



September 9, 2025

Dear Pharmaceutical Company,

For far too long, FDA has permitted misleading direct-to-consumer (DTC) prescription drug advertising. Today, FDA is taking action to rein in violative ads. Going forward, FDA intends to take aggressive action and ensure conformity with the law.

You are hereby directed to remove any noncompliant advertising and bring all promotional communications into compliance.

DTC advertising can distort the patient-clinician relationship and create increased demand for medications regardless of clinical appropriateness. Violative ads can also fundamentally alter patients' risk-benefit perception.

FDA is concerned patients are not seeing a fair balance of the information regarding a drug product. This concern is magnified when serious risks are not clearly presented, or the information is too difficult for seniors to read or hear.

We also live in a new era of social media. An increasing reliance on digital and social media channels, including undisclosed influencer promotion, has blurred the lines among editorial content, user-generated media, and pharmaceutical advertising, making it increasingly difficult for patients to distinguish between evidence-based information and promotional material.

On social media platforms, deceptive advertising is sadly the current norm. A 2024 review in the Journal of Pharmaceutical Health Services Research reveals that while 100% of pharmaceutical social media posts highlight drug benefits, only 33% mention potential harms. Moreover 88% of advertisements for top-selling drugs are posted by individuals and organizations that fail to adhere to FDA "fair balance" guidelines.

The stakes surrounding prescription drug ads are extremely high. While these communications can raise awareness of disease states and beneficial therapies, they must also disclose important risks and limitations. Current law requires fair balance between effectiveness information and side effects/contraindications—requirements that are regularly ignored. FDA will no longer tolerate such deceptive practices.

We are issuing this letter to provide notice to all application holders. This notice also serves to demand compliance with the FD&C Act and FDA implementing regulations and requires companies to remove any and all DTC prescription drug advertising that violates the law.



We appreciate your attention to this significant public health issue.

Sincerely,

Martin A. Makary, M.D., M.P.H.
Commissioner of Food and Drugs