GOVERNMENT OF GUAM
DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES
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PRESS RELEASE
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Pfizer Company Meridian Medical Technologies and Mylan N.V. EpiPen® Auto-Injector Expanded Voluntary Worldwide Recall

The Department of Public Health and Social Services, in coordination with the U.S. Food & Drug Administration, would like to inform the public of a worldwide voluntary recall involving Meridian Medical Technologies', a Pfizer company and Mylan's manufacturing partner, EpiPen® Auto-Injector, select lots of EpiPen (epinephrine injection, USP) and EpiPen Jr® (epinephrine injection, USP) Auto-Injectors to now include additional lots distributed in the U.S. and other markets.

The recall includes the following U.S. impacted lots listed below:

Product/Dosage	NDC Number	Lot Number	Expiration Date
EpiPen Jr 2-Pak® Auto-Injectors, 0.15 mg	49502-501-02	5GN767	April 2017
EpiPen Jr 2-Pak® Auto-Injectors, 0.15 mg	49502-501-02	5GN773	April 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	5GM631	April 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	5GM640	May 2017
EpiPen Jr 2-Pak® Auto-Injectors, 0.15 mg	49502-501-02	6GN215	September 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	6GM082	September 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	6GM072	September 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	6GM081	September 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	6GM088	October 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	6GM199	October 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	6GM091	October 2017
EpiPen 2-Pak® Auto-Injectors, 0.3 mg	49502-500-02	6GM198	October 2017
EpiPen 2-pak® Auto-Injectors, 0.3 mg	49502-500-02	6GM087	October 2017

This recall is being conducted as a result of the receipt of two previously disclosed reports outside of the U.S. of failure to activate the device due to a potential defect in a supplier component. The potential defect could make the device difficult to activate in an emergency (failure to activate or increased force needed to activate) and have significant health consequences for a patient experiencing a life-threatening allergic reaction (anaphylaxis). Both reports are related to the single lot that was previously recalled. The incidence of the defect is extremely rare and testing and analysis across the potentially impacted lots has not identified any units with a defect.

However, the recall is being expanded to include additional lots as a precautionary measure out of an abundance of caution.

The recalled product was manufactured by Meridian Medical Technologies, a Pfizer company, and distributed by Mylan Specialty between December 2015 and July 2016. The expanded voluntary recall is being initiated in the U.S. and also will extend to additional markets in Europe, Asia, North and South America.

The recall impacts the 0.3 mg and 0.15 mg strengths of EpiPen Auto-Injector. None of the recalled lots include the authorized generic for EpiPen Auto-Injector, which is also manufactured by Meridian Medical Technologies.

To date, the Division of Environmental Health has determined that one affected product (EpiPen 2-Pak® Auto-Injectors, 0.3 mg, 49502-500-02, 6GM082, September 2017), was dispensed from Sagan Amot Pharmacy in Agat. No additional affected products were found in their shelves; however, there may be affected product already distributed.

The Department has not received any local report of injuries or illnesses associated with the use of these recalled commodities. Patients who are in possession of the items listed above are urged to return it to the place of distribution.

For any questions, please contact the Consumer Commodities Program at the Division of Environmental Health at 735-7221.

JAMES W. GILLAN
Director