Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: October 6, 2014

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Sagent Pharmaceuticals, Inc. - RECALL [Drug]

AFFECTED PRODUCT: **Ketorolac Tromethamine Injection, USP**

SUMMARY: **Unclassified Recall; The recall is due to the product being labeled with an incorrect expiration date. The labeled expiration date is longer than the known stability of the product.**

Ketorolac Tromethamine Injection, USP, 30mg/mL single-dose vials (NDC numbers 25021-701-01 and 25021-701-02) manufactured by Cadila Healthcare Limited and distributed by Sagent. The lot numbers being recalled are MP5021, MP5024 and MP5025.

The recalled products were distributed to hospitals, wholesalers and distributors nationwide from September 17, 2014 through October 1, 2014.

SUGGESTED ACTION: **For consumer inquiry only. Any questions about returning unused product should be directed to the customer call center at (866) 625-1618 M-F 8am-7pm CST. Healthcare workers who have medical questions about Ketorolac Tromethamine Injection, USP may contact Sagent Medical Affairs (866-625-1618, Option 3) M-F 8am-5pm CST.**

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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.

Sagent Pharmaceuticals Initiates a Nationwide Voluntary Recall of Three Lots of Ketorolac Tromethamine Injection, USP, 30mg/ml Due to Labeling the Product with the Incorrect Expiration Date

Contact
Consumer:
866-625-1618

FOR IMMEDIATE RELEASE - October 3, 2014 - Sagent Pharmaceuticals, Inc. today announced the voluntary nationwide recall of three lots of Ketorolac Tromethamine Injection, USP, 30mg/mL single-dose vials (NDC numbers 25021-701-01 and 25021-701-02) manufactured by Cadila Healthcare Limited and distributed by Sagent. Sagent has initiated this voluntary recall of Ketorolac Tromethamine Injection, USP, 30mg/mL to the user level due to labeling the product with the incorrect expiration date. The labeled expiration date is longer than the known stability of the product.

Sagent is not aware of any adverse patient events resulting from the use of this product.

The lot numbers being recalled are MP5021, MP5024 and MP5025 which were distributed to hospitals, wholesalers and distributors nationwide from September 17, 2014 through October 1, 2014. Ketorolac Tromethamine Injection, USP, 30mg/mL is a nonsteroidal anti-inflammatory drug (NSAID) indicated for short-term management of moderately severe acute pain that requires analgesia at the opioid level, usually in a postoperative setting, and is supplied in a single-dose vial.

Customers are being notified by fax, email, FedEx, and/or certified mail that includes arrangements for return of all recalled product. Customers have been instructed to examine their inventory immediately and to quarantine, discontinue distribution of and return the recalled lots of product. Customers who may have further distributed this product have been requested to identify their customers and notify them at once of this product recall. The necessary form by which to document this information as well as other information regarding this recall is available at www.Sagentpharma.com.

Any questions about returning unused product should be directed to the customer call center at (866) 625-1618 M-F 8am-7pm CST. Healthcare workers who have medical questions about Ketorolac Tromethamine Injection, USP may contact Sagent Medical Affairs (866-625-1618, Option 3) M-F 8am-5pm CST.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product.

Any adverse events that may be related to the use of this product should be reported to the FDA's MedWatch Program either online, by regular mail or by fax.

- Online: www.fda.gov/medwatch/report.htm
- Regular mail: use postage-paid, pre-addressed Form FDA3500 available at www.fda.gov/MedWatch/getforms.htm
- Fax: 1-800-FDA-0178

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

About Sagent Pharmaceuticals, Inc.
Sagent Pharmaceuticals, Inc., founded in 2006, is a specialty pharmaceutical company focused on developing, manufacturing, sourcing and marketing pharmaceutical products, with a specific emphasis on injectables. Sagent has created a unique global network of resources, comprising rapid development capabilities, sophisticated manufacturing and innovative drug delivery technologies, resulting in an extensive and rapidly expanding pharmaceutical product portfolio that fulfills the evolving needs of patients.

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