



Michael R. Pence  
Governor

William C. VanNess II, MD  
State Health Commissioner

**DATE:** May 10, 2013  
**TO:** All Local Health Departments  
Attn: Chief Food Inspection Officer  
**FROM:** A. Scott Gilliam, MBA, CP-FS  
Director, Food Protection Program  
**SUBJECT:** Pure Herbs Ltd. Recall

**SUGGESTED ACTION:** Unclassified Recall; 4oz and 1oz bottles of Protein Extract because they contain undeclared allergens - milk and soy; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the recalled products were distributed in the State of Indiana. The recalled products were shipped to distributors nationwide. The products reached consumers through mail orders, direct delivery or retail stores. Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-8475.

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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.

### Pure Herbs Ltd. Issues Allergy Recall Alert on Undeclared Allergens (Milk and Soy) in Protein Extract Urgent Undeclared Allergen Labeling Recall In Pure Herbs Ltd. Protein Extract

**Contact:**  
Consumer:  
586-446-8200

**FOR IMMEDIATE RELEASE** - May 6, 2013 - Today, Pure Herbs Ltd., Sterling Heights, MI is voluntarily recalling the 4oz and 1oz bottles of Protein Extract because they contain undeclared allergens - milk and soy. This labeling error was discovered during a routine Food and Drug Administration (FDA) inspection when a review of the ingredients found that milk and soy allergen ingredients were not listed on our main label. People who have an allergy or severe sensitivity to milk or soy run the risk of serious or life-threatening allergic reaction if they consume this product. There have been no illnesses reported to date in connection with this product. This product is a food safety concern only for people who are allergic to milk or soy. Customers with an allergy or sensitivity to milk or soy should not consume this product.

This product has been shipped to distributors nationwide. The product reached consumers through mail orders, direct delivery or retail stores.

The Protein extract product recalled was distributed prior to April 30, 2013. There are no expiration dates on the Protein extract. The Protein extract is packaged in 4oz and 1oz amber glass bottles with a Pure Herbs Ltd. Logo, Natural Herbal Extracts underneath the logo, and the name Protein on the front panel. This voluntary recall is limited to the Protein Extract packaged in 4oz and 1oz amber glass bottles. All lot numbers are included. Lot numbers 243 and 050812, represent batch 101310 which was manufactured on October 13, 2010 and was distributed from February 2012 to February 2013. Lot number 012712A was manufactured on January 27, 2012 and was distributed from March 2013 to April 2013. The lot numbers are printed on the bottom of the front panel to the right. No other Pure Herbs, Ltd. products are impacted.

Pure Herbs, Ltd. will work with Distributors to ensure that the recalled products are removed from their shelves. We ask that any un-used product be returned to be re-labeled. New labels have been printed that do declare these allergens and the product is currently being labeled utilizing this new label beginning May 3, 2013. In the event that consumers who are allergic to milk or soy have purchased the impacted product, they may return it to Pure Herbs for a full refund. Consumers who wish to return the product or have questions about this issue may call (586)446-8200 between the hours of 9:00 a.m. to 5:30 p.m. EST to speak with Dana Smith or Barb Jacobs, Monday thru Fri.

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[RSS Feed for FDA Recalls Information<sup>1</sup> \[what's this?\]<sup>2</sup>](#)

[Photo: Product Labels<sup>3</sup>](#)