FREQUENTLY ASKED QUESTIONS

Can I report anonymously?

Yes, anonymous complaints often alert FDA to potential problems. However, complaints accompanied by names and contact information are helpful in cases for which FDA needs to follow-up for more information.

Will DDMAC be able to stop the misleading promotion?

In many cases, yes, especially if evidence is provided. Evidence can include the actual promotional materials or documentation of oral statements made by company representatives.

What will happen to my complaint once I have contacted DDMAC?

The information you provide will be sent to a Regulatory Review Officer in DDMAC responsible for this class of drugs. The reviewer will evaluate it and determine if it may serve as the basis for a potential enforcement action or as valuable information for our ongoing surveillance activities.

How do I learn more?

To learn more about DDMAC in-service training for large medical group/hospitals or to speak directly with a DDMAC Reviewer, call 301-796-1200.

WHAT YOU CAN DO: RECOGNIZE & REPORT

RECOGNIZE

Be aware of the many advertisements and promotions that you see every day.

REPORT

Help FDA stop violations by reporting activities and messages that you consider false or misleading.

Phone: 877-RX-DDMAC (877-793-3622)

E-Mail: BadAd@fda.gov

Write: FDA/CDER/DDMAC
5901-B Ammendale Rd.
Beltsville, MD 20705-1266

Fax: 301-847-8444

April 2010

DDMAC

A message from the U.S. Food and Drug Administration's Division of Drug Marketing, Advertising, and Communications

TRUTHFUL PRESCRIPTION DRUG ADVERTISING AND PROMOTION:

THE PRESCRIBER'S ROLE

Help the FDA ensure that prescription drug advertising and promotion is truthful and not misleading.

U.S. Department of Health and Human Services

U.S. Food and Drug Administration

TRUTHFUL PRESCRIPTION DRUG ADVERTISING AND PROMOTION:

THE PRESCRIBER'S ROLE -- RECOGNIZE AND REPORT

The prescriber can play an important role in ensuring that prescription drug advertising and promotion is truthful by recognizing and reporting misleading drug advertising and promotion.

DDMAC's Mission

FDA's Division of Drug Marketing, Advertising, and Communications is responsible for ensuring truthful advertising and promotion of prescription drugs. Our mission is to…

- Protect the public health by assuring prescription drug information is truthful, balanced, and accurately communicated.
- Guard against false and misleading advertising and promotion through comprehensive surveillance, enforcement, and educational programs.

Prescription drug advertising must:

- Be accurate
- Balance the risk and benefit information
- Be consistent with the prescribing information approved by FDA
- Only include information that is supported by strong evidence from clinical studies

What types of promotion does DDMAC regulate?

- Sales representative presentations
- Speaker program presentations
- TV and radio advertisements
- All written or printed drug promotional materials

DDMAC does not regulate promotion of:

- Over-the-Counter Drugs
- Dietary Supplements
- Medical Devices

Common Violations:

- Omitting or downplaying of risk
- Overstating the effectiveness
- Promoting off-label, or unapproved, uses
- Misleading drug comparisons

EXAMPLES OF VIOLATIONS

Example of Omission of Risk

You attend a speaker program which features a slide show that presents efficacy information about Drug X, but no risk information.

This presentation would be misleading because it fails to include a fair balance of benefit and risk information for Drug X.

Example of Unapproved Use

You are in a commercial exhibit hall and a company representative tells you that a drug is effective for a use that is not in the FDA-approved product labeling.

This presentation would be illegal because it promotes an off-label use.

Example of Overstating the Effectiveness

"Doctor Smith, Drug X delivers rapid results in as little as 3 days."

This presentation is misleading because the majority of patients studied in the clinical trials for Drug X showed results at 12 weeks, with only very few showing results in 3 days.