

FOR IMMEDIATE RELEASE

March 2, 2011

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AAAAI Explains Distinction of Unapproved Drugs and the Components of These Products

MILWAUKEE—As the U.S. Food and Drug Administration announced today that they are requiring the removal of unapproved prescription cold, oral cough and allergy products from the market, the American Academy of Allergy, Asthma & Immunology (AAAAI) recommends that physicians and patients only use FDA approved drugs. There are many alternative FDA-approved products that can be prescribed to treat cough and allergies.

“In light of the FDA announcement, it is important to make a distinction between these unapproved drugs and the individual components within the drugs,” explains AAAAI Executive Vice President Thomas B. Casale, MD, FAAAAI. “Many of the components can be obtained over-the-counter or by prescription and are approved by the FDA. However, the listed drugs for removal have not proven safe and effective by adequately approved FDA studies. Furthermore, some combination of the components contained in these drugs could result in adverse effects.”

For example, some of these non-approved drugs have been on the market for years and contain first generation/sedating antihistamines. Newer, non-sedating antihistamines carry fewer side effects. Many of the decongestants, expectorants and cough suppressives in the unapproved drugs have little to no data to support their efficacy, and in some cases, have the potential for abuse.

Patients who have concerns about the drugs they are using should contact their physicians.

An allergist/immunologist has specialized training and experience to effectively and safely diagnose and treat allergies, asthma and immunodeficiency diseases. By visiting the office of an allergist, you can expect an accurate diagnosis, a safe and appropriate treatment plan that works and educational information to help you manage your disease.

Find an [allergist/immunologist](#) in your area with the AAAAI Physician Referral Directory at www.aaaai.org/physref.

Visit www.aaaai.org for more resources and expert advice from allergists.

The [AAAAI](#) represents allergists, asthma specialists, clinical immunologists, allied health professionals and others with a special interest in the research and treatment of allergic and immunologic diseases. Established in 1943, the AAAAI has nearly 6,500 members in the United States, Canada and 60 other countries.

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The complete list of affected drugs and the FDA announcement are available online with the following links:

- [Unapproved Prescription Cough, Cold, and Allergy Products Federal Register Notice](#)
- [List of Unapproved Prescription Cough, Cold, and Allergy Drug Products Affected by Today's Action, Based on Firm's Listing with FDA](#)
- [Unapproved Drugs Enforcement Actions \(By Drug Class\)](#)