Lannett – Recall of levetiracetam oral solution

- On December 18, 2019, Lannett announced a voluntary, consumer-level recall of two lots of levetiracetam oral solution due to contamination with *Bacillus subtilis*. *Bacillus subtilis* was identified during an evaluation of a raw material used to manufacture the product.

Product Description	NDC #	Lot #	Expiration Date
Levetiracetam oral solution 100 mg/mL	54838-548-80	2190A, 2191A	7/2021

- Levetiracetam is indicated for the treatment of partial-onset seizures in patients 1 month and older. It is also indicated for adjunctive therapy of myoclonic seizures in patients 12 years of age and older with juvenile myoclonic epilepsy and primary generalized tonic-clonic seizures in patients 6 years of age and older with idiopathic generalized epilepsy.

- *Bacillus subtilis* is ubiquitous in the environment and although the pathogenic potential has been described as low, serious systemic infections have been reported. The likelihood of the health hazard depends on the degree of microbial contamination, the dose and duration of treatment, and the patient's underlying conditions. It is possible that a severe infection may occur in immunocompromised patients.

- Lannett has not received any reports of adverse events related to this recall to date.

- Patients that have the recalled levetiracetam should contact their pharmacy to return product.

- Anyone with an existing inventory of the recalled product should stop use and distribution.

- For more information regarding this recall, contact Inmar at **1-866-255-4938**.