FDA News Release

FDA alerts consumers of nationwide voluntary recall of EpiPen and EpiPen Jr

For Immediate Release

March 31, 2017

Release

The U.S. Food and Drug Administration is alerting consumers to Meridian Medical Technologies' **voluntary recall (http://newsroom.mylan.com/2017-03-31-Mylan-Provides-Update-on-Meridian-Medical-Technologies-a-Pfizer-Company-Expanded-Voluntary-Worldwide-Recall-of-EpiPen-R-Auto-Injector)** **(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** 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 Mylan at 800-796-9526 or **customer.service@mylan.com (mailto:customer.service@mylan.com)** with any questions.

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	April 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:

- Completing and submitting the report online at **www.fda.gov/medwatch/report.htm (http://www.fda.gov/medwatch/report.htm)**, or
- Downloading and completing the **form (/downloads/AboutFDA/ReportsManualsForms/Forms/UCM349464.pdf)**, then submitting it via fax at 800-FDA-0178.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Consumers

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