

## Unapproved Cough, Cold, Allergy Products: FDA Prompts Removal From Market

**AUDIENCE:** Consumer, Family Practice, Pharmacy

**ISSUE:** FDA announced that it intends to remove certain unapproved prescription cough, cold, and allergy drug products from the U.S. market. Unapproved prescription cough, cold, and allergy drug products have not been evaluated by the FDA for safety, effectiveness, and quality. People may be at greater risk when using these products than when using FDA-approved prescription drugs or drugs that are appropriately marketed over-the-counter (OTC).

Many health care providers are unaware of the unapproved status of drugs and have continued to unknowingly prescribe them because the drugs' labels do not disclose that they lack FDA approval.

**BACKGROUND:** Cough, cold, and allergy drug products are used to relieve symptoms associated with the common cold or upper respiratory allergies. These symptoms may include coughing, chest congestion, nasal congestion, itchy eyes, and sneezing. Some cough, cold, and allergy products may be purchased over the counter (OTC), while others require a prescription. See link below for a list of the unapproved prescription cough, cold, and allergy drug products FDA intends to remove from the market.

**RECOMMENDATION:** Consumers who believe they are taking an unapproved prescription cough, cold, or allergy product should contact their health care provider to discuss alternatives.

Healthcare professionals and patients are encouraged to report adverse events, side effects, or product quality problems related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

Complete and submit the report Online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)

[Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch safety alert, including links to the News Release, Q&As, and List of Unapproved Prescription Cough, Cold, and Allergy Products at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm245279.htm>

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**You are encouraged to report all serious adverse events and product quality problems to FDA MedWatch at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)**