Prescription Drug Advertising: Questions and Answers

These are some frequently asked questions about direct-to-consumer (DTC) advertising. FDA requirements, as well as activities of the Office of Prescription Drug Promotion (OPDP), are shown in this section. Contact us if you have any additional questions.

- Does the FDA control advertisements for all drugs?
- Does the FDA review and approve all advertisements for drugs before their release?
- Does Federal law ban ads for drugs that have serious risks?
- Does the FDA require drug companies to use hard-to-understand medical language in ads directed to consumers?
- Can the FDA limit the amount of money spent on prescription drug ads?
- Does the FDA work with drug companies to create prescription drug ads?
- Does the FDA approve ads for prescription drugs before they are seen by the public?
- What must product claim ads tell you?
- What are ads not required to tell you?
- How do the “brief summary,” “prescribing information,” “major statement,” and “adequate provision” differ?
- Does the law say anything about the design of ads for prescription drugs?
- Has FDA done research on DTC advertising?
- How can an ad violate the law?
- Who should I tell if I think that a prescription drug ad violates the law?
- What does FDA do if it determines that an ad violates the law?
- How can I learn more about a medical condition or a drug?

Does the FDA control advertisements for all drugs?
- No. The FDA does not oversee the advertising of over-the-counter (OTC) drugs. The Federal Trade Commission (FTC) is responsible for regulating OTC drug ads. The FDA regulates advertising only for prescription drugs. We also oversee the advertising for certain kinds of medical devices, such as hearing aids, the lasers used in LASIK procedures, and contact lenses.

Does the FDA review and approve all advertisements for drugs before their release?
- No. In most cases, federal law does not allow the FDA to require that drug companies submit ads for approval before the ads are used. We see many ads at about the same time the public sees them. Many drug companies voluntarily seek advice from us before they release TV ads. However, if we believe that an ad violates the law, we send a letter to the drug company asking that the ads be stopped right away.
effects. However, companies cannot use reminder ads\(^2\) for drugs with certain serious risks (drugs with "boxed warnings"\(^3\)).

**Does the FDA require drug companies to use hard-to-understand medical language in ads directed to consumers?**

- No. We encourage drug companies to use language that is clear and understandable to the general public. The law requires that all risks be communicated. However, it is sometimes difficult to express scientific and medical language in simpler terms without changing the meaning.

**Can the FDA limit the amount of money spent on prescription drug ads?**

- No. We do not have any authority to affect the amount of money drug companies spend on ads.

**Does the FDA work with drug companies to create prescription drug ads?**

- We do not help create any prescription drug ads. Drug companies create these ads themselves, often with help from advertising agencies.

**Does the FDA approve ads for prescription drugs before they are seen by the public?**

- No, generally we do not. Except in unusual instances, we cannot require drug companies to submit ads for approval before they are used. Drug companies must only submit their ads to us when they first appear in public. This rule is the same whether the ads are aimed toward healthcare providers or consumers. This means that the public may see ads that violate the law before we can stop the ad from appearing or seek corrections to the ad. Consumers should know that they may not necessarily be able to tell whether any specific DTC ad includes false or misleading information.

**What must product claim ads tell you?**

- At least one approved use for the drug
- The generic\(^4\) name of the drug
- All the risks of using the drug
  - Under certain circumstances, ads can give only the most important risks
  - For more detail, see brief summary\(^5\) and adequate provision\(^6\)

**What are ads not required to tell you?**

- Cost
- If there is a generic\(^7\) version of the drug (a drug with the same active ingredient that might be cheaper)
- If there is a similar drug with fewer or different risks that can treat the condition
- If changes in your behavior could help your condition (such as diet and exercise)
  - Sometimes this information is required. It depends on the prescribing information for the particular drug
- How many people have the condition the drug treats
- How the drug works (its "mechanism of action")
- How quickly the drug works
  - However, if the ad claims that the drug works quickly, the ad must explain what "quickly" means
- How many people who take the drug will be helped by it
How do the "brief summary," "prescribing information," "major statement," and "adequate provision" differ?

- These terms refer to different rules for how risk information must be included with materials that advertise prescription drugs. We require different types of benefit and risk disclosures for different types of promotions.
- "Prescribing information" includes the most complete information about a prescription drug. It includes technical information about the chemistry of the drug, its proper use overall and in specific types of patients, and details about possible side effects. It is written for healthcare providers. When we approve a drug for marketing, we also approve the prescribing information.
- The "brief summary" includes all the risk information about a prescription drug and is generally based on the prescribing information. The brief summary may leave out non-risk information, such as the chemical description of the drug, how it works in the body, and directions for using it. For DTC ads, we recommend that brief summaries be written in language that consumers can understand.
- A "major statement" is required only for broadcast (TV, radio and telephone) ads. It consists of the drug's most important risks. The major statement must be presented in a clear, conspicuous, and neutral manner. The risks are generally similar to the risks required for "fair balance" in print ads.
- "Adequate provision" applies only to broadcast ads. Broadcast ads must include either the "brief summary" or make "adequate provision" for the audience to find the drug's prescribing information. This requirement can be met by offering a variety of sources, including a healthcare provider, a toll-free telephone number, the current issue of a magazine containing a print ad for the drug, and a Web site address.

Does the law say anything about the design of ads for prescription drugs?

- Yes. The layout of an ad — the way information is presented — can affect whether an ad meets the fair balance requirement. For example, ads must present side effect information in a manner similar to that used for the benefit information. Various ways of presenting information that can affect fair balance include type size, bulleting, amount of white space, and headlines.

Has FDA done research on DTC advertising?

- Yes. The Office of Prescription Drug Promotion (OPDP) of the FDA's Center for Drug Evaluation and Research (CDER) conducts research on direct-to-consumer (DTC) advertising. This includes telephone surveys of DTC-related patient and physician attitudes and behaviors. This research helps OPDP make decisions about DTC advertisements. For more about the research conducted by OPDP, go to OPDP Research.

How can an ad violate the law?

- These are a number of ways in which an ad may violate the law. For example, the ad could:
  - State or imply that the drug can treat a condition when the FDA has not approved the drug for such use
  - Make claims that are not supported by adequate evidence
  - Misrepresent data from studies
  - Overstate the drug's benefits
  - Suggest that the drug can be used in patients with specific characteristics when the drug hasn't been shown to work or to be safe in such patients
  - Leave out or downplay risk information
  - Fail to present a "fair balance" of information relating to the drug's risks and benefits (required for "product claim ads" and "promotional labeling")
  - Leave out a "brief summary" (required for "product claim ads")
  - Fail to attach the drug's prescribing information (required for "promotional labeling")
  - Fail to include sources to help the audience find the "prescribing information" for the drug (for product claim ads on TV, radio, or by telephone)
Who should I tell if I think that a prescription drug ad violates the law?

- Contact FDA's Office of Prescription Drug Promotion (OPDP) about prescription drug ads you believe violate the law by being false, misleading, or lacking in "fair balance". Consumers can call OPDP at 301-796-1200. Or, consumers may submit their complaint in written form to OPDP at:

  Food and Drug Administration  
  Center for Drug Evaluation and Research  
  Office of Prescription Drug Promotion  
  5901-B Ammendale Road  
  Beltsville, MD 20705-1266

What does FDA do if it determines that an ad violates the law?

- We have different ways to enforce the laws that apply to advertisements for prescription drugs. The simplest and most common way is to send a letter to the drug company. The letter explains how the ad has violated the law. It generally asks the drug company to remove the ad and stop the unlawful behavior.
- In some cases, we will ask the drug company to fix the misimpression made by the violative ad. The fix could include publishing a corrective ad. We are most likely to take this action when the misimpression poses a serious threat to public health.
- We post the enforcement letters issued by OPDP on the Warning Letters web page.
- Sometimes we take additional enforcement action. This may include taking drug companies to court and even taking ("seizing") supplies of the drug. Court actions can include asking for an injunction (court-enforced ban of specific activities) and bringing criminal charges against the drug company.

How can I learn more about a medical condition or a drug?

- Browse Information for Consumers (Drugs) for links to information on medical conditions. Or, use Drugs@FDA to search for specific brand and generic drugs.
- To find out if a medical condition is something you should be concerned about or if a particular drug is right for you, talk with your doctor or other healthcare provider.

Note: This website does not purport to set forth all the ways in which an ad may violate the law, but rather to explain to the public some of the basic concepts related to drug advertising.

This site was developed as a collaborative effort between FDA and EthicAd to educate consumers about DTC prescription drug advertisements.