

Report Misleading Rx Drug Promotion



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.



Prescription drug advertising must:

- Be accurate
- Balance the risk and benefit information
- Be consistent with the prescribing information (PI) approved by FDA
- Only include information that is supported by substantial evidence or substantial clinical experience

What types of prescription drug promotion does the Office of Prescription Drug Promotion (OPDP) monitor?

- All written or printed drug promotional materials
- TV and radio advertisements
- Sales representative or company-sponsored speaker presentations

OPDP does not regulate promotion of:

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

Common Issues:

- Omitting or downplaying of risk
- Overstating the effectiveness
- Promoting uses not addressed in FDA-approved PI
- Misleading drug comparisons

EXAMPLES OF PROMOTIONAL ISSUES

Example of Omission of Risk

You attend a company-sponsored 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 Promoting Use Not Addressed in FDA-Approved PI

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 PI.

This presentation may be used as evidence to establish that the drug is intended for a use that is not approved and for which the adequate directions for safe and effective use are not provided in the FDA-approved PI.

Example of Overstating the Effectiveness

You see a journal ad that states, "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.

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 OPDP 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 OPDP?

The information you provide will be sent to a Regulatory Review Officer in OPDP 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 OPDP in-service training for large medical group/hospitals or to speak directly with a OPDP Reviewer, call 301-796-1200.

REPORT

Be aware of the many advertisements and promotions that you see every day. Help FDA stop false or misleading promotion by reporting any issues that are concerning to you.

Phone: 855-RX-BADAD (855-792-2323)

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