Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: February 19, 2013

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

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

SUBJECT: Reumofan Plus USA, LLC Recall

SUGGESTED ACTION: **Unclassified Recall; "Reumofan Plus" Tablets, Lot# 99515, exp. 09/16, because they contain undeclared active pharmaceutical ingredients: methocarbamol, dexamethasone, and diclofenac; Information is being provided in case of consumer inquiry.**

From the information provided by FDA, the recalled product may have been distributed in the State of Indiana. Reumofan Plus was distributed nationwide through internet sales.

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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.

Reumofan Plus USA, LLC & Reumofan USA, LLC is Voluntarily Recalling all lots of Reumofan Plus Tablets Due to Undeclared Drug Ingredients

Contact:
Consumer:
610-544-9761

Media:
Joseph Mclean
610-544-9761

FOR IMMEDIATE RELEASE - Feb. 15, 2013 - SPRINGFIELD, Pa., /PRNewswire/-- Reumofan Plus USA, LLC and Reumofan USA, LLC is recalling "Reumofan Plus" Tablets, Lot# 99515, exp. 09/16, because they contain undeclared active pharmaceutical ingredients: methocarbamol, dexamethasone, 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.

One illness has been reported to date in connection with this problem.

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

Distribution of the product has been completely terminated by Reumofan Plus USA, LLC and Reumofan USA.

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 them, to; Reumofan Plus USA, LLC & Reumofan USA, LLC, 737 Buttonwood Drive, Springfield, PA 19064, where they will be exchanged for a new all-natural supplement of herbs only. This product was independently lab-tested to contain only all-natural herbs.

Consumers with questions may contact the company at (610)544-9761, Monday thru Friday, between 10:00 a.m. and 2:00p.m. EST.

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[1]
- **Regular Mail**: use postage-paid, pre-addressed Form FDA 3500 available at: http://www.fda.gov/MedWatch/getforms.htm[2].
  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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