Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

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

DATE: August 28, 2012

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

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

SUBJECT: **Unclassified Recall; Samantha Lynn Inc.**

AFFECTED PRODUCT(S): **Reumofan Plus Tablets** Due to Undeclared Drug Ingredients

SUGGESTED ACTION: Information provided in case of consumer inquiry.

From the information provided by FDA, the products being recalled may have been distributed in the State of Indiana. The recalled products were distributed nationwide via the internet. Consumers with questions regarding this recall can contact Samantha Lynn Inc. by email to naturallifeandhealth@aol.com Monday - Friday between 8am to 5pm, Pacific Standard Time. Consumers should contact their physician or healthcare provider if they have any health questions or have experienced any problems that may be related to taking or using this product. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-351-7190.

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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.

Samantha Lynn Inc. Issues Voluntary Nationwide Recall of Reumofan Plus Tablets Due to Undeclared Drug Ingredients

Contact:
Consumer:
562-929-6994
naturallifeandhealth@aol.com

FOR IMMEDIATE RELEASE - August 24, 2012 - Samantha Lynn Inc. is voluntarily recalling 500 lots of Reumofan Plus Tablets to the consumer level due to findings of undeclared drug ingredients.

The Food and Drug Administration (FDA) sample analysis has found the product to contain methocarbamol and diclofenac. Use of this product could result in life-threatening hypersensitivity reactions and anaphylaxis and could cause a temporary and reversible increase in CNS depression. Samantha Lynn Inc. has not received any reports of adverse events related to this recall.

The product is used as a treatment for muscle pain, arthritis, osteoporosis, bone cancer and other conditions. The affected Reumofan Plus lots may include the following lot number(s): 99515 ex096 and expires: 2016. **The product is marketed in a green bottle containing 30 lavender round tablets and is distributed nationwide via the internet.**

If you purchased Reumofan Plus from Samantha Lynn Inc. between Feb 2012 and June 2012, you will receive an email shortly notifying you of your options. If you purchased Reumofan Plus from elsewhere, DO NOT CONTACT Samantha Lynn Inc. Contact your local FDA office. Consumers that have Reumofan Plus should be aware that the product may pose a health risk and are advised to consult their family doctor/stop using/return to place of purchase or discard.

Consumers with questions regarding this recall can contact Samantha Lynn Inc. by email to naturallifeandhealth@aol.com Monday - Friday between 8am to 5pm, Pacific Standard Time. Consumers should contact their physician or healthcare provider if they have any health questions or have experienced any problems that may be related to taking or using this 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**: http://www.fda.gov/MedWatch/report.htm[11]
- **Regular Mail**: use postage-paid, pre-addressed Form FDA 3500 available at: http://www.fda.gov/MedWatch/getforms.htm[22].
  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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