

Prescription Drug Advertising

Message Points

- Advertisement of prescription drug products is governed by federal regulations (FDA); outdoor advertising formats are suitable for certain types of drugs ads
- Advertisement of non-prescription (over the counter) products is suitable for outdoor formats



Background

Federal law regulates advertising of prescription drugs. The Food, Drug & Cosmetic Act prohibits false claims and calls for a fair balance between information about effectiveness of drugs and risks. The federal enforcement agency is the Food and Drug Administration (FDA).

The outdoor medium is used to advertise prescription drugs, in full compliance with federal regulations.

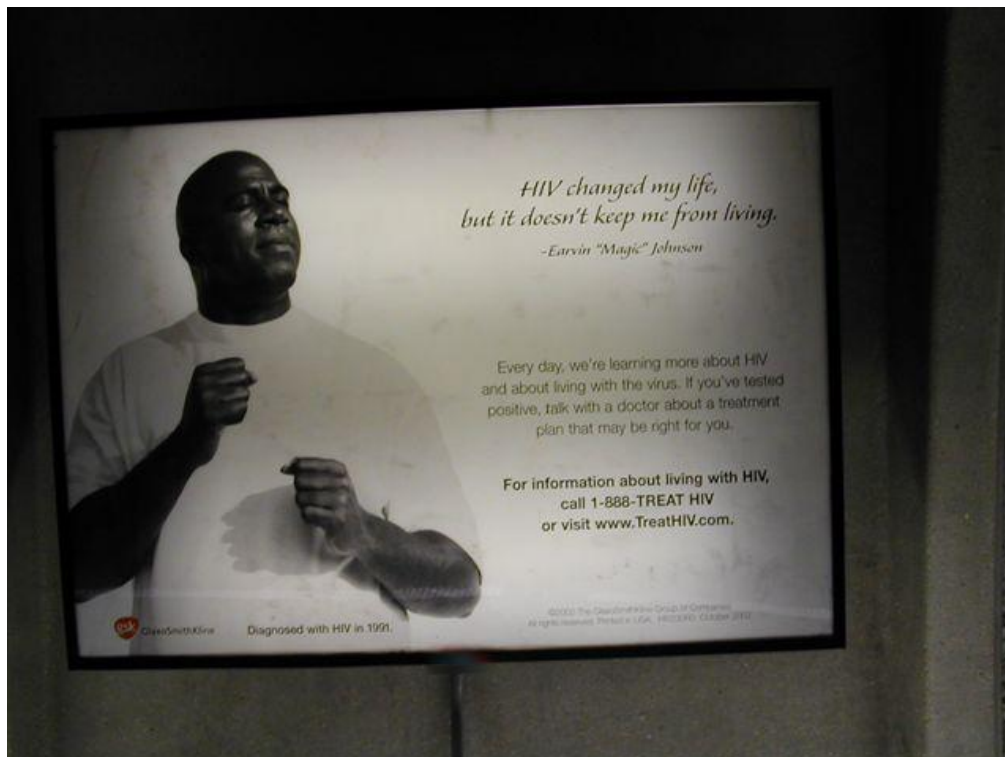
The Food and Drug Administration closely monitors the promotion of drug products to consumers, to assure accuracy and a fair balance between claims of effectiveness and information about risk. Most violations cited by the FDA involve overstatement of a product's efficacy, minimization of risk, or omission of relevant information. Federal regulators can stop violative promotions, order steps to correct mis-impressions, or seize misbranded drugs.

Federal (FDA) regulators recognize three types of direct-to-consumer (DTC) advertising of prescription drugs:

- “Product-claim” ads: include the product’s name and its use, and can make claims about the drug. Product-claim ads must provide information about risks (print ads publish a summary about side effects, contra-indications and effectiveness.)
- “Reminder” ads: provide the name of the product and can disclose limited descriptive information such as dosage form or cost. Reminder ads do not make claims or representations about the product, nor do they compare one product to another. Disclosure information is not required for reminder ads.
- “Help-seeking” ads: discuss a disease or condition, and advise people to “see your doctor” for possible treatment. Help-seeking ads do not include risk information.

Prescription drug advertisers use outdoor formats in all three categories. The Viagra billboard shown on the cover of this issue brief is a “Reminder” ad (it displays the brand, but includes no product claim), which is not accompanied by disclosure information.

Glaxo featured former NBA star Magic Johnson in an outdoor campaign promoting treatment for HIV. The transit poster shown below is an example of a “Help-seeking” advertisement. Like the “Reminder” ad, it does not require disclosure information.



FDA clarifies “Product Claim” ads

Federal regulators (FDA) have provided the outdoor industry (OAAA) with authoritative documentation confirming that drug ads presently run in other print media can be displayed via transit, shelter or mall displays.

On April 16, 2004, FDA transmitted to OAAA unambiguous documentation signed by top federal drug advertising regulators: Mr. Thomas Abrams, who directed the Division of Drug Marketing, Advertising and Communications, and Carol Barstow, the Division’s Regulatory Counsel.

The full text of the FDA memo and legal analysis prepared by OAAA Legal Counsel Eric Rubin are included in this issue brief as an addendum starting on page six.

Although written in jargon, this FDA document will be understood by potential drug advertising clients. It says that regulators accept prescription-drug ads in pedestrian-oriented outdoor formats, accompanied by proper disclaimer information.

“Product-Claim” ads published in newspapers and magazine include disclaimer information known as the “brief summary” regarding health risks and possible side effects. The “brief summary” is an oxymoron; it is not so brief. However, the “brief summary” standard is a model of brevity compared to its regulatory alternative: printing the entire label information, which is much more extensive.

The bottom line: drug companies are free to use either the “brief summary” or the more cumbersome label information in pedestrian-oriented outdoor media. (See example of product claim ad displayed via bus shelter format.)

Note: This statement of FDA policy does not apply to billboards. Unlike pedestrian formats, posters and bulletins may not accommodate the disclosure information required by “Product-Claim” ads in sufficiently large type face to be effective. However, drug advertisers use billboards for ads that do not require disclaimers, such as “Reminder” ads that feature only the brand, not a product claim.

Are depression symptoms
keeping you from where you want to be?



EXISTING FUNCTIONING BACK TO ME

Are these symptoms of depression interfering with your life?
 You're not sleeping
 You're not eating
 You're not going to work or school
 You're not doing the things you used to enjoy
 You're not feeling like yourself

Now EFFEXOR XR helps treat depression.
 EFFEXOR XR helps you feel better and get back to where you want to be. It's a prescription medicine that helps you feel better and get back to where you want to be.

Talk to your doctor about your symptoms, and ask if EFFEXOR XR is right for you.
 EFFEXOR XR is a prescription medicine that helps you feel better and get back to where you want to be. It's a prescription medicine that helps you feel better and get back to where you want to be.

For more information,
call 1-888-325-8477 or
visit www.EFFEXORXR.com

VENLAFAXINE HCl
EFFEXOR XR
 The change you deserve.™

EFFEXOR XR (venlafaxine HCl) Extended-Release Tablets, 375 mg, is a prescription medicine used to help treat major depressive disorder (MDD) and generalized anxiety disorder (GAD) in adults. It is not known if EFFEXOR XR is safe and effective in children and teenagers. EFFEXOR XR is not for use in patients with a history of seizures, a history of alcohol abuse, or a history of drug abuse. Tell your doctor if you are taking any other medicines, including over-the-counter medicines, vitamins, or herbal products. Tell your doctor if you are pregnant, planning to get pregnant, or are breastfeeding. Tell your doctor if you have any allergies. Tell your doctor if you have any medical conditions, including heart disease, high blood pressure, low blood pressure, diabetes, thyroid disease, kidney disease, liver disease, or a history of seizures. Tell your doctor if you are taking any other medicines, including over-the-counter medicines, vitamins, or herbal products. Tell your doctor if you are pregnant, planning to get pregnant, or are breastfeeding. Tell your doctor if you have any allergies. Tell your doctor if you have any medical conditions, including heart disease, high blood pressure, low blood pressure, diabetes, thyroid disease, kidney disease, liver disease, or a history of seizures. Tell your doctor if you are taking any other medicines, including over-the-counter medicines, vitamins, or herbal products. Tell your doctor if you are pregnant, planning to get pregnant, or are breastfeeding. Tell your doctor if you have any allergies. Tell your doctor if you have any medical conditions, including heart disease, high blood pressure, low blood pressure, diabetes, thyroid disease, kidney disease, liver disease, or a history of seizures.

References

Advertising Definitions (includes terms, procedures, and labeling guidelines)

<http://www.fda.gov/cder/handbook/adverdef.htm>

Consumer Reaction to DTC Advertising of Prescription Medicines (Prevention Annual Survey). Highlights from Prevention's 6th Annual survey

www.patientadvocacy.org/Patient_Coalition.pdf

Direct-to-Consumer Advertising of Prescription Drugs (National Consumers League Study).

<http://www.nclnet.org/NCLDTCsurvey.ppt>.

FDA survey of doctors about drug advertising, why it works, and its importance to patient education

<http://www.fda.gov/cder/ddmac/globalsummit2003/index.htm>

Frequently Asked Questions (FAQs) about drug advertising

<http://www.fda.gov/cder/ddmac/FAQS.HTM>

Impact of DTC Advertising Relative to Patient Compliance (Pfizer/RxRemedy survey).

www.pfizer.com/are/about_public/mn_about_dtcadsdoc.html.

Laws, Regulations, Guidance and Enforcement Actions for the advertising community

<http://www.fda.gov/cder/ddmac/lawsregs.htm>

Submitting Promotional Materials for review by FDA

<http://www.fda.gov/cder/ddmac/E-submissions.htm>

Types of drug advertising (from Congressional testimony by Deputy Director of the Division of Drug Marketing, Advertising, and Communication)

<http://www.fda.gov/ola/2001/drugpromo0724.html>

April 2004

SPECIAL LEGAL REPORT:
FDA Clarifies Prescription Drug Advertising in Outdoor Media.

The U.S. Food & Drug Administration (FDA) has provided the OAAA with an authoritative determination confirming that precisely the same prescription drug advertisements that presently run in other print media may also be disseminated without modification on pedestrian-oriented outdoor media such as mall displays, bus shelters and transit advertising. Simply stated, when you see a full-page prescription drug ad in a newspaper or magazine, that ad can just as easily be printed as a transit or bus shelter poster.

The FDA determination came in response to concerns raised by the OAAA, that drug manufacturers have indicated reluctance to use outdoor for direct-to-consumer “product claim” ads that promote the use of a specific drug for use in treating a specific ailment. That reluctance was reportedly based on confusion over whether the FDA would permit the use of ads incorporating the same “brief summary” disclosure of risks and precautions that accompany prescription drug ads in other print media. In fact, several OAAA members had reported that potential advertisers were concerned that the FDA’s “brief summary” regulation did not extend to outdoor, and that outdoor product claim ads have to include the more extensive “labeling” disclosures that are packaged and distributed with each prescription at point-of-purchase. In response, OAAA undertook what became a year-long effort to secure a determination from the FDA that would conclusively resolve this problem. We now have that document.

On April 16, 2004, OAAA counsel received a letter from Carol Barstow, Regulatory Counsel to the FDA’s Division of Drug Marketing, Advertising and Communications (“DDMC”), transmitting a memo that documents FDA policy with respect to outdoor advertising of prescription drugs. The FDA letter memorializes a meeting between OAAA representatives and FDA Associate Commissioner Thomas

Abrams, who directs DDMC, FDA Deputy General Counsel Seth Ray, and other agency staff. The FDA memo states unequivocally:

“Decisions reached: . . .

Historically, FDA has not objected when a company ensures that its promotion placed in outdoor media meets the requirements applicable to either “advertisements” (e.g., “brief summary” requirement) or “labeling” (e.g., ‘PI’ requirement) ... FDA does not see any reason to change this practice at this time.

The text of the FDA’s memo is attached. Although written in FDA bureaucratese, the agency’s decision is unambiguous and will be understood by potential prescription drug-advertising clients. The bottom line is that, as with product claim ads in other print media, drug companies are free to use either the brief summary or the more extensive label disclosure in pedestrian-oriented outdoor media.¹

Anyone who has seen a newspaper ad for a prescription drug will remember that a “brief summary” often is not so brief, even though it is written in relatively small print. As a result, product claim ads for most prescription drugs are probably not appropriate for poster and bulletins which, unlike pedestrian formats, may not be able to accommodate most “brief statement” disclosures in sufficiently large type face to be effective. However, as explained in two previous OAAA Legal Reports dealing with the prescription drug issue, (see OAAA Legal Reports for March and June, 2003) larger format outdoor advertising is completely appropriate for “help seeking” advertisements and “reminder” advertisements, the two other categories of pharmaceutical advertising also permitted under FDA rules. Unlike, “product claim” ads, which must be accompanied by the “brief summary,” neither of these advertisement classifications involves any affirmative disclosure.

To summarize, “help seeking” ads may refer to a specific ailment, encourage the consumer to see a doctor for more information, and identify the name of a sponsor

¹ In fact, at our meeting, the FDA staff expressed genuine surprise that there was confusion regarding the use of the “brief summary” in outdoor media. Indeed, as the FDA memo points out, within the past year, the agency has actually cleared two prescription drug ads for transit and mall displays.

that produces a drug that is prescribed for treating the named condition. A “reminder ad” identifies the specific product and its manufacturer, but may not refer to a specific condition for which that the drug is prescribed. A good example of this category is the poster campaign for Viagra, which simply names the product in conjunction with a headline that reads “Good Morning.”

The FDA’s new memorandum provides the foundation for renewed industry marketing efforts to penetrate into prescription drug advertising. Outdoor companies should feel free to use this Legal Report and the attached FDA document, which is signed by Thomas Abrams as well as his counsel, to resolve any future issues regarding the use of a “brief summary” in the dissemination of prescription drug product claim advertising in outdoor media.

Prepared by Eric Rubin (Rubin, Winston, Diercks, and Harris & Cooke) for the OAAA on
April 26, 2004.

FDA Memo:



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

David Adams, Esq.
Venable LLP
Terrell Place
575 7th Street, NW
Washington, DC 20004-1601

Eric Rubin, Esq.
Rubin, Winston, Diercks, Harris & Cooke
1155 Connecticut Avenue N.W.
6th floor
Washington, DC 20036

RE: Meeting Minutes

Dear Mr. Adams and Mr. Rubin:

Per your request, I am enclosing a copy of the meeting minutes from our January 6, 2004 meeting with the Outdoor Advertising Association of America (OAAA). We appreciate having the opportunity to meet with you and your client to discuss their questions and concerns regarding outdoor promotion of prescription drugs.

Sincerely,

Carol H. Barstow
Regulatory Counsel
Division of Drug Marketing,
Advertising and Communications

Meeting Minutes

Meeting Date: Tuesday, January 6, 2004

Time: 11:00 AM – 12:00 PM

Location: FDA, Conference Room M
Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

FDA Attendees:

Mike Landa, Office of Chief Counsel
Seth Ray, Office of Chief Counsel
Thomas Abrams, Division of Drug Marketing, Advertising, and Communications
Carol Barstow, Division of Drug Marketing, Advertising, and Communications
Amie Braman, Division of Drug Marketing, Advertising, and Communications

External Attendees:

David Adams, Venable LLP
Jill Deal, Venable LLP
Eric Rubin, Rubin, Winston, Diercks, Harris & Cooke
Ken Klein, Outdoor Advertising Association of America

Purpose of Meeting: To discuss questions and concerns of the Outdoor Advertising Association of America (OAAA) related to compliance with the promotional regulations when promoting prescription drugs in outdoor media, such as billboards or posters displayed in bus shelters.

Discussion Points:

- Whether companies placing promotion for prescription drugs in outdoor media, such as billboards or posters displayed in bus shelters, can follow the advertising regulations and include a “brief summary” rather than providing the full prescribing information (“PI”) with the promotion.
- Whether outdoor promotion can be presented in a “two-sided” format whereby the “brief summary” information would be placed on the reverse side panel and be accessible to the consumer by walking around the outdoor venue (e.g.,

walking from the inside of the bus shelter, where the panel with the main body of the promotion appears, to the outside of the bus shelter, where the "brief summary" panel would appear).

Decisions reached:

- Historically, FDA has not determined whether prescription drug promotion placed in outdoor media, such as billboards or posters displayed in bus shelters, constitutes an "advertisement" under section 502(n) of the Federal Food Drug & Cosmetic Act or falls within the definition of "labeling" in section 201(m). FDA has indicated this in previous telephone discussions with Mr. Adams representing OAAA and other clients. Neither OAAA nor FDA sees any reason for FDA to reach such a determination at this time.
- Historically, FDA has not objected when a company ensures that its promotion placed in outdoor media meets the requirements applicable to either "advertisements" (e.g., "brief summary" requirement) or "labeling" (e.g., "PI" requirement). This is the position that FDA has taken in previous communications with Mr. Adams representing OAAA and other clients (e.g., in giving advisory comments on specific draft promotional pieces). FDA does not see any reason to change this practice at this time. OAAA stated that such a practice would sufficiently meet the needs of its member companies in using outdoor media to promote prescription drugs.
- OAAA did not wish to discuss or pursue the concept of placing the "brief summary" information on the reverse side panel of the outdoor media, for example, of a bus shelter. OAAA and FDA agreed that having this information placed such that people would need to walk over to another location to read it is not acceptable and would not effectively communicate this important information.

Signature, minutes preparer:

Carol Baustow

Concurrence:

Theresa Alcorn