LANNETT ISSUES VOLUNTARY NATIONWIDE RECALL OF LEVETIRACETAM ORAL SOLUTION, 100MG/ML DUE TO MICROBIAL CONTAMINATION

December 18, 2019 – Philadelphia, PA - Lannett Company, Inc. today announced that it is voluntarily recalling two (2) lots of Levetiracetam Oral Solution, 100mg/mL to the consumer level due to contamination with *Bacillus subtilis*. The *Bacillus subtilis* was identified during an evaluation of a raw material used to manufacture the product.

Risk Statement: *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 and is packaged in bottles of 16 fluid ounces (one pint) (NDC 54838-548-80). 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

The product can be identified by NDC number and batch numbers provided above. Levetiracetam Oral Solution was distributed nationwide in the USA to wholesalers/distributors.

Lannett is notifying its distributors and customers via email and via the Lannett website and is arranging for return of all recalled products. Wholesalers and distributors (direct customers of Lannett) that have Levetiracetam which is being recalled should contact Inmar for instructions with regard to returning any remaining stock. Consumers that have Levetiracetam which is being recalled should contact their pharmacy to return product.

Consumers with questions regarding this recall can contact Inmar by phone at (866) 255-4983, Monday-Friday, 9:00 a.m. - 5:00 p.m. (EST). Consumers with medical questions can contact the Lannett Medical Information Department at (844) 834-0530, Monday-Friday, 9:00a.m. – 5:00 p.m. (EST). Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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