Pharmacy_Subscriberlist@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Thursday, October 15, 2015 9:25 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Acetaminophen Tablets by Medline Industries: Recall - Mislabeling with Incorrect Strength

AUDIENCE: Pharmacy, Consumer

ISSUE: On October 9, 2015, 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. See the firm Press Release for further details.

BACKGROUND: 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.

RECOMMENDATION: 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.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form 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.

Read the MedWatch safety alert, including a link to the firm Press Release, at:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm467076.htm