



Montreal, QC, August 12, 2019 –

On August 1, 2019, the Administrative Law Judge (ALJ) presiding over Jubilant Radiopharma’s case at the United States International Trade Commission (ITC) found that Jubilant Radiopharma’s importation and sale of RUBY-FILL Generators and RUBY Elution Systems in the United States does not violate section 337 of the Tariff Act of 1930.

The ALJ’s determination in Jubilant’s favor is in response to a complaint filed by Bracco Diagnostics at the ITC, which alleged that the importation and sale of RUBY-FILL Generators and RUBY Elution Systems infringed three of Bracco’s U.S. patents. The complaint also included a request for an order to stop Jubilant from importing and selling those products in the United States.

Pramod Yadav, CEO Jubilant Pharma Limited stated, “Jubilant Radiopharma is gratified with the outcome of the ALJ’s determination in the ITC case, and we are pleased to continue to provide our products to our valued customers. Jubilant believes that fair competition in the marketplace is positive for customers and compels the entire industry to continue to invest in providing cutting-edge technology for customers and patients.”

Jubilant Radiopharma’s RUBY-FILL Generator and RUBY Elution System provide the latest and most advanced technology in PET Rubidium-82 myocardial imaging. Made available in the U.S. market in May 2017, the RUBY-FILL portfolio provides customers a choice of the next generation product, with safety, efficiency and automation advancements. RUBY-FILL and other Jubilant Radiopharma products are a key part of our greater commitment to investing in the growth and continued advancements of nuclear medicine and, especially, the global cardiac PET market.

For more information on RUBY-FILL and the RUBY Elution System technology features and benefits, please visit the website at www.RUBY-FILL.com or www.jubilantradiopharma.com

A Jubilant Pharma Company

OUR VALUES



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Indication for Use: RUBY-FILL is a closed system used to produce rubidium (Rb-82) chloride injection for intravenous use. Rubidium (Rb-82) chloride injection is a radioactive diagnostic agent indicated for Positron Emission Tomography (PET) imaging of the myocardium under rest or pharmacologic stress conditions to evaluate regional myocardial perfusion in adult patients with suspected or existing coronary artery disease.

New Important Safety Information April 2019

Please note changes in Boxed Warning, Dosage and Administration, Directions for Eluting Rubidium Rb 82 Chloride Injection (2.5), Contraindications (4), Warnings and Precautions, High Level Radiation Exposure with Use of Incorrect Eluent (5.1).

WARNING: HIGH LEVEL RADIATION EXPOSURE WITH USE OF INCORRECT ELUENT AND FAILURE TO FOLLOW QUALITY CONTROL TESTING PROCEDURE

Please see full prescribing information for complete boxed warning

High Level Radiation Exposure with Use of Incorrect Eluent

Using incorrect eluent can cause high Sr 82 and Sr 85 breakthrough levels (5.1)

- Use only additive-free 0.9% Sodium Chloride Injection USP to elute the generator (2.5)
- Immediately stop the patient infusion and discontinue the use of the affected RUBY-FILL generator if the incorrect solution is used to elute the generator (4)
- Evaluate the patient's radiation absorbed dose and monitor for the effects of radiation to critical organs such as bone marrow (2.9).

Excess Radiation Exposure with Failure to Follow Quality Control Testing Procedure

Excess radiation exposure occurs when the levels of Sr 82 or Sr 85 in the rubidium Rb 82 chloride injection exceed specified limits (5.2)

- Strictly adhere to the generator quality control testing procedure (2.6)
- Stop use of a generator at any of its Expiration Limits (2.7)

The risk information provided here is not comprehensive. Please visit RUBY-FILL.com for full Prescribing Information including BOXED WARNING.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088.