Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

**DATE:** May 9, 2013

**TO:** All Local Health Departments
Attn: Chief Food Inspection Officer

**FROM:** A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

**SUBJECT:** Xymogen Recall

**SUGGESTED ACTION:** **Unclassified Recall; Artriphen is being recalled because it contains traces of the undeclared allergens soy and milk. Although there have been no reported allergic reactions or any adverse events in connection with the product to date, consumers are urged to return this product for a full refund.**

**Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-8569.**

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## Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

## XYMOGEN identifies allergen oversight by third-party manufacturer; issues recall of artriphen™

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**FOR IMMEDIATE RELEASE** - May 1, 2013 - Nutraceutical company XYMOGEN in Orlando, Fla., is recalling artriphen, a product recommended for the support of healthy joint function, because it contains traces of the undeclared allergens soy and milk.

People who have an allergy or severe sensitivity to either allergen run the risk of serious or life-threatening allergic reaction if they consume this product. Although there have been no reported allergic reactions or any adverse events in connection with the product to date, consumers are urged to return this product for a full refund.

XYMOGEN learned that artriphen might contain the two allergens and immediately discontinued sale of the product. XYMOGEN then had a third-party laboratory test the product to confirm the presence of the allergens.

"In the past, our contract manufacturing partners applied labels to our products, thus the weight of responsibility on what allergens were or were not declared rested with them as the party handling the raw materials," said Brian Blackburn, XYMOGEN'S president and CEO. "Making the big leap of taking on your own manufacturing dramatically shifts the weight. As a result, we have been, since day one, stringently verifying the presence or absence of allergens in raw materials we purchase, along with bulk items or finished products received from third-party manufacturers, as part of our due diligence to ensure product safety and compliance with U.S. Food and Drug Administration regulations."

XYMOGEN discovered the allergens were not included in the product's labeling while preparing to buy artriphen in bulk and then label and package it for the first time at its new 136,000-square-foot manufacturing facility and headquarters in Orlando.

"We were afraid the manufacturer had been fraudulently labeling the product after we received from them our mandatory allergen checklist, indicating both allergens as present in the formula," Blackburn said. "After questioning them on this discovery, we were able to confirm this was the case and that we had been dealing with a company that was clearly incompetent of segregating allergenic raw materials and communicating their presence in customer's formulas. If it were not for XYMOGEN's experienced and diligent team members that handle these processes, and our overall team's commitment to the utmost quality, this serious error may have remained undiscovered."

The U.S. Food and Drug Administration's (FDA) regulations on dietary manufacturing, packaging and distribution require manufactures to disclose any of eight identified allergens in the labeling and marketing of products.

In addition to discontinuing the sale of artriphen, XYMOGEN is phasing out two other products, coolsens™ and dolorox™, provided by the same company, neither of which has any known safety concerns.

artriphen was available in quantities of either 90 or 180 capsules.

## About XYMOGEN

XYMOGEN, a family-owned, health sciences company with headquarters in Orlando, Fla., has been providing high-quality dietary supplements to licensed health care practitioners for more than a quarter century.

The nutraceutical company has introduced numerous innovations to the functional medicine community; its Medical Board of Advisors consists of clinical practitioners who represent a broad range of specialties.

XYMOGEN's strength as a company was reinforced in 2007, 2008, 2010, 2011 and 2012 when it was recognized by Inc. Magazine as one of the 5,000 fastest-growing private companies in America.

The company's 136,000-square-foot manufacturing facility is GMP (good manufacturing practices) and GMP for Sport Athletic Banned Substances Program registered by NSF International.

More information is available at www.xymogen.com

Please email pr@xymogen.com for comments or inquiries.

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Photo: Product Labels[3]

Recalled Product Photos Are Also Available on FDA's Flickr Photostream.[4]

**XYMOGEN identifies allergen oversight by third-party manufacturer; issues recall of artriphen™**
**Photos**