Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: January 15, 2014

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

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

SUBJECT: Human Science Foundation [Drug]

AFFECTED PRODUCT: **All lots of Pro ArthMax 120 count bottle, labeled and sold as a dietary supplement.**

SUMMARY: **Unclassified Recall; The product has been found to contain undeclared active pharmaceutical ingredients (APIs), making it an unapproved new drug. FDA sample analysis tested the product to contain the following APIs: 2.4mg of Chlorzoxazone, 0.78mg of Nefopam, 2.5mg of Diclofenac, 7.7mg of Ibuprofen, 2.1mg of Naproxen, and 1.9mg of Indomethacin.**

Product was distributed to direct consignees in the state of California then further distributed nationwide to retail stores and via internet sales.

SUGGESTED ACTION: **For consumer inquiry only. Consumers with questions regarding this recall can contact Human Science Foundation by email to hsf@hs-foundation.com from Monday through Friday, 10 AM and 4 PM, PST.**

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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.

Human Science Foundation Issues Voluntary Nationwide Recall of Pro ArthMax Due to Undeclared Active Pharmaceutical Ingredients

Contact
Consumer:

213-800-1118

Media:
Sean Lee
213-800-1118
hsf@hs-foundation.com

FOR IMMEDIATE RELEASE - Jan 13, 2014 - Gardena, CA, Human Science Foundation is voluntarily recalling all lots of Pro ArthMax 120 count bottle, labeled and sold as a dietary supplement to the consumer level. The product has been found to contain undeclared active pharmaceutical ingredients (APIs), making it an unapproved new drug. FDA sample analysis tested the product to contain the following APIs: 2.4mg of Chlorzoxazone, 0.78mg of Nefopam, 2.5mg of Diclofenac, 7.7mg of Ibuprofen, 2.1mg of Naproxen, and 1.9mg of Indomethacin.

Use of this product containing the undeclared drug ingredients listed above, has a reasonable probability of resulting in fatal adverse events in consumers and patients with underlying illnesses, including known allergy to the hidden ingredients, cardiac, gastrointestinal, hepatic, and renal conditions as well as patients who recently undergone cardiac bypass graft surgery. Consumers would be unaware that the product contains Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) (and other ingredients), may inadvertently overdose by taking another NSAID concurrently, thus increasing the risk for NSAID associated adverse events, which include but are not limited to, myocardial infarction, stroke, congestive heart failure, renal toxicity, and bleeding, ulceration, or perforation of the stomach or intestines.

The product is marketed as a dietary supplement for joint pain and arthritis and is packaged in 120-count tablets per bottle, in a white plastic screw top bottle. Product was distributed to direct consignees in the state of California then further distributed nationwide to retail stores and via internet sales.

Company is notifying its distributors and customers by telephone and e-mail and is arranging for return for credit of all recalled products. Consumers/distributors/retailers that have product which is being recalled should stop using and return to place of purchase for credit.

Consumers with questions regarding this recall can contact Human Science Foundation by email to hsf@hs-foundation.com from Monday through Friday, 10 AM and 4 PM, PST. 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.

- Complete and submit the report Online: http://www.fda.gov/MedWatch/report.htm
- Regular Mail or Fax: Download form http://www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a

reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

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

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