



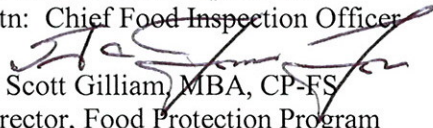
**Indiana State  
Department of Health**  
*An Equal Opportunity Employer*

**Mitchell E. Daniels, Jr.**  
*Governor*

**Gregory N. Larkin, M.D., F.A.A.F.P.**  
*State Health Commissioner*

**DATE:** September 6, 2011

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

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

**SUBJECT:** Pure Encapsulations Recall

**SUGGESTED**

**ACTION:** Unclassified Recall; PreNatal Nutrients lot number 3560111, because it may contain undeclared egg allergen; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the products being recalled were distributed in the State of Indiana. PreNatal Nutrients was distributed nationwide through healthcare practitioners. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.

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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 Encapsulations, Inc. Issues Allergy Alert On Undeclared Egg Allergen In Prenatal Nutrients**

**Contact:**  
Jean Gagnon, VP of Operations  
800-753-2277 x335  
jgagnon@purecaps.com

**FOR IMMEDIATE RELEASE** - August 31, 2011 - Pure Encapsulations of Sudbury, Massachusetts is voluntarily recalling PreNatal Nutrients lot number 3560111, because it may contain undeclared egg allergen. People who have an allergy or severe sensitivity to egg run the risk of serious or life-threatening allergic reaction if they consume these products.

PreNatal Nutrients is available as two-piece hard capsules in white HDPE plastic bottles in both 120 count (product code PRE12) as well as 60 count (PRE6) under the brand name Pure Encapsulations. The lot number and best by date are 3560111A or 3560111B best by date 01/13.

PreNatal Nutrients was distributed nationwide through healthcare practitioners.

One report of an allergic reaction in an individual has been confirmed to date.

The recall was initiated after a physician customer reported an allergic reaction by one of their patients. Immediately upon receipt of this report, Pure Encapsulations sent retention samples to an independent, 3rd party laboratory for testing of the top eight allergens. Results indicated the presence of egg allergen. Pure Encapsulations has on file Allergen Statements from each supplier of each of the ingredients used in the batch of this formulation. All Allergen Statements indicate that the ingredients do not contain any of the 8 major allergens including egg. Pure Encapsulations has sent reserve samples of each of the lots of the ingredients used in this batch, in addition to the empty capsules, for testing to determine which ingredient caused the positive result for egg allergen.

Consumers who have purchased Pure Encapsulations PreNatal Nutrients are urged to return it to the place of purchase for a full refund. Consumers with questions may contact Mr. Jean Gagnon, Vice President of Operations, at 1-800-753-2277 x335. Monday through Friday between 9:00 am – 5:00 pm.

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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>