Jacobus – Recall of Ruzurgi® (amifampridine)

- On September 13, 2021, Jacobus announced a voluntary, consumer level recall of three lots of Ruzurgi (amifampridine) because the tablets have been found to be contaminated with yeast, mold, and aerobic bacteria based on laboratory test results.
    - Other Ruzurgi tablets are not being recalled and are available for patients to use.
- Ruzurgi was distributed to specialty pharmacies and physicians from June 1, 2021 through August 30, 2021:

Product Description	NDC #	Control# (Expiration Date)
Ruzurgi (amifampridine) 10 mg tablets, 100 count bottle	49938-110-01	18038 (3/2023); 18039 (3/2023); 18079 (5/2023)

- Ruzurgi is approved for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 to less than 17 years of age.
- Oral products heavily contaminated with yeast, mold, and aerobic bacteria may result in serious and life-threatening infections. The use of the defective product in patients with underlying immunosuppressive conditions such as LEMS increases the concern for serious infections.
- To date, Jacobus has not received reports of any adverse events or identifiable safety concerns attributed to the recalled lots.
- Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to the recalled Ruzurgi tablets.
- Anyone with an existing inventory of the recalled product should stop use, distribution and quarantine the product immediately.
- Contact Jacobus at **1-609-799-8221, ext. 2120** for further information regarding this recall.