

Medmarc®

Social Media & FDA Regulations







DuVal & Associates

drug, device & food law

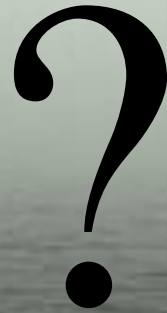
Agenda

- Introduction
- How FDA regulates social media
- Spotting issues
- Proposals on how to specifically regulate
- Questions



Medium	Example	Description	Drawback	Benefit
Social Networks	Facebook 	Company can post photos, videos, links and provide short updates and messages to “friends.”	Less direct than Twitter. Must monitor comments if they are enabled.	More robust interface than Twitter.
Micro-blogging	Twitter 	Company has 140 characters or less to “tweet” information with “followers.”	Limited to 140 characters. Must monitor comments if they are enabled.	Great for short updates.
Video-sharing	YouTube 	Create videos or “channels” to disseminate information through the voice of a patient, employee, or practitioner.	Less interactive. Must monitor comments if they are enabled.	Easy for any user to access and view.
Blogs	Blogger 	Patients and HCPs “blog” or write about their experiences with the therapy.	Intense compliance demands. Must monitor comments.	Creates communal sense.

FDA's position on social media . . .



Social media use for FDA regulated products under fire by some . . .

FDA should regulate medical devicemakers' DTC advertising, advocates say

September 18, 2008 — 11:35am ET | By Anne Zieger

- TOOLS
- Subscribe
 - Email
 - Print
 - Comment
 - Contact Author
 - Reprint

- TAGS
- Cardiac Stents
 - Artificial Hips
 - pharmaceutical companies
 - Medical Device Industry
 - direct to consumer advertising
 - Medical Device Maker

Recently, critics have made quite an uproar over the prevalence of direct-to-consumer advertising created by pharmaceutical companies, suggesting that such ads could be the dangers of new drugs were promoted by pharmaceutical companies. At a hearing, the Prescription Project, a watchdog group, called on the U.S. Food and Drug Administration (FDA) to require the companies to withdraw the videos from YouTube, including an ad promoting Medtronic's Prestige Cervical Disc.

Group blasts Medtronic's YouTube ads

YouTube spots were called illegal. Medtronic says they've been pulled.

By JANET MOORE, Star Tribune
Last update: December 3, 2008 - 9:14 PM

A watchdog group charged Wednesday that Medtronic Inc. and two other medical device firms have illegally advertised their products on the popular website YouTube without warning consumers about potential complications.

The Boston-based group, the Prescription Project, called on the U.S. Food and Drug Administration (FDA) to require the companies to withdraw the videos from YouTube, including an ad promoting Medtronic's Prestige Cervical Disc.

Group says YouTube medical device ads may be illegal

December 5, 2008 — 1:06pm ET | By Anne Zieger

- TOOLS
- Subscribe
 - Email
 - Print
 - Comment
 - Contact Author

A consumer group has raised a protest over a group of ads for medical devices running on video site YouTube, arguing that the ads may be illegal. The group, Prescription Project, would like to see the vendors involved, including Medtronic Inc. and Johnson & Johnson, pulled from the site. The group includes an artificial spine disk drug-coated stent Xience.

- Print this story
- E-mail this story

- Save to del.icio.us
- Share on Facebook
- Share on Digg



Get more maps + stats

Minnesota business by the number
See Minnesota's top earning companies, CEOs and non-profits

Does this spell retreat?



No!

Social media is on FDA's radar screen . . .

- **September 2, 2009** CDRH opens its first Twitter account, “*FDACdrhIndustry.*”
- **November 12-13, 2009** - FDA holds a public meeting titled, “*Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools,*” to gather input from the pharmaceutical and medical device industries on Internet marketing.
- **November 18, 2009** – Bob Temple leaves post as Director of the Office of Medical Policy where he was “renowned for his firm stance against . . . direct-to-consumer advertising.” -- *The Pink Sheet Daily*

twitter



More headlines. . .

- **February 9, 2010** - Dr. Jean-Ah Kang, DDMAC, states the Agency is trying to, “. . . determine whether explicit Internet- and social media-specific guidance should be drafted . . .” -- *PRNewswire*
- **May 3, 2010** - “. . . the agency is reevaluating first amendment rights and how to regulate product claims on social media tools. . .” -- Ben Moscovitch, *Inside Washington Publishers*
- **May 12, 2010** - CDRH begins Tweeting on recalls. It’s second Twitter site, “*FDADeviceInfo.*”
- **July 29, 2010** – In a warning letter sent to Novartis Pharmaceuticals FDA tells the company that its use of Facebook to promote Tasigna is incomplete and misleading.

In some ways, we've been here before:

- **Déjà vu? Recall that before social media, FDA wrestled with the Internet too . . .**
 - FDA called upon to do something in the 1990s
 - They were not sure what to do
 - Some called for new regulations/guidance
 - Many said existing rules sufficient
 - **FDA chose to apply existing rules**
 - Precedent developed by way of Warning Letters

What's required for compliance? Follow the Food Drug & Cosmetic Act ("FDCA")

- **FDCA:**

- FDCA requires all ads to be **truthful, not misleading, fairly balanced** and have **adequate directions for use**--this can be accomplished by a "**brief statement**" ("brief summary" for drugs)
 - 21 U.S.C. 352(r)(2) requires ads to contain "***a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications***"
- Comparative advertising requires substantiation

Social media is direct-to-consumer (DTC) advertising, so follow FDA's DTC guidance:

- **FDA requires the following for DTC ads:**
 1. **“Major statement” of risks and benefits,**
 2. **“Adequate provision” made for full prescribing information 1(800)#, URL, concurrent print ads with information**
 3. **A directive to “Please see your health care professional”**
- **Other types of ads:**
 - ***“Help seeking” ad = disease claim only, no name***
 - ***“Reminder” ad = name and cost only***
 - **If *claim* and *name* then must have **fair balance**:**
 - Recall that 21 U.S.C. 352(r)(2) requires a brief statement (devices)/brief summary (drugs), must include;
 - ***intended uses of the device and relevant warnings, precautions, side effects, and contraindications”***



Arbitraer

(misvastatium) 100mg tablets

1

2

Makes breathing easier
... immediately

3

Arbitraer will help
control your asthma symptoms

4

5 out of 6 seasonal allergy
sufferers agree ...

Arbitraer is the best!

6

ACE

Pharmaceuticals

5

Side effects include coughing and
headaches.

This advertisement is entirely fictional—the connection between Arbitraer and any real company or product is intended, expressed, or implied.

Incorrect Product Claim Ad

4

As stated above, although claims generally must be supported by data from well-designed studies, consumers may not know if such studies exist or what they show. If FDA determines that claims are not supported, it will take action to have the ad fixed. In the short term, if you have doubts about a claim in an advertisement, you should talk to your healthcare provider.

1

The image of the young girl in the ad is misleading because the fictional drug is approved for use only in adults 18 years of age and older.

5

This ad presents Arbitraer's risks in small type size and positions this information far from where the benefits are discussed, so it is harder for the reader to notice and read the risks. "Fair balance" requires that risks and benefits be similarly clear.

2

Although claims generally must be supported by data from well-designed studies, consumers may not know if such studies exist or what they show. If FDA determines that claims are not supported, it will take action to have the ad fixed. In the short term, if you have doubts about a claim in an advertisement, you should talk to your healthcare provider.

6

The ad does not include the "brief summary," which includes additional required risk information. The law requires that ads include this "brief summary." Also, the ad does not include the statement "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088." This statement is required to be included in print ads by the Food and Drug Amendments Act of 2007.

3

This ad falsely states that Arbitraer is approved to help control asthma symptoms. This fictional drug (see the Correct Product Claim Ad) is approved to treat seasonal nasal allergy symptoms.

Apply the Regs and Guidance

YouTube Search Browse Upload

Men Who Can't Pee: A Failed Commercial

Subscribe! 241 videos



RhettandLink | August 11, 2009 362,690

<http://www.youtube.com/watch?v=W-jB9RDN-mE>

“Men Who Can’t Pee: A Failed Commercial”

- Does it meet the FDCA requirements?
 - Is it truthful, not misleading, fairly balanced and have adequate directions for use?
- Is it meant for consumers? Does it meet DTCA Guidance?
 - Does it include a “**major statement**” of risks and benefits, does meet the “**adequate provision**” requirement (full prescribing information 1(800)#, URL, concurrent print ads with information), is there a directive to “**see your health care professional?**”
- Is it a reminder ad or a help seeking ad?
 - Disease state AND product name brand used multiple times
- Hilarious video, yet doesn’t technically meet FDA’s DTCA guidance
 - No major statement, adequate provision not met, no clear reference to see your doctor

What are some of the FDA advertising and promotion issues related to social media?

- Sponsored links are a serious FDA issue—14 Warning Letters were issued in April 2009 due to violations
- Sponsored blogs, chat rooms and message boards are an issue
- You may be making claims:
 - You may “own” the content of what is said by employees and agents of the company (e.g. third party vendors and consultants)
- Off-label, extra-label dialogue an issue
- You have responsibility for what you participate in
- You may have responsibility to act upon the dialogue you hear/see
- FDA follows the “two click” rule

HIPAA privacy issues related to social media?

- Are you posting protected health information (“PHI”)?
- Is it de-identified?
- Are others posting this information?
 - Pictures
 - Text

Product liability issues related to social media?

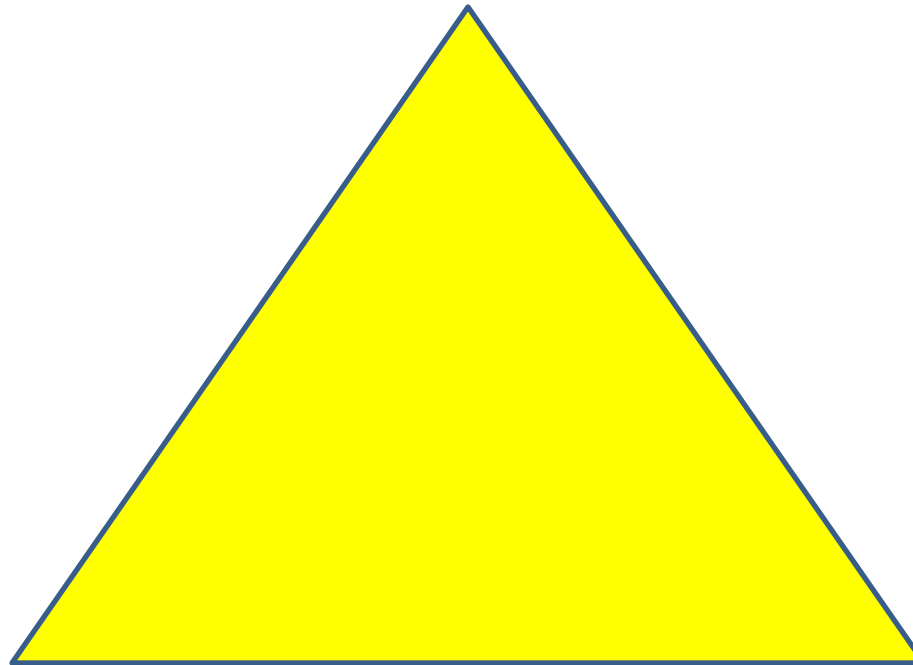
- Are users posting product problems?
- When did you know or should you have known about such problems?
- Did you correct any misstatements or misimpressions about the product?
- Did you redesign the product?

Other issues related to social media?

- **MDR issues?**
 - Did you learn something on-line that requires reporting as a medical device report?
- **Reimbursement and/or off-label issues?**
 - Did you learn information that needs to be corrected or put into context?
- **Are your competitors posting on your site?**

Analysis of responsibility for promotion in social media is a function of three factors:

1) Content



2) Participation

3) Control

Content on the social media site:

- **What did you say, sponsor, encourage or allow to be said?**
 - comparative claims?
 - risk-minimization?
 - unsubstantiated performance claims?
 - reimbursement?
 - HIPAA issues?
 - off-label?
 - practice medicine?
- **Did you rectify the issue?**

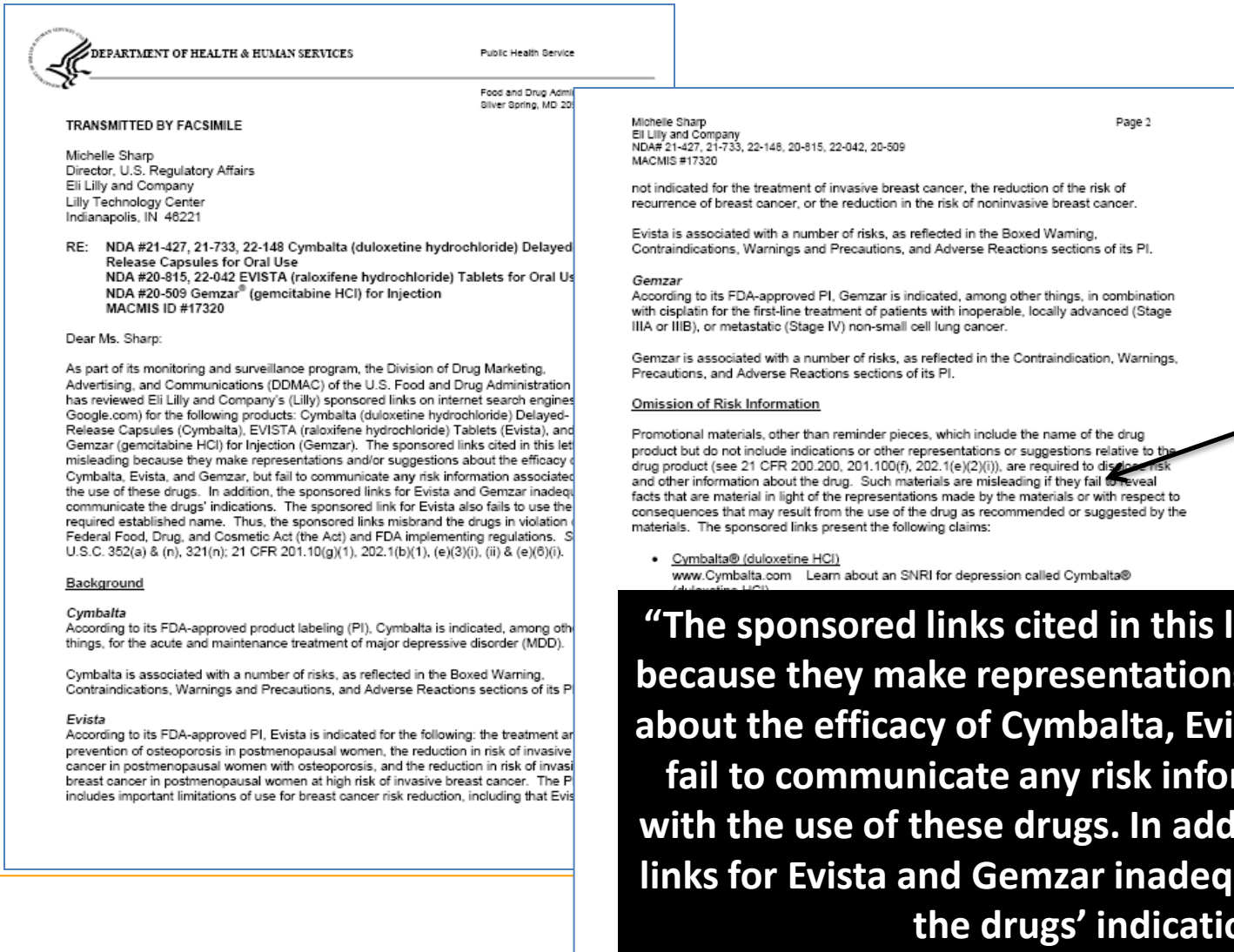
Participation on the social media site:

- **What was your role?**
 - moderator?
 - participant?
 - defender?
 - listener?
- **What did you say, *sponsor, encourage* or *allow* to be said?**
- **Did you disclose anything?**

Control of the social media site:

- **Did you have control over the content?**
 - can you correct the issues?
 - do you have a financial relationship with any participants?
- **What did you say, *sponsor, encourage* or *allow* to be said?**
- **Did you disclose anything on the site?**

DDMAC issued “14” Warning Letters last year, sample:



FDA cites specific sponsored links

“The sponsored links cited in this letter are misleading because they make representations and/or suggestions about the efficacy of Cymbalta, Evista, and Gemzar, but fail to communicate any risk information associated with the use of these drugs. In addition, the sponsored links for Evista and Gemzar inadequately communicate the drugs’ indications.”

Social media regulatory proposals from industry:

**FDA Part 15 Hearing
Promotion of FDA-Regulated
Medical Products Using the Internet and
Social Media Tools
Nov. 12-13, 2009**

Recall current ad requirements:

- FDCA regulations and DTCA guidance
- *“Help seeking” ad* = disease claim only, no name
- *“Reminder” ad* = name and cost only
- If *claim* and *name* then must have **fair balance**:
 - Recall that 21 U.S.C. 352(r)(2) requires a brief statement (devices)/brief summary (drugs), must include;
 - *intended uses of the device and relevant warnings, precautions, side effects, and contraindications”*
 - No real estate for this on a banner ad
- **Industry ignored FDA and went ahead without these statements and got themselves into trouble**

Industry responded at the November 2009 hearings with their suggestions:



A Proposal for Sponsored Links Connecting Consumers to Important Health Information

November 2009

Mary Ann Belliveau, Director, Health, Google
Amy Cowan, Head of Industry, Health, Google

Agenda

1 Online for Health Information

2 Role of Sponsored Links

3 Google's Proposed Sponsored Link Ad Formats

Google is Go-To Source for Health Info

Sponsored "Paid" Advertising
Advertisers can bid on these positions

The screenshot shows a Google search for "breast cancer". At the top, the Google logo is on the left, followed by a search bar containing "breast cancer" and a "Search" button. To the right of the search bar is a link for "Advanced Search". Below the search bar, a blue bar indicates "Web" and "Show options...". On the right side of this bar, it says "Results 1 - 10 of about 36,900,000 for breast cancer (0.24 seconds)".

The search results are divided into two main sections:

- Sponsored Links (Right Column):** This section contains five sponsored advertisements for breast cancer services and information, including links to "Breast Cancer Treatment Options", "Breast Cancer Radiation", and "Breast Cancer Advances".
- Organic "Natural" Search Results (Left Column):** This section contains five organic search results, including a "Facts About Breast Cancer" link, a "Breast cancer" overview link, "News results for breast cancer" with a video and several articles, and links to "BreastCancer.org" and the "Susan G. Komen Breast Cancer Foundation".

Blue lines from the text above point to the sponsored link area, and a red line from the text below points to the organic search results area.

Organic "Natural" Search Results
Cost free: results are based on Google
ranking algorithm of relevance to search query

Agenda

1 Online for Health Information

2 Role of Sponsored Links

3 Google's Proposed Sponsored Link Ad Formats

Proposed Standard for Product Claim Sponsored Links

Web Images Videos Maps News Shopping Gmail more ▾

Google

arbitraer

Search

[Advanced Search](#)

Web [Show options...](#)

Results 1 - 10 of about 1,250 for arbitraer. (0.09 seconds)

Arbitraer® Official Site

Sponsored Link

www.Arbitraer.com (misvastatum) 100 mg tablets. Help relieve seasonal allergy symptoms.
Warning: Avoid if you have liver problems. Not indicated for children under 18. [More Info](#)

PDF Be Smart About Prescription Drug Advertising – Arbitraer Brief ...

File Format: PDF/Adobe Acrobat - [View](#)

Arbitraer is a prescription drug called an antihistamine. Arbitraer is used to treat seasonal allergy symptoms, such as runny nose, sneezing, itchy nose or ...

www.fda.gov/downloads/Drugs/ResourcesForYou/.../ucm083522.pdf - [Similar](#)

Incorrect Product Claim Ad

Jun 24, 2009 ... The ad misleadingly suggests that Arbitraer is approved to treat children by showing an image of a young girl. Remember that these ads must ...

www.fda.gov/Drugs/ResourcesForYou/.../ucm082282.htm - [Cached](#) - [Similar](#)

Headline will link to designated landing page, such as the homepage

“Warning:” is fixed & cannot be modified; the remaining 62 characters can be modified

This additional “More Info” link will direct to risk information

Proposed Standard for Black Boxed Sponsored Links

Web Images Videos Maps News Shopping Gmail more ▾

Google

zinaxa

Search

[Advanced Search](#)

Web [+ Show options...](#)

Results 1 - 10 of about 794 for **zinaxa**. (0.37 seconds)

ZINAXA ® (azioglitazone)

Sponsored Link

[www.ZINAXA.com](#) Get important product information & find questions for your doctor.
Click to see full safety and prescribing information, including boxed warning, [More Info](#)

[Depression Center: Symptoms, Causes, Medications, and Therapies](#)

An estimated 19 million American adults are living with major **depression**. Here you'll find out in-depth **depression information** including symptoms, medications, ...

[www.webmd.com/depression/default.htm](#) - [Cached](#) - [Similar](#)

[About Zinaxa & Depression](#)

Facts about **depression**, including how to manage it and how to live with this medical condition.

[www.depression.com/](#) - [Cached](#) - [Similar](#)

[Zinaxa Information](#)

Researchers Work to Explain **Depression** and Related Diseases · **Information** on coping with traumatic events; Occurrence in: ...

[www.nimh.nih.gov/health/topics/depression/index.shtml](#) - [Cached](#) - [Similar](#)

Headline will link to designated landing page, such as the homepage

The "safety & prescribing" statement is fixed & cannot be modified

This additional "More Info" link will direct to risk information

FDA Regulated Medical Product Promotion Using Internet and Social Media Tools

John Kamp

On Behalf of

*The American Association of Advertising
Agencies*

-and-

The Coalition for Healthcare Communication

November 12, 2009

The Need:

Creating new mindset for role of FDA-regulated information

- New “safe spaces” for consumers/professionals to find FDA regulated information (FRI)
- Innovative FDA approaches to enable and foster safe, reliable information across the Internet
- New intra-industry and inter-agency efforts fighting widespread Web healthcare inaccuracy and fraud
- A new regulatory mindset pathway, with several “can do’s” and “can not’s” recognizing:
 - The use and capability of the Internet
 - The differences from traditional media
 - The power and public health promise of the medium

The Goal:

New policies, direction strengthening Public Health potential

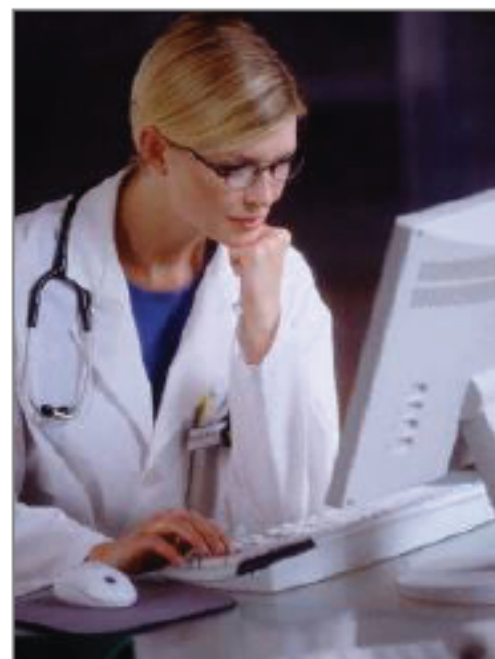
- FRI becomes recognized “gold standard”
- FRI easily identified as having been subject to objective regulatory review
- Robust FRI would support legitimate sites, easier browsing by professionals and consumers and better information supporting public health



The Outcome:

Fostering Safe Space for Accurate Information

- Professionals and consumers would recognize sites, networks designed to offer authoritative, accurate information
- Visitors would know industry promotion is overseen by FDA
- Would create “safe street” alternatives to sometimes “unknown street” environment





New Medicines. New Hope.



Communicating the Benefits and Risks of Medicines Responsibly Using the Internet and Social Media Tools

Jeffrey K. Francer
Assistant General Counsel, PhRMA
November 12 - 13, 2009

PhRMA's Proposal: FDA-Approved Use of Universal Safety Symbol



[DRUGEXX® \(Drugeride\)](#)

www.DRUGEXX.com

Approved for treating swollen tonsils.

Sponsored Link



[All drugs have risks. Click here for important safety information from the manufacturer.](#)

- **Universal safety symbol** (FDA logo or other FDA-approved symbol) and universal statement would indicate that linked page contains FDA-regulated risk information (*e.g.*, official Prescribing Information, Medication Guide)
- Throughout the web, a universal symbol would help healthcare professionals and consumers identify official, FDA-regulated medical product web sites. Prominence of graphic could drive clicks to comprehensive information
- Include established name and true abbreviated indication if Internet media do not allow for full information
- Include affirmative statement about risks, even if abbreviated
- Universal symbol could be used on search engines, blogs, microblogs, video
- FDA would set conditions on use of the safety symbol by manufacturers

Novartis Received a Warning Letter in July

“The shared content is misleading because it makes representations about the efficacy of Tsigina but fails to communicate any risk information associated with the use of this drug. In addition, the shared content inadequately communicates Tsigina’s FDA-approved indication and implies superiority over other products.

Bloomberg Businessweek

Monday August 23, 2010

Available on the iPad

Home

Financial

IDG

US FDA warns pharma firm about Facebook promotion

August 06, 2010, 5:00 PM EDT

 IDG *By Grant Gross*

The [U.S. Food and Drug Administration](#) has warned a pharmaceutical company that its use of the Facebook Share button to promote a cancer-fighting medication violates FDA requirements for disclosing information about drugs.

The FDA, in a [letter sent](#) to drug-maker [Novartis Pharmaceuticals](#) July 29, tells the company that its use of Facebook Share to promote Tsigina is incomplete and misleading.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

TRANSMITTED BY FACSIMILE

Lisa Drucker, PharmD, MBA
Director, Regulatory Affairs - Oncology
Novartis Pharmaceuticals Corporation
180 Park Avenue, Building 104 / 3K30
Florham Park, NJ 07932

RE: NDA # 022068
Tasigna® (nilotinib) Capsules
MACMIS # 18870

Dear Dr. Drucker:

As part of its monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) of the U.S. Food and Drug Administration (FDA) has reviewed Novartis Pharmaceuticals Corporation's (Novartis) U.S. website for Tasigna® (nilotinib) 200 mg Capsules (Tasigna). This website contains a "Facebook Share" social media widget¹ that generates Novartis-created information for Tasigna² that can be shared with Facebook users (i.e., "shared content").³ The shared content is misleading because it makes representations about the efficacy of Tasigna but fails to communicate **any** risk information associated with the use of this drug. In addition, the shared content inadequately communicates Tasigna's FDA-approved indication and implies superiority over other

Conclusions

- Use social media, but follow the general FDCA regulations and existing DTC guidance.
- Learn how to spot issues or get help making sure you are in compliance.
- Stay current, we suspect FDA will release guidance specific to social media sometime in 2011.

Questions?

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