U.S. FOOD & DRUG ADMINISTRATION

September 16, 2025

Humayun J. Chaudhry, DO, MS, FACP, FACOI
President and Chief Executive Officer
Federation of State Medical Boards
400 Fuller Wiser Road, Suite 300
Euless, TX 76309
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Dear Dr. Chaudhry:

The purpose of this letter is to bring to the attention of the Federation of State Medical Boards information related to the increasing prevalence of providers and patients receiving compounded drug products through third parties (e.g., telehealth platforms, marketing firms, or operators of websites that are not pharmacies or outsourcing facilities) and FDA's recent actions in this area.

FDA is aware of increased consumer interest in, and interaction with, third parties to easily obtain drug products for treatment of certain medical issues or conditions. Third parties may provide consumers with connections to affiliated medical providers who prescribe drug products. These third parties then appear to use compounding pharmacies or FDA-registered outsourcing facilities to fill patients' prescriptions with compounded drug products.[1]

FDA understands that obtaining certain products through third parties is a growing health management tool and may provide greater access to care and/or prescription customization for some patients. However, use of these third parties may produce a limited or short-term relationship between patients, providers, and compounders. Such limited or short-term relationships may affect a patient's ability to receive comprehensive and coordinated medical care. Furthermore, FDA has received adverse event reports and complaints concerning drug products obtained through third parties although patients who are receiving the drugs may not be aware that they are using compounded drug products or of the risks of such drug products.

The limited or short-term relationship with providers and pharmacists fostered by some of these third parties raises other risks as well. For instance, some information found online may not be accurate or may omit risk information and basing medical decisions on misinformation can lead patients to seek treatments that are not safe and effective, or to forgo treatments that are, which can have adverse consequences.

[1] Compounded drugs can serve an important role for patients whose medical needs cannot be met by an FDA-approved drug product. However, these drugs present a higher risk to patients than approved drugs. Compounded drugs are not FDA-approved and have not been reviewed by the Agency for safety, effectiveness, or quality before they are marketed. Because compounded drugs are subject to a lower regulatory standard than approved drugs, patients should not receive them unless an approved drug does not meet their medical needs.

Consistent with the concerns noted above, FDA is taking steps to address conduct of third parties that may be inconsistent with provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act), such as the prohibition on introducing or delivering for introduction into interstate commerce unapproved new and misbranded drugs, and the prohibition on false or misleading labeling, promotion, or advertising.[2] On September 9, 2025, FDA issued Warning Letters to 58 third parties[3] that offer drug products through their websites, including some involving unapproved new and misbranded drugs (such as retatrutide).[4] The third parties also made claims concerning compounded drug products that are false or misleading under sections 502(a) and 502(bb) of the FD&C Act. Under section 502(a) of the FD&C Act, a drug is misbranded if its labeling is false or misleading in any particular. Furthermore, under section 502(bb) of the FD&C Act, a compounded drug is misbranded if its advertising or promotion is false or misleading in any particular.

We encourage you to share the information in this letter with your members and encourage state boards of medicine to be aware of these activities and provide any relevant information to the FDA. We look forward to continuing to work with you on matters related to drug compounding. If you have questions or wish to submit any relevant information, please contact the Office of Compounding Quality and Compliance at compounding@fda.hhs.gov.

We are also sending this letter to the National Association of Boards of Pharmacy and National Council of State Boards of Nursing to facilitate communication among associations with shared goals regarding these matters.

Sincerely,

Frances G. Bormel -S

Digitally signed by Frances G. Bormel -S
Date: 2025.09.16 14:30:38 -04'00'

F. Gail Bormel, RPh, JD
Director
Office of Compounding Quality and Compliance
Center for Drug Evaluation and Research

[2] See sections 301(a) and 301(d) of the FD&C Act.
[3] See U.S. Food and Drug Administration, Warning Letters (searchable listing of FDA's issued Warning Letters), available at: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters.
[4] See "FDA Launches Crackdown on Deceptive Drug Advertising" (September 9, 2025), available at: https://www.fda.gov/news-events/press-announcements/fda-launches-crackdown-deceptive-drug-advertising.