Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: October 15, 2015

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Medline Industries, Inc. - RECALL [Drug]

AFFECTED PRODUCT: **Acetaminophen tablets, 500mg**

SUMMARY: **Unclassified Recall; The recall has been initiated because the Acetaminophen tablets, 500mg is incorrectly labeled as 325 mg tablets.**

Acetaminophen tablets is an over the counter (OTC) oral medication used to temporarily relieve minor aches and pains due to minor pain of arthritis, muscular aches, back aches, headaches, toothaches, the common cold, premenstrual and menstrual cramps, and reduces fever. This item is packaged as 100 tablets per bottle, Medline Item Number: OTC20101, NDC#: 53329-641-30. The recalled Acetaminophen 500mg, Tab 100/BT (OTC20101) includes lot # 45810 with expiration date May 2018.

This lot was distributed nationwide from June 12, 2015 through September 18, 2015.

SUGGESTED ACTION: **Recommend notification of affected parties via phone, fax, or e-mail. Consumers with questions regarding this recall can contact Medline Industries, Inc. by phone 866-359-1704 or recalls@medline.com Monday through Friday between the hours of 8am and 5pm CST. Furthermore, if any recalled products are found, notify this office at 317-233-8475.**

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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.

Recall: Firm Press Release

Medline Industries, Inc. Issues A Voluntary Nationwide Recall Of One Lot Of Acetaminophen Tablets, 500mg, Due To Mislabeling With Incorrect Strength

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.

For Immediate Release

October 9, 2015

Contact

Consumers

Medline Industries, Inc.
recalls@medline.com
866-359-1704

Media

Kathy Cummings
KCummings@medline.com
847-643-3308

Firm Press Release

Medline Industries, Inc. announced that it will initiate a voluntary nationwide recall of lot # 45810 of Acetaminophen tablets, 500mg, uncoated compressed tablets to the consumer level. The Acetaminophen 500mg, Tab 100/BT (OTC20101) has been found to be mislabeled displaying "Acetaminophen 325mg" (OTC10101) instead of "Acetaminophen 500mg". The Acetaminophen tablets, 500mg is incorrectly labeled as 325 mg tablets. This error is not easily identifiable by the user or prescriber. If the product is taken at the maximum labeled dose, every four hours, five doses a day, or with other medications containing acetaminophen, it may lead to liver toxicity or liver failure. To date, Medline Industries, Inc. has not received any reports of adverse events associated with this product.

Acetaminophen tablets is an over the counter (OTC) oral medication used to temporarily relieve minor aches and pains due to minor pain of arthritis, muscular aches, back aches, headaches, toothaches, the common cold, premenstrual and menstrual cramps, and reduces fever. This item is packaged as 100 tablets per bottle, Medline Item Number: OTC20101, NDC#: 53329-641-30. The recalled Acetaminophen 500mg, Tab 100/BT (OTC20101) includes lot # 45810 with expiration date May 2018.

This lot was distributed nationwide from June 12, 2015 through September 18, 2015. Medline Industries, Inc. is investigating to determine the root cause and corrective and preventative actions. Medline Industries, Inc. notified its distributors, consumers and/or retailer customers by First Class Mail on September 25th, 2015 and is arranging for return and credit of all recalled products. Consumers, distributors, and/or retailers that have product which is being recalled should stop using and return to Medline Industries, Inc.

Consumers with questions regarding this recall can contact Medline Industries, Inc. by phone 866-359-1704 or recalls@medline.com Monday through Friday between the hours of 8am and 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 drug product.

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

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