



**Indiana State
Department of Health**
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: March 13, 2014

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

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

SUBJECT: Pain Free By Nature – RECALL [Drug]

**AFFECTED
PRODUCT:** "Reumofan Plus" Tablets

SUMMARY: Unclassified Recall; The recall is due to the product containing undeclared active pharmaceutical ingredients: methocarbamol and diclofenac.

This product comes in thirty (30) tablet containers and is packaged in a green and gold box.

"Reumofan Plus" Tablets are purchased through their website at www.painfreebynature.com and distributed nationwide through internet sales.

**SUGGESTED
ACTION:** For consumer inquiry only. Consumers with questions may contact the company at (719) 235-8864, Monday thru Friday, between 10:00 a.m. and 2:00p.m. MST.

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.

Pain Free by Nature is Voluntarily Recalling Reumofan Plus Tablets Due to Undeclared Drug Ingredients

Contact

Consumer:
719-235-8864

Media:
719-235-8864

FOR IMMEDIATE RELEASE - March 12, 2014 - Woodland Park, CO. Pain Free By Nature is recalling "Reumofan Plus" Tablets purchased through their website at www.painfreebynature.com, because they contain undeclared active pharmaceutical ingredients: methocarbamol and diclofenac. Use of this product could result in serious and life-threatening injuries.

Reumofan Plus is used as a treatment for muscle pain, arthritis, osteoporosis, bone cancer and other conditions. This product comes in thirty (30) tablet containers and is packaged in a green and gold box. Reumofan Plus was distributed nationwide through internet sales.

The recall was initiated after the US Food and Drug Administration discovered that the product was distributed in packaging that did not reveal the presence of the active pharmaceutical ingredients, making it an unapproved drug.

Pain Free By Nature did not manufacture the product but did distribute to customers nationwide. Distribution has been completely terminated by the company.

Consumers that have Reumofan Plus should be aware that the product may pose a serious health risk. Consumers who are taking these products or who have recently stopped taking Reumofan Plus should immediately consult a health care professional. Consumers who have purchased the thirty (30) tablet containers of Reumofan Plus are urged to return all unopened bottles to; Pain Free By Nature, LLC, Attn: Nilsen, 211 West 11th Street, Harper, KS, 67058. Refunds will be mailed immediately following processing.

Consumers with questions may contact the company at (719) 235-8864, Monday thru Friday, between 10:00 a.m. and 2:00p.m. MST.

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:** <http://www.fda.gov/MedWatch/report.htm>
- **Regular Mail:** use postage-paid, pre-addressed Form FDA 3500 available at: <http://www.fda.gov/MedWatch/getforms.htm>.
Mail to address on the pre-addressed form.
- **Fax:** 1-800-FDA-0178

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

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Photo**



