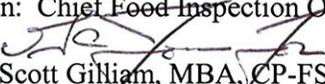




DATE: February 1, 2012

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

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

SUBJECT: Vitaflo USA Recall

SUGGESTED

ACTION: **Unclassified Recall; Renastart 14.11 oz (400g) cans, Batch Number 12832 (shown on underside of can), because some of the product shipped throughout the United States during the period December 29, 2011 through January 26, 2012 has been incorrectly labeled; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the products being recalled were distributed in the State of Indiana. Some immediate consequences of using the incorrectly labeled product may result in high potassium blood levels (hyperkalemia) or high sodium levels in the blood (hypernatremia). In most cases, symptoms may be hard for an individual to detect, but can result in significant health consequences potentially leading to death. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.

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.

Vitaflo USA Announces Nationwide Voluntary Recall of Renastart 14.11 oz (400g) Cans Batch Number 12832 Due to Possible Health Risk

No Cases of Illness Reported

Contact:

Media:

Mary Wade
612-384-8484

Consumer:

Vitaflo
888-848-2356

FOR IMMEDIATE RELEASE - January 30, 2012 - Vitaflo USA has announced a voluntary recall of Renastart 14.11 oz (400g) cans, Batch Number 12832 (shown on underside of can), because some of the product shipped throughout the United States during the period December 29, 2011 through January 26, 2012 has been incorrectly labeled. Renastart is a powdered medical food used in the dietary management of pediatric renal disease, for patients one year and older in the United States. All other Vitaflo products, including Renastart cans in batches other than 12832 and Renastart packed in sachets, **are not affected** in any way.

Some immediate consequences of using the incorrectly labeled product may result in high potassium blood levels (hyperkalemia) or high sodium levels in the blood (hypernatremia). In most cases, symptoms may be hard for an individual to detect, but can result in significant health consequences potentially leading to death, which is the importance for contacting a health care professional. Longer term consequences can result in increased levels of calcium, phosphorus, and protein.

There have been no cases of illness or other adverse effects reported to Vitaflo USA. Following a customer complaint regarding the way the product was dissolving, Vitaflo determined that a small number of cans of a different product may have been wrongly labeled as Renastart. The company is investigating to make sure we continue to safely meet the needs of our patients and as a precautionary measure has issued this immediate voluntary recall.

Vitaflo USA is urging anyone who has any Renastart 14.11oz (400g) cans Batch Number 12832 to **immediately stop using** the product and to contact Vitaflo to arrange return of the product, at Vitaflo's expense. **All patients who have consumed any Renastart from this batch should contact their health care professional immediately to determine next steps, including nutritional management alternatives.**

"The health and safety of our patients is our number one priority," said Jennifer Szymanski, General Manager, Vitaflo USA. "We have communicated directly with renal centers and health care providers to immediately stop using the specific batch of product. Patients are being asked to contact their health care professional, and our Clinical Science Liaison is available to answer any questions that health care professionals may have in addressing the needs of their patients. We have also notified the US FDA and are keeping them informed of all actions we are taking."

Renastart 14.11oz (400g) product in cans is sold only in the United States. This product is not sold under any other name.

Anyone who has Vitaflo's Renastart 14.11oz (400g) cans Batch Number 12832 is urged to contact Vitaflo at **888-848-2356**. Vitaflo has extended its hours of availability through this toll-free

number to 24 hours a day, seven days a week to answer any questions health care professionals and patients may have in addressing this situation. **Patients should always contact their health care professional.**

Vitaflo is dedicated to serving the metabolic community through innovative and specialized medical food solutions for the nutritional management of rare metabolic disorders, pediatric renal disease and disease related malnutrition. Vitaflo USA products are sold to pharmacists, hospitals and home health providers. They are not available to retail customers without a prescription. More information can be found on www.vitaflousa.com¹ ².

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[RSS Feed for FDA Recalls Information](#)³ [what's this?⁴]

[Photo: Product Labels](#)⁵