



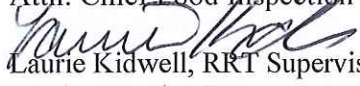
**Indiana State
Department of Health**
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: June 18, 2015

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

FROM: 
Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: **G & C Natural Nutrition, Inc. – RECALL [Drug]**

AFFECTED

PRODUCT: Pyrola, 430mg/capsule

SUMMARY: Undeclared Recall; The recall of the Advanced Joint Formula capsules may contain undeclared diclofenac and chlorpheniramine.

Diclofenac is a non-steroidal anti-inflammatory drug (commonly referred to as NSAIDs). NSAIDs may cause increased risk of cardiovascular events, such as heart attack and stroke, as well as serious gastrointestinal damage, including bleeding, ulceration, and fatal perforation of the stomach and intestines. Chlorpheniramine is an over-the-counter (OTC) antihistamine used for allergies. Antihistamines may cause drowsiness and affect mental alertness

SUGGESTED

ACTION: **For consumer inquiry only.** Consumers with questions regarding this recall can contact G&C Natural Nutrition, Inc. by 800-970-8198 or by email at contact@gcnatural.com during the hours of 9AM to 5PM Pacific Time, Monday through Friday. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

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.

**G&C Natural Nutrition, Inc. Issues Voluntary
Nationwide Recall of Pyrola Due to Undeclared
Drug Ingredients**



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To promote and provide
essential public health services.

Contact:

Consumer:

866-970-8198

Email: contact@gcnatural.com

FOR IMMEDIATE RELEASE — June 12, 2015 — Fullerton, CA — G&C Natural Nutrition, Inc. is voluntarily recalling all lots of Pyrola, 430mg/capsule. Advanced Joint Formula capsules may contain undeclared diclofenac and chlorpheniramine.

Diclofenac is a non-steroidal anti-inflammatory drug (commonly referred to as NSAIDs). NSAIDs may cause increased risk of cardiovascular events, such as heart attack and stroke, as well as serious gastrointestinal damage, including bleeding, ulceration, and fatal perforation of the stomach and intestines. Chlorpheniramine is an over-the-counter (OTC) antihistamine used for allergies. Antihistamines may cause drowsiness and affect mental alertness.

The product is packaged in a white bottle in capsule form, with all lots being recalled. The product was sold to distributors and consumers nationwide through phone orders and online from April, 2013 through June, 2015.

To date the company has received no reports of illnesses or adverse events associated with the consumption of the recalled product. G&C Natural Nutrition, Inc. will be contacting all distributors regarding this matter by phone calls and/or mail, and encourage them to stop distribution and return the product to the company for refund.

Consumers who may have purchased this product directly from G&C Natural Nutrition, Inc. should dispose it or return it to our office location by mail.

Consumers with questions regarding this recall can contact G&C Natural Nutrition, Inc. by 800-970-8198 or by email at contact@gcnatural.com during the hours of 9AM to 5PM Pacific Time, Monday through Friday. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: www.fda.gov/medwatch/report.htm¹
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm². Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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*G&C Natural Nutrition, Inc. Issues Voluntary Nationwide Recall of Pyrola Due to Undeclared Drug
Ingredients
Photo*



