Clifton Health Department
Food Recall Notification

Public Health
Prevent. Promote. Protect.

Food/Drug/Pet Recall: Alvogen, Inc.

Alvogen, Inc. is voluntarily recalling two lots of Fentanyl Transdermal System 12 mcg/h transdermal patches to the consumer level. A small number of cartons labeled 12 mcg/h Fentanyl Transdermal System patches contained 50 mcg/h patches. The 50 mcg/h patches that were included in cartons labeled 12 mcg/h are individually labeled as 50 mcg/h. This transdermal system is manufactured by 3M Drug Delivery Systems, St. Paul, MN.

Application of a 50 mcg/h patch instead of a prescribed 12 mcg/h patch could result in serious, life threatening, or fatal respiratory depression. Groups at potential increased risk could include first time recipients of such patches, children, and the elderly. To date, Alvogen Inc. has not received any reports of adverse events related to this issue.

The product is indicated for the management of pain in opioid tolerant patients and is packaged in primary cartons of five individually wrapped and labeled pouches. The affected Fentanyl Transdermal System lots include:

Lot 180060 of Fentanyl Transdermal System, 12 mcg/h, expiration date 05/2020.
Lot 180073 of Fentanyl Transdermal System, 12 mcg/h, expiration date 06/2020.
The mislabeled product is packaged in a 12 mcg/h primary carton. These lots of Fentanyl Transdermal System were distributed Nationwide to the pharmacy level.
See images example for lot 180073.

Alvogen Inc. is notifying its distributors and direct customers by certified letter and is arranging for return and replacement of all recalled products. Pharmacies are requested not to dispense any product subject to this recall. Patients that have product subject to this recall should immediately remove any patch currently in use and contact their health care provider. Patients with unused product should return it to point of purchase for replacement.

Questions regarding this recall should be directed to Alvogen Customer Complaints by calling 866-770-3024 or sending an e-mail to pharmacovigilance@alvogen.com from Monday to Friday from 9:00 am to 5:00 pm EST. Consumers should contact their physician or health care 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 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

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

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No action is required of local health departments at this time for any of these recalls. If any requests for assistance are received from FDA, the Public Health and Food Protection Program will contact you. For additional information regarding warnings and recalls, please click on the weblink below.

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For all recalls - http://www.recalls.gov/recent.html