Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: September 13, 2013

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

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

SUBJECT: Ge Pharma, LLC Recall [Drug]

AFFECTED PRODUCT: **Creafuse Powder Grape; Lot: GE4568, 600 gram container, expires: 2/2015**
Creafuse Powder Fruit Punch Lot: GE4570, 600 gram container, expires: 2/2015

SUMMARY: **Unclassified Recall; Ge Pharma, LLC of North Haven, CT is recalling Creafuse Powder Grape Lot# GE4568, and Creafuse Powder Fruit Punch Lot #GE4570, packaged in a white, 600 gram container with an expiration date of 2/2015 because it contains 1,3 dimethylamylamine (DMAA). DMAA is commonly used as a stimulant, pre-workout, and weight loss ingredient in dietary supplement products. The Food and Drug Administration (FDA) has warned that DMAA is potentially dangerous to health. Ingestion of DMAA can elevate blood pressure and lead to cardiovascular problems. The product was distributed nationwide and was sold via telephone and email. No reports of adverse events associated with these products have been reported.**

SUGGESTED ACTION: **Recommend notification of affected parties via phone, fax, or e-mail. Additionally, be aware of this recall in case of consumer concern. Direct all consumers who may have purchased the affected lots of Creafuse to immediately discontinue its use and contact their health care professional if they have experienced any adverse effects. Consumers can contact GE Pharma LLC at gerry@gepharma.com or call 1-203-675-1057, Monday – Friday, 11 a.m. – 5 p.m. EST to receive further instructions for disposing, returning the product(s), refunds, credits, exchanges, or with any questions. Furthermore, if any recalled products are found, please notify this office at 317-233-3213.**

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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

GE Pharma, LLC Announces a Recall of Dietary Supplement Creafuse Powder Due to Possible Health Risk

Contact
Consumer:
1-203-675-1057
gerry@gepharma.com

FOR IMMEDIATE RELEASE - September 12, 2013 - Ge Pharma, LLC of North Haven, CT is recalling Creafuse Powder Grape Lot# GE4568 and Creafuse Powder Fruit Punch Lot #GE4570, packaged in a white, 600 gram container with an expiration date of 2/2015 because it contains 1,3 dimethylamylamine (DMAA).

DMAA is commonly used as a stimulant, pre-workout, and weight loss ingredient in dietary supplement products. The Food and Drug Administration (FDA) has warned that DMAA is potentially dangerous to health. Ingestion of DMAA can elevate blood pressure and lead to cardiovascular problems. A number of adverse effects associated with DMAA containing dietary supplements have been reported to the FDA. The FDA has also warned that DMAA is not a dietary ingredient and thus, is not Dietary Supplement Health and Education Act (DSHEA) compliant.

The product was distributed nationwide and was sold via telephone and email. There have been no reports of adverse events associated with these products to date.

No other products distributed by Ge Pharma LLC are subject to recall.

Consumers who may have purchased the affected lot numbers of Creafuse should immediately discontinue use of the product and contact their health care professional if they have experienced any adverse effects. Consumers can contact GE Pharma LLC at gerry@gepharma.com or call 1-203-675-1057, Monday – Friday, 11 a.m. – 5 p.m. EST to receive further instructions for disposing, returning the product(s), refunds, credits, exchanges, or with any questions.

Adverse reactions or quality problems experienced with the use of these product(s) may be reported to the FDA's MedWatch Adverse Event Reporting program online, by regular mail, or by fax. The form and instructions for the form may be found at http://www.fda.gov/Medwatch/getforms.htm[1]

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