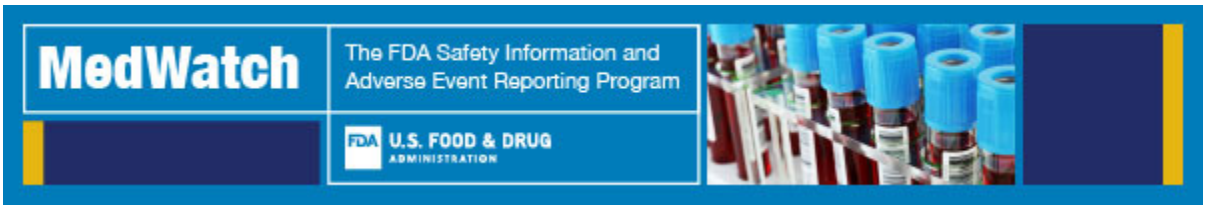

MedWatch - The FDA Safety Information and Adverse Event Reporting Program

A *MedWatch* Safety Alert was added to the FDA Drug Safety and Availability webpage.

TOPIC: EpiPen Auto-Injector by Pfizer and Authorized Generic Versions: Statement - Errors Related to Device Malfunctions and User Administration

AUDIENCE: Pediatrics, Allergy and Immunology, Emergency Medicine, Pharmacy

ISSUE: FDA is alerting patients, caregivers and health care professionals that EpiPen 0.3 mg and EpiPen Jr 0.15 mg Auto-Injectors, and the authorized generic versions, may potentially have delayed injection or be prevented from properly injecting due to:

1. Device failure from spontaneous activation caused by using sideways force to remove the blue safety release
2. Device failure from inadvertent or spontaneous activation due to a raised blue safety release
3. Difficulty removing the device from the carrier tube
4. User errors

In a letter to health care providers, the manufacturer detailed how these devices may activate prematurely if the blue safety release is removed using a sideway force.

RECOMMENDATION: Health care providers, patients and caregivers should periodically review the EpiPen user instructions and practice using the EpiPen trainer to ensure proper understanding and utilization of the EpiPen.

Patients and caregivers should inspect their EpiPen prior to needing it to ensure the blue safety release is not raised and that the device can be easily removed from the carrier tube. Patients should always seek emergency medical help right away after using their EpiPen.

Pharmacists should inspect the products before dispensing them to patients to ensure quick access to the auto-injector and should not dispense any product which does not easily slide out of its carrier tube or has a raised blue safety release.

Health care providers, patients and caregivers 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.
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the form, or submit by fax to 1-800-FDA-0178.

Read Statement

U.S. Food and Drug Administration
10903 New Hampshire Avenue, Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)