ALERTS AND UPDATES

FDA Removes More Than 500 Unapproved Prescription Cough, Cold and Allergy Drug Products from the U.S. Market

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The U.S. Food and Drug Administration (FDA) announced in the *Federal Register* on March 3, 2011, that it will remove unapproved prescription cough, cold and allergy medications from the market as part of its ongoing Unapproved Drugs Initiative to stop the sale of drugs that do not meet current standards.

Prior to the FDA's Unapproved Drugs Initiative, a company could market an unapproved drug if the drug product predated legislation requiring evidence of safety and effectiveness. Affected companies that have already registered their products with the FDA, but which the FDA has not approved, must stop manufacturing the drugs by June 1, 2011—and stop shipping the unapproved products by August 30, 2011. Companies that have not yet registered their products with the FDA are required to stop manufacturing and shipping them immediately.

More than 500 medications are involved in the FDA's latest enforcement action. The affected products fall into three categories: products in extended-release form, products that contain active ingredients that are in tannate salt form (*e.g.*, phenylephrine tannate) and certain immediate-release products. The FDA is removing these products from the market because it believes they pose an untenable risk to consumers. Specifically, the FDA noted its belief that some drugs were inappropriately labeled for use in infants and children; some products may be manufactured incorrectly and could lead to inappropriately large or ineffective dosages; and some products have potentially risky combinations of ingredients.

The FDA found that many healthcare providers were unaware of the unapproved status of these products and have unknowingly prescribed them because the drugs' labels do not disclose they are not FDA-approved. "Removing these unapproved products from the market will reduce potential risks to consumers," Deborah Autor, director of the Office of Compliance at the FDA's Center for Drug Evaluation and Research, said in a written statement. A complete list of products is available on the FDA website.

For Further Information

If you have any questions about this *Alert*, please contact Frederick (Rick) R. Ball, any member of the Pharmaceutical, Pharmacy & Food industry group or the attorney in the firm with whom you are regularly in contact.