have been developed by FDA specifically for new media.<sup>2</sup>

**A. THE FIRST AMENDMENT RIGHT OF FREE EXPRESSION IS BETTER PROTECTED BY RULEMAKING THAN BY GUIDANCE**

FDA’s regulation of manufacturer communications about medical products on the Internet and through social media implicates important First Amendment values. Even product-specific manufacturer communications that merely propose a commercial transaction are subject to First Amendment protection, and much product-specific information is so scientific in nature that it is subject to the highest level of constitutional protection. In addition, the First Amendment protects not only the freedom of a medical product manufacturer to engage in truthful and non-misleading communications, but also the freedom of patients and prescribers to receive information on the full range of issues—both scientific and commercial—that interest them. See *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 756 (1976) (“Freedom of speech presupposes a willing speaker. But where a speaker exists, . . . the protection afforded is to the communication, to its source and to its recipients both. This is clear from the decided cases.”).

For FDA to regulate in this sensitive area through guidance instead of rulemaking inherently raises First Amendment concerns because of the nature of the process used to develop guidance, and the nature of the Agency pronouncements that result. A particular concern here relates to vagueness. A law “must be carefully drawn or be authoritatively construed to punish only unprotected speech and not be susceptible of application to protected expression.” *Gooding v. Wilson*, 405 U.S. 518, 522 (1972). “Because First Amendment freedoms need breathing space to survive, government may regulate in the area only with narrow specificity.” *NAACP v. Button*, 371 U.S. 415, 433 (1963); see also *Baggett v. Bullitt*, 377 U.S. 360, 366 (1964) (holding a loyalty oath unconstitutional on vagueness grounds). Rulemaking is designed to produce specific, codified

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<sup>2</sup> Although we believe that notice-and-comment rulemaking would be the most effective procedural option for FDA to pursue in crafting those pathways for the reasons discussed below, we believe that there is an appropriate role for guidance documents as well, particularly as an interim measure. Guidance is an appropriate choice where the law is clear but FDA’s interpretation is not, or where the statute or the regulations are unclear. Guidance could be used to affirm, for example, that statements made by users in the context of manufacturer-supported online forums are not subject to regulation by FDA and will not be attributed to the supporting manufacturer. This is the approach that FDA took in clarifying its expectations with respect to industry-supported scientific and educational activities. It therefore represents (we believe) FDA’s current view, but the lack of a guidance document clearly and specifically applicable to the Internet and social media means questions continue to arise. Moreover, FDA’s guidance on consumer-directed television advertising represents a useful precedent in its approach to the presentation of risk information in the context of time and space constraints, but further guidance would be necessary to make clear that—and precisely how—a similar approach would be appropriate in the Internet and social media context.

standards through a rigorous process of analysis of public comments on proposed requirements. Guidance, by contrast, tends to be less specific and typically includes extensive narrative discussion of various issues. For these reasons, guidance in this area presents greater risk of vagueness than rulemaking in terms of the First Amendment.

Moreover, as FDA is well aware, guidance documents purporting to regulate speech have engendered extensive litigation. Perhaps the best-known First Amendment litigation against FDA involved a trio of guidance documents that Agency personnel developed in the 1990s. WLF v. Friedman, 13 F. Supp. 2d 51 (D.D.C. 1998), appeal dismissed sub nom. WLF v. Henney, 202 F.3d 331 (D.C. Cir. 2000). There, as here, FDA was confronted with entirely new types of communicative activity. Rather than undertake notice-and-comment rulemaking, FDA sought to establish a new set of regulatory expectations through guidance documents, leading to years of litigation and uncertainty. Pfizer believes it would be imprudent for FDA to repeat this pattern of seeking to address an entirely new field of conduct, where First Amendment rights are clearly at stake, without the discipline that comes with a rulemaking proceeding. Further, since the WLF litigation, the courts have only become more aggressive in policing FDA regulation of speech.<sup>3</sup>

## **B. EFFECTIVE COMPLIANCE AND ENFORCEMENT REQUIRE RULEMAKING**

Regulations are ultimately required to establish legally binding standards. Specifically, although FDA may use guidance documents to “describe the agency’s policy and regulatory approach to an issue,” 62 Fed. Reg. 8961, 8967 (Feb. 27, 1997), guidance documents “do not legally bind the public or FDA,” 21 C.F.R. § 10.115(d). As FDA has acknowledged, “[t]he only binding requirements are those set forth in the statute and FDA’s regulations.” 62 Fed. Reg. at 8963. Therefore, FDA cannot use statements contained in guidance documents as the basis for enforcement action. See Gen. Elec. Co. v. EPA, 290 F.3d 377 (D.C. Cir. 2002) (holding agency guidance was legislative rule subject to APA where it imposed binding obligations on agency and applicants). Guidance also cannot be used to allow manufacturer communications in online media that would contravene existing regulations. Even if regulations already in effect could be read to permit particular activities, FDA would have to engage in new rulemaking in order to alter its interpretation of an existing rule. See, e.g., Alaska Prof’l Hunters Ass’n v. FAA, 177 F.3d 1030, 1033-34 (D.C. Cir. 1999).

In the past, FDA has developed guidance documents that sought to encourage particular forms of promotion by describing the circumstances in which the Agency would generally not intend to commence enforcement action despite the presence of an apparent legal violation. This was FDA’s approach, for example, in the draft guidance recommending the use of user-friendly alternatives to the traditional “brief summary” in consumer-directed print advertisements. FDA theoretically could take that same approach to address particular forms of online promotion that FDA believed should be permitted as a matter of enforcement discretion, despite statutory or regulatory

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<sup>3</sup> The constitutional boundaries of FDA’s authority to regulate manufacturer communications remain a subject of active judicial consideration. See, e.g., Commonwealth Brands, Inc. v. United States, No. 1:09-cv-117-M (W.D. Ky. Jan. 4, 2010); Complaint, Allergan v. FDA, No. 1:09-cv-01879-JDB (D.D.C. Oct. 1, 2009). Any actions by FDA with respect to promotional activities on the Internet and social media will be subject to close scrutiny by the courts. Rulemaking would enable FDA to obtain helpful comments from interested members of the public regarding the First Amendment implications of the Agency’s approach, and would provide the procedural rigor and discipline necessary to assure that the speech regulatory aspects of FDA’s actions in this area comport with First Amendment limitations.

provisions that apparently would preclude those communications. Such an approach would not be ideal, however, if FDA genuinely wants to encourage manufacturers to increase their level of engagement in online activities. Many manufacturers simply will decide, as a risk management matter, that they will not engage, irrespective of any guidance from FDA, because the enforcement discretion reference means that the Agency regards that engagement as potentially violating a statutory or regulatory provision. Given the possibility—some would say likelihood—of enforcement action by the Department of Justice, private plaintiffs, or state authorities, manufacturers have little choice but to take a risk-averse approach in this area.

### **C. MEANINGFUL MANUFACTURER PARTICIPATION IN AND RESULTANT FDA OVERSIGHT OVER NEW MEDIA REQUIRE RULEMAKING**

Manufacturers have to date remained largely absent from the many conversations taking place in social media concerning FDA-regulated medical products. A recent Pfizer review of social media communications relating to 22 prescription drugs over 30 days reveals substantial interest in and conversation about prescription drugs across a wide variety of social media platforms. (A straight-line projection would yield an annual total of over 1.4 million conversations about these 22 products alone.)<sup>4</sup> As the U.S. Supreme Court recently recognized, “manufacturers have superior access to information about their drugs,”<sup>5</sup> as well as access to extensive information about many non-product-specific health-related topics. They have, however, limited their participation in online activities because of the lack of clear regulatory standards. As a consequence, most online information about FDA-regulated products is provided by sources not regulated by FDA, and is of highly variable quality.

As shown in greater detail in Appendix A, a recent Internet search of eight Pfizer prescription drug products using the search engine Google<sup>TM</sup> found that only 22 percent of the first-page results and linking sites were regulated by FDA. Of the unregulated content, 33 percent were international pharmacy sites, 32 percent were unregulated drug information sites, 14 percent were “spam” sites or links, 11 percent were user-generated sites, including blogs and forums, two percent were plaintiffs’ attorneys sites, and one percent were non-sale international sites. Absent a comprehensive new set of regulatory standards for product communications through the Internet and in the social media setting that encourage manufacturers to engage in these new media, subject to appropriate FDA oversight, the conversations taking place in these media will remain largely unregulated.

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<sup>4</sup> The review, conducted on January 10, 2010, involved an analysis of 117,522 posts generated over the 30-day period. The 22 brands were evaluated for overall volume of conversation; sources/locations of conversation; legitimacy of conversation (*i.e.*, spam vs. real content); and mention of benefit and risk. The brands were: TOVIAZ® (fesoterodine fumarate), LYRICA® (pregabalin), VIAGRA® (sildenafil citrate), LIPITOR® (atorvastatin calcium), CHANTIX® (varenicline), CELEBREX® (celecoxib), SPIRIVA® HANDIHALER® (tiotropium bromide inhalation powder), CADUET® (amlodipine besylate and atorvastatin calcium), ARICEPT® (donepezil HCl), ABILIFY® (aripiprazole), ACIPHEX® (rabeprazole sodium), HEXALEN® (altretamine), ALOXI® (palonosetron HCl), GLIADEL® (polifeprosan 20 with carmustine implant), ZONEGRAN® (zonisamide), FRAGMIN® (dalteparin sodium), BANZEL® (rufinamide), SALAGEN® (pilocarpine HCl), TARGRETIN® (bexarotene), DACOGEN<sup>TM</sup> (decitabine), PANRETIN® (alitretinoin gel 0.1%), and NEUPRO® (rotigotine transdermal system). Non-Pfizer trademarks are the property of their respective owners.

<sup>5</sup> Wyeth v. Levine, 129 S. Ct. 1187, 1202 (2009).

## **II. THE NEW REGULATORY PARADIGM SHOULD BE DESIGNED TO FACILITATE TRUTHFUL AND NON-MISLEADING PRODUCT COMMUNICATIONS USING THE INTERNET AND SOCIAL MEDIA**

HCPs and patients do not bring their conventional print and broadcast media user expectations to the Internet and social media. The actions manufacturers need to take in order to ensure that their Internet and social media communications disclose all material facts and otherwise are truthful and non-misleading therefore differ from those necessary in the context of conventional media. “Old media” rules would be unnecessary for users to receive accurate and complete information and would thwart the potential for manufacturers to contribute in helpful ways to the health information that HCPs and patients are increasingly obtaining from online sources. New rules, specific to the Internet and social media, are needed.

Although further research is necessary to determine the specific requirements that would be necessary in the Internet and social media context to assure that communications about medical products are truthful and non-misleading,<sup>6</sup> the foundation of the new regulatory scheme and of any interim guidance can already be determined based on certain fixed legal and regulatory principles. First, statements by unregulated persons on manufacturer-hosted (or -supported) online forums are not statements by the manufacturers themselves. See FDA, Guidance for Industry: Industry-Supported Scientific and Educational Activities (Nov. 1997) (recognizing that a manufacturer’s support of an activity does not necessarily make that activity promotional or otherwise an activity “by or on behalf of” the manufacturer); see also 47 U.S.C. § 230 (website operation does not cause a person to become a speaker under the Communications Decency Act).

Second, not all product-related communications by or on behalf of a manufacturer are within FDA’s regulatory authority. See, e.g., 21 C.F.R. § 312.7(a) (FDA does not regulate product-specific “scientific exchange” by manufacturers); Kordel v. United States, 335 U.S. 345, 348, 351 (1948) (“labeling” is “written, printed, or graphic matter” that “performs the same function as it would if it were on the article or on the containers or wrappers”); United States v. Albery Food Prods., 98 F. Supp. 23, 27 (S.D. Cal. 1951) (“the scope of ‘accompanying’ should be limited under Kordel . . . to cases where the literature . . . will likely reach the hands of the consumer to serve the purposes for which labeling is intended” (citations omitted)), aff’d, 194 F.2d 463 (9th Cir. 1952). Thus, for example, a manufacturer’s correction of a medically inaccurate product-related error on a wiki site should not be regarded by FDA as promotional labeling or as advertising. Similarly, scientifically-based, non-promotional statements made by non-commercial manufacturer personnel (e.g., medical affairs representatives) should not be regarded as subject to FDA regulation.

Third, the phrase “labeling and advertising” within the meaning of 21 C.F.R. § 314.81(b)(3)(i) does not necessarily include every statement made by or on behalf of a manufacturer on the Internet or in the social media context, and the reference in that regulation to “specimens” means that not every single communication is subject to the post-market submission requirement, even

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<sup>6</sup> Pfizer acknowledges the limitations affecting FDA’s ability to execute this research agenda unilaterally, particularly given statutory and resource constraints. FDA has available to it many established mechanisms for research and experimentation by manufacturers with novel communication techniques that would give the Agency the ability to monitor and the ability to accumulate experience with these new approaches. See, e.g., FDA, Guidance for FDA Staff: The Leveraging Handbook (June 2003). Indeed, FDA has already invoked its leveraging policies for the purpose of executing a Memorandum of Understanding with an Internet/social media health information provider. See 73 Fed. Reg. 73,941 (Dec. 4, 2008) (Memorandum of Understanding with WebMD, LLC); 74 Fed. Reg. 57,316 (Nov. 5, 2009) (Addendum).

if it were to qualify as “labeling” or “advertising.” Thus, for example, it should be adequate for a manufacturer to submit to FDA template scripts or similar documents that reflect its typical contributions to Internet forums, and FDA should not assert that a manufacturer is required to submit every single online statement made by it or on its behalf. FDA’s regulations for medical devices do not include a provision that is analogous to § 314.81(b)(3)(i), so no issue arises with respect to the submission of medical device-related promotional materials disseminated through the Internet or in the social media context.

Fourth, disclosure requirements must reflect inherent space limitations. FDA’s prescription drug advertising regulations and the corresponding statutory provision recognize that the constraints inherent in television advertising make it inappropriate to apply the same approach to risk disclosure to that medium as the approach required by FDA in contexts where manufacturers may have more latitude to provide risk information (e.g., through full product labeling). 21 C.F.R. § 202.1; 21 U.S.C. § 352(n) (requiring only a “true statement” in “brief summary”). It is an established FDCA principle that promotional communications occurring in space-limited media are governed by reduced risk disclosure requirements, subject to the central requirement that they be truthful and non-misleading.<sup>7</sup> It is similarly the case that promotion designed merely to draw attention to the name of the product generally need not provide comprehensive risk information. See 21 C.F.R. §§ 202.1(e)(2)(i), 201.100(f). In the context of Internet and social media promotion of medical products, FDA should establish new requirements that reflect users’ “click-through” behavior and other ways in which their approach to obtaining risk and other qualifying information may differ from the conventional media setting. See Nov. 12 Internet Public Hearing Tr. at 438-40.

Consistent with these principles, Pfizer is providing in Appendix B several hypothetical examples of the types of communications by prescription drug manufacturers in the Internet and social media context that are truthful and non-misleading and should be permitted by FDA. These examples, which involve a fictitious product called XELATRAN® (cryptitron), illustrate potential approaches to providing risk information and responding to comments posted to a manufacturer-sponsored YouTube® video, providing risk information and responding to user posts on a manufacturer-sponsored discussion forum, and providing risk information and responding to comments on a mobile communication version of a manufacturer-sponsored discussion forum. Pfizer believes that the existing statutory and regulatory provisions should be adequate to allow manufacturers to participate in many Internet and social media communications and that FDA could confirm this, as well as the permissibility of Pfizer’s proposed approach, through guidance. But enough ambiguity exists that it is likely manufacturers will engage in more novel communications in these “new media” contexts only if given clear regulatory pathways to do so.

### **III. CONCLUSION**

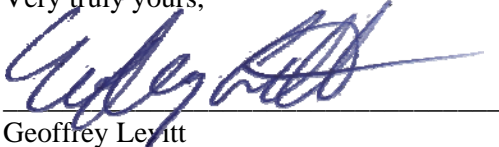
Pfizer believes that FDA should establish new requirements for the Internet and social media that recognize their unique characteristics and are informed by actual user behavior and expectations in these new media. To assure that these requirements are legally enforceable and respect First Amendment values, the Agency should ultimately establish these new rules through notice-and-comment rulemaking even if the Agency initially proceeds through guidance. Pfizer has identified a number of guiding principles that, we believe, should inform FDA’s development of a new regulatory

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<sup>7</sup> FDA’s justification for impinging on First Amendment values is highest when the agency focuses on prohibiting promotional communications that are false or misleading, Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n, 447 U.S. 557, 566 (1980), and restrictions appropriately tailored to prevent false or misleading promotional communications generally will not run afoul of First Amendment protection of commercial speech.

paradigm and any interim guidance for medical product promotion on the Internet and in the social media context. The touchstone should be that product communications in the Internet and social media contexts must be truthful and non-misleading, and the specific regulatory techniques that FDA employs to achieve that objective must be evidence-based. Pfizer intends to remain active in pursuing research opportunities to gain further insight into the user behaviors and expectations of both patients and HCPs in the online environment. We would be pleased to provide FDA with further information regarding our efforts and findings.

Very truly yours,



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**APPENDIX A**

**THE HETEROGENEITY OF THE CURRENT ONLINE ENVIRONMENT**

The typical user begins an online health inquiry with a search engine.<sup>8</sup> On that basis, Pfizer engaged WeissComm Group (WCG) to conduct searches, using the most popular search engine, Google™, for information relating to eight Pfizer products. The searches were conducted on February 4, 2010. The average number of search results returned on the first page was 18.5. We limited our analysis to the first page results, as 90 percent of those who search for information online do not look beyond the first page.<sup>9</sup>

<b>Brand</b>	<b>Number of Search Results</b>	<b>Organic: Sponsored Results</b>	<b>Percent FDA-Regulated</b>	<b>Percent Non-Regulated</b>	<b>Breakdown of Links to Non-Regulated Sites</b>
ARICEPT® (donepezil HCl)	19	10:9	21%	79%	<b>15 Non-regulated sites (8 sponsored, 7 natural):</b> 6 international pharmacy ads (40%) 6 drug info sites (40%) 2 advocacy groups (13%) 1 Wiki (7%)
CELEBREX® (celecoxib)	19	10:9	16%	84%	<b>16 Non-regulated sites (9 sponsored, 7 natural):</b> 8 international pharmacy ads (50%) 7 drug info sites (44%) 1 Wiki (6%)

<sup>8</sup> See Noah Elkin, iCrossing, How America Searches: Health and Wellness 12 (Jan. 2008), available at <http://www.icrossing.com> (presenting data from a survey of 1,084 adults conducted in December 2007).

<sup>9</sup> See Search Engine Referral Rates by Page in SERPs (May 22, 2008), available at <http://www.enquiste.com/2008/05/search-engine-referral-rates-by-page-in-serps/>.

Brand	Number of Search Results	Organic: Sponsored Results	Percent FDA-Regulated	Percent Non-Regulated	Breakdown of Links to Non-Regulated Sites
CHANTIX® (varenicline)	23	12:11	13%	87%	<b>20 Non-regulated sites (10 sponsored, 10 natural):</b> 4 spam sites (20%) 4 online pharmacies (20%) 3 international pharmacy ads (15%) 3 drug info sites (15%) 2 lawsuit sites (10%) 2 group-advocacy/public service sites (10%) 2 user generated sites (10%)
LIPITOR® (atorvastatin calcium)	19	10:9	26%	74%	<b>14 Non-regulated sites (6 sponsored, 8 natural):</b> 7 international pharmacy ads (50%) 3 drug info sites (22%) 2 online pharmacies (14%) 2 user generated content sites (14%)
LYRICA® (pregabalin)	12	11:1	33%	67%	<b>8 Non-regulated sites (1 sponsored, 7 natural):</b> 5 drug info links (64%) 3 user generated content sites (36%)
SPIRIVA® (tiotropium bromide inhalation powder)	20	10:10	25%	75%	<b>15 Non-regulated sites (9 sponsored, 6 natural):</b> 7 international pharmacy ads (47%) 5 drug info sites (33%) 2 spam sites (13%) 1 User generated (7%)

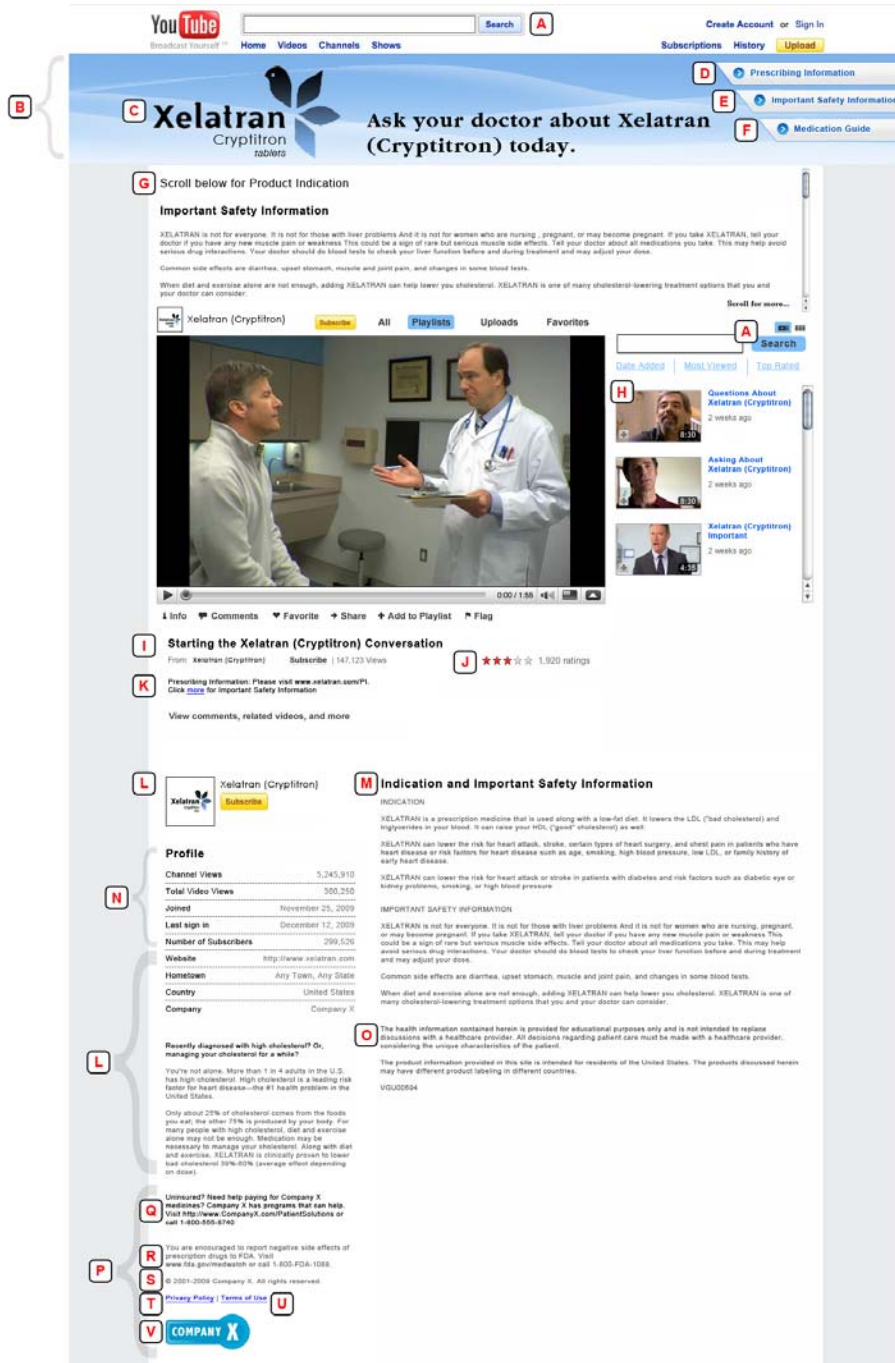
Brand	Number of Search Results	Organic: Sponsored Results	Percent FDA-Regulated	Percent Non-Regulated	Breakdown of Links to Non-Regulated Sites
TOVIAZ® (fesoterodine fumarate)	13	10:3	31%	69%	<b>9 Non-regulated sites (2 sponsored, 7 natural):</b> 6 drug info links (67%) 2 international pharmacies (22%) 1 International link (non-sales) (11%)
VIAGRA® (sildenafil citrate)	23	12:11	13%	87%	<b>20 Non-regulated sites (11 sponsored, 9 natural):</b> 10 spam sites (50%) 5 International pharmacy ads (25%) 3 user generated (15%) 2 drug info sites (10%)

## **APPENDIX B**

### **EXAMPLES OF COMMUNICATIONS REGARDING XELATRAN® (CRYPTITRON) FORMATTED FOR ONLINE MEDIA**

Appendix B uses a fictitious product called XELATRAN® (cryptitron) to demonstrate how regulated companies could engage in social media in a truthful, non-misleading way.

**Branded YouTube® Channel – Version A:** This illustrative mockup represents one possible template for a YouTube® Channel based on our understanding of FDA’s current interpretation of its rules and regulations. This example does not allow users to interact with the page, beyond rating videos (closed field only). We believe that there may be ways to enhance the user experience. See e.g., Version B.



- A. YouTube Search - Allows people to search within YouTube for other videos or channels
- B. Header Image
- C. Brand Logo
- D. Link to PI/PPi
- E. Link to ISI
- F. Link to Medication Guide
- G. Scrollable ISI and Indication
- H. Video Playlist
- I. Video Title
- J. Video Rating System
- K. Video Descriptions\*
- L. Video Channel Profile - Company X Generated
- M. Indication & ISI
- N. Video Channel Profile - YouTube Generated
- O. Disclaimer Statements
- P. Additional Area
- Q. Company X Patient Solutions
- R. FDA MedWatch Statement
- S. Copyright
- T. Privacy Policy
- U. Terms of Use
- V. Company X Logo

\*The video description space is used to provide a link to the PI and to insert the ISI so that this information is included with the video if it is viewed outside of the branded Channel.

**Branded YouTube® Channel – Version B:** This illustrative mockup represents an example of the type of branded YouTube® Channel that allows users to fully interact with the page, thereby enhancing user experience, while still providing for adequate provision of risk information. It allows for consumers to post comments to the Channel and for a company spokesperson to respond to comments. The mockup includes direct links to brand risk information and the FDA MedWatch page.

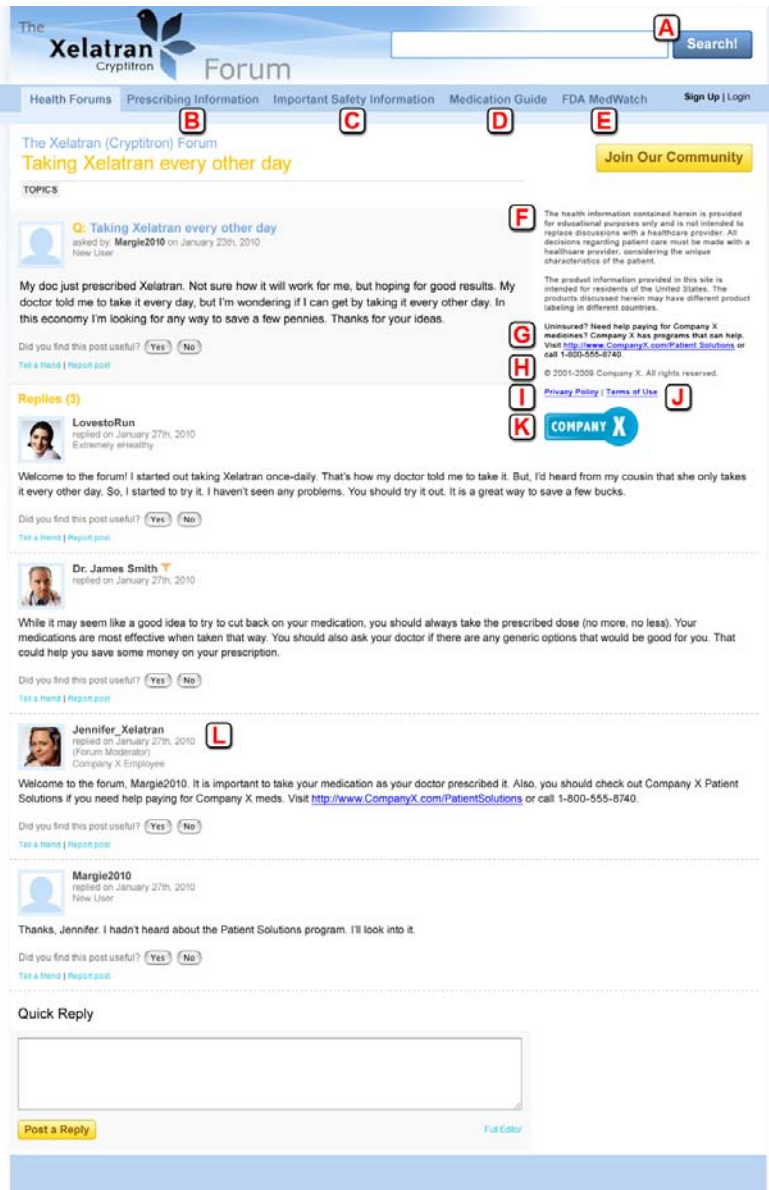
In terms of submission, we propose that the sponsor submit to FDA (1) the site template and (2) the company spokesperson’s responses to anticipated frequently asked questions. Any responses that fall outside of the standard responses would be batched and submitted on a monthly basis.

The image shows a branded YouTube channel for Xelatron (Cryptitron). The channel banner features the Xelatron logo and the text "Ask your doctor about Xelatron (Cryptitron) today." Below the banner, there is a video player showing a doctor and a patient. To the right of the video player, there is a list of videos with titles like "Managing Cholesterol with Xelatron (Cryptitron)", "Joe's Experience with Xelatron (Cryptitron)", and "Xelatron (Cryptitron) for Cholesterol". Below the video player, there is a section for "How I Lowered My Cholesterol with Xelatron (Cryptitron)" with a video thumbnail and a "Prescribing Information" link. To the left of the video player, there is a "Profile" section for Xelatron (Cryptitron) with statistics like "Channel Views: 5,245,910" and "Total Video Views: 300,260". Below the profile, there is a "Channel Comments (5)" section with user avatars and comments. At the bottom of the page, there is a "COMPANY X" logo and a search bar. Various callout letters (A-W) are placed around the page to identify specific features and elements.

- A** YouTube Search
- B** Header Image
- C** Brand Logo
- D** Prescribing Information
- E** Important Safety Information
- F** Medication Guide
- G** FDA MedWatch
- H** Brand Messages
- I** Disclaimer Statements
- J** Video Playlist
- K** Video Title
- L** Video Rating System
- M** Video Descriptions
- N** Video Channel Profile
- O** Video Channel Profile
- P** Channel Comments
- Q** Company X Spokesperson
- R** Additional Area
- S** Company X Patient Solutions
- T** Copyright
- U** Privacy Policy
- V** Terms of Use
- W** Company X Logo

**Branded Patient Forum:** This illustrative mockup represents an example of a branded forum that allows users to ask questions and respond to questions. It also allows for a company spokesperson to respond to comments. The mockup includes direct links to brand risk information and the FDA MedWatch page.

In terms of submission, we propose that the sponsor submit to FDA (1) the site template and (2) the company spokesperson’s responses to anticipated frequently asked questions. Any responses that fall outside of the standard responses would be batched and submitted on a monthly basis.



- A** Search
- B** Prescribing Information (Links to the Xelatran PI)
- C** Important Safety Information (Links to the Xelatran ISI)
- D** Medication Guide (Links to the Xelatran Medication Guide)
- E** FDA MedWatch (Links to www.fda.gov/medwatch)
- F** Disclaimer Statements
- G** Company X Patient Solutions
- H** Copyright
- I** Privacy Policy
- J** Terms of Use
- K** Company X Logo
- L** Company X Spokesperson

**Branded Mobile Application:** This illustrative mockup represents an example of a branded mobile application. The entry screen includes some disclaimer language and an “okay” button that users must click before they are directed to the discussion. The application allows users to ask questions and respond to questions. It also allows for a company spokesperson to respond to comments. The mockup includes links to brand risk information and the FDA MedWatch page.

In terms of submission, we propose that the sponsor submit to FDA (1) the site template and (2) the company spokesperson’s responses to anticipated frequently asked questions. Any responses that fall outside of the standard responses would be batched and submitted on a monthly basis.

