Levetiracetam Oral Solution

This notice is to inform you that on December 18, 2019 the U.S. Food and Drug Administration (FDA) announced that Lannett Company, Inc. is voluntarily recalling two (2) lots of Levetiracetam Oral Solution, 100mg/mL due to contamination with *Bacillus subtilis*. The *Bacillus subtilis* was identified during an evaluation of a raw material used to manufacture the product.

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.

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. The affected Levetiracetam Oral Solution lots include the following:

Product	NDC	Lot Number	Expiration Date
Levetiracetam Oral Solution 100mg/mL	54838-548-80	2190A	07/2021
Levetiracetam Oral Solution 100mg/mL	54838-548-80	2191A	07/2021

Patients are asked to continue taking their medication and should consult with their healthcare provider or pharmacy to determine if they have the affected product lots.