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CLINICAL BULLETIN

Bulletin #	Title			Date Issued
38		EpiPen Recall		April 4, 2017
Superseded	Released By	Approved By	Source	
	V. Blanchard	Dr. Jim Suozzi	FDA	

Please see the following news release from the Federal Drug Administration from March 31, 2017:

The U.S. Food and Drug Administration is alerting consumers to Meridian Medical Technologies' voluntary recall of 13 lots of Mylan's EpiPen and EpiPen Jr (epinephrine injection) Auto-Injector products used for emergency treatment of severe allergic reactions. This recall is due to the potential that these devices may contain a defective part that may result in the devices' failure to activate. The recalled product was manufactured by Meridian Medical Technologies and distributed by Mylan Specialty.

While the number of reported failures is small, EpiPen products that potentially contain a defective part are being recalled because of the potential for life-threatening risk if a severe allergic reaction goes untreated. Consumers should keep and use their current EpiPens if needed until they get a replacement. Consumers should contact Stericycle at 877-650-3494 to return the product.

As stated on the product label, consumers should always seek emergency medical help right away after using their EpiPens, particularly if the device did not activate.

At this time, the 13 lots identified – distributed between Dec. 17, 2015, and July 1, 2016 – are the only EpiPen lots impacted by the U.S. recall. Consumers who have EpiPens from lots that are not included in this recall, do not need to replace their EpiPen prior to its expiration date.

Product/Dosage	NDC Number	Lot Number	Expiration Date
EpiPen Jr Auto-Injector, 0.15 mg	49502-501-02	5GN767	April 2017
EpiPen Jr Auto-Injector, 0.15 mg	49502-501-02	5GN773	April 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	5GM631	April 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	5GM640	May 2017
EpiPen Jr Auto-Injector, 0.15 mg	49502-501-02	6GN215	September 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	6GM082	September 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	6GM072	September 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	6GM081	September 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	6GM088	October 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	6GM199	October 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	6GM091	October 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	6GM198	October 2017
EpiPen Auto-Injector, 0.3 mg	49502-500-02	6GM087	October 2017

The FDA asks health care professionals and consumers to report any adverse reactions or device malfunctions to the FDA's MedWatch program, by:

Bureau of Emergency Medical Services Bureau of Fire Training and Administration Business: (603) 223-4200 Toll Free: 1-800-371-4503 Fax: (603) 271-1091

http://www.nh.gov/safety/divisions/fstems/

- Completing and submitting the report online at www.fda.gov/medwatch/report.htm, or
- Downloading and completing the <u>form</u>, then submitting it via fax at 800-FDA-0178.