Jacobus Pharmaceutical Company Inc. Issues Voluntary Worldwide Recall of Ruzurgi® (amifampridine) 10 mg Tablets Due to Yeast, Mold, and Bacterial Contamination

Company Contact:

Richard W. Pursell, Vice President

Jacobus Pharmaceutical Company Inc.

(609)799-8221 ext. 2120

FOR IMMEDIATE RELEASE - September 13, 2021, Plainsboro, New Jersey, Jacobus Pharmaceutical Company Inc. is voluntarily recalling 3 lots of Ruzurgi® (amifampridine) 10 mg tablets to the consumer level. The products have been found to be contaminated with yeast, mold, and aerobic bacteria based on laboratory test results.

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 Lambert Eaton Syndrome (LEMS) increases the concern for serious infections.

The product is used as a treatment for LEMS in patients ages 6 to less than 17 and is packaged in 100 count bottles (NDC: 49938-110-01). The affected Ruzurgi® (amifampridine) tablets lots include the following control numbers and expiration dates:

Control Number 18038, Expiration 03/2023

Control Number 18039, Expiration 03/2023

Control Number 18079, Expiration 05/2023

The Control Number is located to the right of the bottle's front panel below the D2 Barcode.

Ruzurgi® (amifampridine) was distributed worldwide to specialty pharmacies and physicians.

Jacobus was informed of this issue by their Canadian partner that was conducting confirmatory full testing on Control Number 18038. Jacobus conducted an expanded investigation which identified Control Numbers 18039 and 18079.

Control Number 18038 was distributed between 05/25/2021 – 08/26/2021 (Canada only)
Control Number 18039 was distributed between 06/01/2021 – 08/10/2021
Control Number 18079 was distributed between 08/10/2021 – 08/30/2021

Jacobus Pharmaceutical Company Inc is notifying its distributors and customers via regular mail and electronic mail and is arranging for return of all recalled products. Consumers that have Ruzurgi® (amifampridine) which is being recalled should stop using and return this product.

If shipping via US Postal Service ship to:
Jacobus Pharmaceutical Company, Inc.
P.O. Box 5290, Princeton, NJ 08540.

If shipping via courier service (i.e., UPS, FedEx, etc.) ship to:
Jacobus Pharmaceutical Company, Inc.
IRL Building
31 Schalks Crossing Road
Plainsboro, NJ 08356.

Consumers with questions regarding this recall can contact Jacobus Pharmaceutical Company Inc. by phone at (609)799-8221 ext. 2120, Monday thru Friday from 9:00 AM to 5:00 PM Eastern Standard Time.
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 and other health authorities.