

Conference Highlight Reprint # 43-05

Applying FDA Marketing Regulations to Internet Promotions

By John Mack

At the recent CBI *eMarketing for the Pharmaceutical Industry* conference held in Philadelphia, PA, Preeti Pinto, M.S., Senior Director Promotional Regulatory Affairs, AstraZeneca, gave the attendees some insight on the regulatory actions taken by the FDA with respect to online DTC marketing by pharmaceutical companies. She summarized the following most commonly cited violations found on pharmaceutical company web pages:

- Display of promotional information about investigational drugs
- Inclusion of outdated clinical research information
- Lack of fair balance
- Links to outdated PI
- Links to pages containing unapproved uses
- Use of unrepresentative graphical depiction
- Misleading presentation of clinical data

Ms. Pinto identified several specific regulatory citations by the FDA. The table on the next page is Ms. Pinto's current list of alleged violations, including companies, date cited, and URLs.

Be Careful With Web Site Names

Pfizer's use of "leavingpainbehind.com" as a web site name associated with Bextra and Celebrex is an interesting violation cited by the FDA. In a January 10, 2005, letter to Pfizer, FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) claimed that Pfizer's 27-minute TV infomercial "On the Road to Joint Pain Relief" ad on arthritis and joint pain relief is "a drug ad for Celebrex and Bextra that is misleading because it overstates its proven effectiveness and omits important information about the drugs' safety and effectiveness." The letter goes on to state: "In addition to the name of the website, testimonials promise that patients will 'leave pain behind,' and the infomercial features testimonials portraying dramatic efficacy results..."

Online Clinical Trial Registries

In September of 2004, the US industry trade group Pharmaceutical Research and Manufacturers' Association (PhRMA) launched a Clinical Study Results Database (ClinicalStudyResults.org) to provide a centralized repository where member companies have committed to register of all company-sponsored hypothesis-testing (non-exploratory) clinical trials.

In response to public demand, many pharmaceutical companies have started listing clinical trials that they sponsor on their own web sites. The FDA is likely to look closely at both the content and context of these online clinical trial registries associated with pharma corporate and/or product web sites.

Pinto offered a few clinical trial registry best practice suggestions, including:

- The presentation of clinical results should be non-promotional
- Both negative & positive trials should be included
- Data should be factual with all endpoints (not just favorable ones) included

Ms. Pinto recommended that registries "just state the facts and steer clear of conclusions and not be used as off-label promotional tools."

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Contact Info: Preeti Pinto, Sr. Dir. Head Promo Reg. Affairs, AstraZeneca Pharmaceuticals, 302-885-4408

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Table: Pharmaceutical Website Marketing Violations

Company	Date	Alleged Violation	Website
Pfizer Inc.	1/10/2005	Unsubstantiated Overstatement of Effectiveness	www.leavepainbehind.com
Bradley Pharm.	11/9/2004	Unsubstantiated Effectiveness claims; Omission of Risk Information; False/Misleading Safety Claims; Failure to Submit	www.bradpharm.com/pamine.htm
Ortho-McNeil Pharm.	9/15/2004	Omission of Material Risk Information	www.topamax.com
Cubist Pharm.	8/17/2004	Broadening of Indication; Misleading Superiority Claim	www.cubicin.com
Abbott Lab.	6/10/2004	Failure to Submit Updates to Website	www.norvir.com
Vivus Inc.	5/25/2004	Minimization of Risk Information; Unsubstantiated Effectiveness Claims	www.vivus.com
Pfizer Inc.	4/22/2004	Omission of Risk Information	www.zyrtec.com
King & Spaulding	6/18/2003	Unsubstantiated Safety/Efficacy Claim; Failure to Submit	www.Amnesteem.com
Novartis	6/18/2003	Unsubstantiated Superiority/Comparative Claims; Minimization of Risks	www.z-drops.com/ae; www.Zdrops.com; www.Zatidor.com
BMS	3/13/2002	Unapproved Uses / Broadened Indication; Failure to Submit	www.bms.com; www.ifex.com
Lilly ICOS, LLC	1/3/2002	Pre-approval Promotion	https://secure.lillyicos.com/news_level2.cfm; www.icos.com ; www.lilly.com
Merck & Co.	6/20/2001	Lack of Fair Balance	www.FOSAMAX.com
Supergen, Inc.	5/10/2001	Unapproved Uses	www.nipent.com/product/2_3.htm
Supergen, Inc.	5/10/2001	Pre-approval Promotion	www.supergen.com
Cubist Pharm.	11/22/2000	Pre-approval Promotion	www.cubist.com
Synsorb Bio.	9/5/2000	Pre-approval Promotion	www.synsorb.com
Hemispherx	7/7/2000	Pre-approval Promotion	www.hemispherx.com
Boehringer Ingelheim	6/27/2000	Use of Outdated Product Labeling	www.viramune.com
BMS	4/10/2000	Overstatement of Efficacy; Lack of Fair Balance	www.tequin.com
Ozelle	3/7/2000	Pre-approval Promotion	www.ozelle.com
Gel Tex Pharm.	10/23/1998	Pre-approval Promotion	www.geltex.com/ProductPipeline.html
Orphan Med.	9/17/1998	Pre-approval Promotion; Lack of Fair Balance	www.orphan.com/product_information.dbm
Hoffman-La Roche	6/4/1998	Lack of Fair Balance; Failure to Submit	www.roche.com/pharma/Products_Rx.htm
G.D. Searle	7/16/1997	Pre-approval Promotion	www.searlehealthnet.com
Immunex	2/14/1997	False, Misleading, Unsubstantiated Claims	N/A
Liposome Co.	12/11/1996	Lack of Fair Balance	www.lipo.com
Schering	9/20/1996	Lack of Fair Balance	N/A

Source: Preeti Pinto