

## FDA's MedWatch Safety Alerts: May 2011

### Recall: Dietary Supplements Due to Misleading Packaging

Dietary supplements distributed by two companies have been recalled because misleading packaging causes confusion in consumers who mistake them for similarly packaged antibiotics:

- Pentrexyl Forte Natural, distributed by Phoenix Import & Distribution LLC, packaged in a green and white box, containing 30 red and white capsules. The product was sold through retail stores in Texas.
- [Certain dietary supplements](#) by Multi-Mex Distributor Inc. that may be labeled as antibiotic drugs, which they are not. An FDA inspection revealed the packaging resembles packages containing antibiotics readily available in Mexico and possibly familiar to Hispanic consumers. The packaging appeared to be an intentional marketing ploy. The products were distributed in Georgia, Tennessee, California, Illinois, Texas, North Carolina, South Carolina, Colorado, and Indianapolis.

**Risk:** Use of these products by people who are sick could delay legitimate treatment for serious illnesses. Four children were taken to a medical center due to worsening illnesses after being given the Multi-Mex dietary supplement Amoxilina, which the parents may have believed was the antibiotic amoxicillin.

### Recommendations

- Do not use Pentrexyl Forte Natural or any of the recalled products from Multi-Mex Distributor. Return them to the place where you bought them for a full refund.
- Call 678-226-1758 if you have questions about the Multi-Mex products. Call 281-288-9838 if you have questions about the Phoenix product, Pentrexyl Forte Natural

### Recall: Unapproved Drugs Sold as Dietary Supplements

Two products sold as dietary supplements contain drugs that are not declared on the label:

- Slim Xtreme Herbal Slimming Capsule, sold 30 capsules per bottle, distributed by Globe All Wellness. All lots are recalled. The product was marketed for weight loss and sold nationwide through the Internet and at the company's headquarters in Hollywood, Fla.
- Regenerect, by Ethos Environmental Inc., lot number 100521 (blue capsule sold individually in foil packets, expires 5/2012) and lot number 112850 (clear capsule sold individually in foil packets, expires 11/2013). Regenerect was sold in the U.S. and Puerto Rico through the Internet.

Slim Xtreme Herbal Slimming Capsule contains the controlled substance sibutramine, which was withdrawn from the U.S. market in October 2010 for safety reasons. Regenerect contains a compound (sulfoildenafil) of an active ingredient in an FDA-approved drug used to treat erectile dysfunction.

**Risk:** Sibutramine (found in Slim Xtreme) is known to substantially increase blood pressure or pulse rate in some people—especially those with a history of heart disease or stroke. This product may also interact in life-threatening ways with other medications a person may be

taking. Sulfoildenafil (found in Regenerect) may interact with prescription drugs known as nitrates, including nitroglycerin, and cause dangerously low blood pressure. People with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates.

### **Recommendations**

- Do not use Slim Xtreme, or Regenerect lot numbers 100521 and 112850.
- If you have used either of these products and have any negative side effects, call your health care professional as soon as possible.
- If you have questions about Slim Xtreme or need instructions for returning the product, call 954-922-1133 Monday through Friday from 9 a.m. to 4 p.m. Eastern Standard Time.
- If you have questions about Regenerect or need instructions for returning the product, call 866-925-9553 Monday through Friday from 6 a.m. to 6 p.m. Pacific Time.