# FDA Alert: Nationwide Recall of EpiPen and EpipenJr

**FDA News Release: FDA alerts consumers of nationwide voluntary recall of EpiPen and EpiPen Jr**
*For Immediate Release: 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 Mylan at 800-796-9526 or customer.service@mylan.com with any questions. 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:

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