



Mitchell E. Daniels, Jr.
Governor

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

DATE: June 1, 2010

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

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

SUBJECT: Blacksmith Brands, Inc. Recall

SUGGESTED

ACTION: Unclassified Recall; Four children's products in the PediaCare line; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the product being recalled was distributed in the State of Indiana. Blacksmith Brands markets, sells and distributes over-the-counter drug and personal care products. Detail information is not available at this time. In addition, if any recalled product is 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.

Blacksmith Brands Announces Nationwide Voluntary Recall Of Four PediaCare Children's Products

Media Contact:
Gene Grabowski, 202.270.6560

FOR IMMEDIATE RELEASE - May 28, 2010 - Tarrytown, NY - Blacksmith Brands, Inc., in consultation with the U.S. Food and Drug Administration, is voluntarily recalling all lots of four children's products in the PediaCare line. These products are sold exclusively in the United States. These products were manufactured for Blacksmith Brands by McNeil Consumer Healthcare, a Division of McNeil-PPC, Inc., (a Johnson & Johnson Company) at McNeil's Fort Washington, PA plant.

The four PediaCare items involved in the recall are:

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1. PediaCare Multi-Symptom Cold 4oz. UPC # 3 0045-0556-05 9
2. PediaCare Long Acting Cough 4oz. UPC# 3 0045-0465-04 7
3. PediaCare Decongestant 4oz. UPC# 3 0045-0554-04 8
4. PediaCare Allergy and Cold 4oz. UPC# 3 0045-0552-04 4

Blacksmith Brands initiated the recall as a precautionary step because the products were made at the McNeil Consumer Healthcare Fort Washington, PA plant that has been temporarily shut down. A recent FDA inspection at that facility found serious problems in meeting the FDA's current good manufacturing practice requirements. The recall was not initiated as a result of any consumer reports of adverse events and no consumer complaints have been received about the safety or purity of the products.

While the recall was not initiated as a result of either any consumer reports of adverse events or complaints with respect to the PediaCare products, tiny particles have been found in other non-PediaCare products which were manufactured at the McNeil plant.

While the potential for serious medical events is remote, the company advises consumers who have purchased these recalled products to discontinue use. Blacksmith Brands is asking Retail and Wholesale customers to withdraw the four products from their shelves and warehouses and return the product to Blacksmith Brands.

Consumers with questions may contact Blacksmith Brands on Friday, May 28th 5pm – 9pm EST; Saturday-Monday 9am-5pm EST; and normal business hours thereafter at (888) 474-3099. More information is available at blacksmithbrands.com¹.

Any adverse events that may be related to the use of these products should be reported to the FDA's Med Watch Program by fax at 1-800-FDA-0178 or by mail at Med Watch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787. or on the Med watch website at <http://www.fda.gov/safety/medwatch/default.htm>

"We're taking this voluntary step because protecting consumers and maintaining their trust are essential to our company's core values," said Blacksmith Brands Chairman and CEO Peter Mann. "Our brands have a heritage that has made them the favorites of millions of families and we are the guardians of that heritage."

To provide these valued products to consumers again as quickly as possible, Blacksmith Brands has arranged to make them at new manufacturing plants and expects to resume shipments of the recalled items in July from those new facilities.

Items not involved in this recall are PediaCare Allergy 4oz., PediaCare Gentle Vapors Plug in Units, and PediaCare Gentle Vapors refills, all of which are produced in other facilities.

Blacksmith Brands markets, sells and distributes over-the-counter drug and personal care products that for years have provided consumers with superior, dependable results.

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Photos: Product Labels²