

## Drug Advertising: Understanding the Regulatory Framework

### Lay of the Land: Key Points of FDA's Scope

- FDA has authority over direct-to-consumer (DTC) ads for **prescription drug products**. The FTC regulates DTC ads for over-the-counter drug products.
- FDA delineates three kinds of regulated DTC prescription drug ads:
  - **Product claim ads** name **a drug** and **what it treats**
  - **Help-seeking ads** describe **a disease or condition** but do not name a drug
  - **Reminder ads** name **a drug** but do not describe the drug's use
- Product claim ads must be **truthful, not misleading or deceptive**, and present information on risks in a **clear, conspicuous, and neutral manner**.
- **FDA's enforcement authorities** include warning letters, product seizures, marketing disapproval, and criminal penalties.

### FDA's Regulatory Authorities

FDA's regulatory authority stems from Section 502(n) of the **Federal Food, Drug, and Cosmetic Act (FDCA)** and the implementing regulations at 21 CFR 202.1.

Other Guidance Documents and Rules:

- Final Guidance on Consumer-Directed Broadcast Advertisements, 1999
- Final Guidance on Presenting Efficacy and Risk Information in Promotional Communications, 2023
- Final Rule on "Clear, Conspicuous, and Neutral" Major Statements in Broadcast Advertisements, 2023



Starting in September 2025, FDA laid out short- and long-term actions it will take to more closely regulate DTC ads:

- Pursue "**aggressive**" enforcement of DTC prescription drug advertising violations
- Propose rulemaking to close what it characterizes as a "**loophole**" related to the **adequate provision** of risk information in broadcast ads
- Expand oversight to include **social media** promotional activity

## Drug Advertising: FDA's Recent Activity

### Addressing “False and Misleading” Advertisements for Approved and Compounded Drugs

In September 2025, FDA sent **warning letters** to drugmakers, online pharmacies, compounders, and telehealth providers detailing advertisements the agency considered “**false and misleading**” or to be marketing “**misbranded or unapproved**” products due to:

- omission of fact
- overstating of efficacy
- distracting audio, visuals, or design elements in ads
- claiming equivalence of FDA approval (for compounded drugs)

In March 2026, FDA sent **30 additional letters to telehealth companies** selling compounded GLP-1s regarding “false or misleading” marketing advertisements.

**These actions rely on existing FDA authorities and enforcement tools.**

### Rulemaking on the “Adequate Provision” of Safety and Risk Information in DTC Ads

In September 2025, FDA announced actions to “crack down” on DTC advertising, including **pursuing rulemaking to close the “adequate provision loophole.”**

#### *Adequate Provision Explained*

In 1997, FDA determined **product claim ads on broadcast media** could avoid listing a brief summary of the drug’s side effects, contraindications, and effectiveness by including a shorter “major statement” of risks and by including **adequate provision** of the complete labeling information to the audience, for example on a website or by directing viewers to talk to a health care provider.

**FDA must propose a new rule to change the adequate provision standard.**