Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: March 14, 2014

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

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

SUBJECT: Shire Pharmaceuticals – RECALL [Drug]

AFFECTED PRODUCT: **VPRIV: a hydrolytic lysosomal glucocerebroside-specific enzyme indicated for long-term enzyme replacement therapy (ERT) for pediatric and adult patients with type 1 Gaucher disease.**

SUMMARY: **Unclassified Recall; The recall is due to the presence of visible particulate matter, identified as stainless steel and barium sulfate.**

This voluntary recall is limited to the following packaged lots: FEW13-001, FEW13-002, and FED13-006 and all have the same NDC code (54092-701-04) and same expiration date of 10/15 (Oct 2015).

These lots were distributed nationwide to hospitals, infusion clinics, patients, and home health agencies in the United States.

SUGGESTED ACTION: **For consumer inquiry only. Consumers or health care providers with questions regarding this recall can call Shire at 1-888-899-9293 (Monday through Friday between the hours of 8:00am and 5:00pm Eastern Time).**

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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.

Shire Pharmaceuticals Initiates Voluntary Nationwide Recall of One Batch, Packaged into Three Lots, of VPRIV® (velaglucerase alfa for injection)

Contact
Consumer:
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FOR IMMEDIATE RELEASE - March 14, 2014 - Shire Pharmaceuticals announced today the initiation of a voluntary recall in the United States of one batch, packaged into three lots, of VPRIV due to the presence of visible particulate matter, identified as stainless steel and barium sulfate. The particulate matter was found in a small number of vials in the three packaged lots of VPRIV. A Shire investigation identified the particulate matter root cause as the third party supplier fill finish process.

Shire believes the safety risk to patients is very low. If infused, there is a possibility of rare but serious adverse events associated with particulate containing barium sulfate. Shire believes this health risk was and continues to be mitigated by the package insert's required visual inspection of the reconstituted VPRIV product and by administration of VPRIV through an in-line low protein-binding filter. The product is being recalled and should not be used.

Importantly, there have been no reported adverse events or customer complaints associated with the use of these lots. To ensure that patients are not exposed to foreign particles during administration, Shire is reinforcing recommendations of the approved package insert in order to mitigate any risk: (1) visual inspection of the reconstituted VPRIV product should be done prior to administration and (2) VPRIV should be administered through an in-line low protein-binding filter. The safety profile of VPRIV remains unchanged.

VPRIV is a hydrolytic lysosomal glucocerebroside-specific enzyme indicated for long-term enzyme replacement therapy (ERT) for pediatric and adult patients with type 1 Gaucher disease. VPRIV is supplied as a sterile, preservative-free, lyophilized powder in single-use vials, for intravenous use. This voluntary recall is limited to the following packaged lots: FEW13-001, FEW13-002, and FED13-006. These lots were distributed nationwide to hospitals, infusion clinics, patients, and home health agencies in the United States and all have the same NDC code (54092-701-04) and same expiration date of 10/15 (Oct 2015).

Shire has notified patients, hospitals, infusion clinics, and home health agencies via letter not to use product from the recalled lots. Customers should locate and remove all affected product from their facility and/or residence. Affected product should be returned by contacting Shire at 1-888-899-9293 (Monday through Friday between the hours of 8:00am and 5:00pm Eastern Time). Shire has significant quantities of VPRIV to replace any affected product. Shire does not anticipate any disruption in supply as a result of this voluntary recall.

Unaffected lots of VPRIV can continue to be used according to the instructions for use.

Consumers or health care providers with questions regarding this recall can call Shire at 1-888-899-9293 (Monday through Friday between the hours of 8:00am and 5:00pm Eastern Time). Consumers should contact their physician or health care provider if they have experienced any problems that may be related to using this drug product.

Any 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: www.fda.gov/medwatch/report.htm
- Regular mail or fax: Download form 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 voluntary recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

At Shire, patient safety is of the highest priority and corrective and preventative actions have been implemented to prevent reoccurrence.

Shire Pharmaceuticals Initiates Voluntary Nationwide Recall of One Batch, Packaged into Three Lots, of VPRIV® (velaglucerase alfa for injection)

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