



# INDIES PHARMA JAMAICA LTD

"Caring for the Nation's Health"

[www.indiespharma.com](http://www.indiespharma.com)

Member of



June 14, 2023

Chief Regulatory Officer  
Regulatory & Market Oversight Division  
Jamaica Stock Exchange  
40 Harbour Street  
Kingston

**Attention: Mr. Andrae St. P. Tulloch**

Dear Sirs:

**Re: Disclosure of ANDA filing at USFDA, a Paragraph IV filing and Patent Amendment.**

Dear Sir / Madam,

We are pleased to refer to our ANDA (abbreviated new drug application) for Regadenoson Injection, 0.4 mg/5 mL (0.08 mg/mL), dated January 25, 2023, and submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) at the U.S. Food & Drug Administration ("FDA"). We have received Agency's letter titled "PARAGRAPH IV ACKNOWLEDGEMENT ANDA RECEIPT" dated February 28, 2023.

On the 13 June 2023, Indies Pharma has submitted the patent amendment and notified the FDA that the stipulated statutory 45-day period after receipt of notice letter has passed, and no challenge has been filed against Indies Pharma Jamaica Limited by the original patent holder of NDA (new drug application) N022161 noted on the records of the U.S. Food & Drug Administration ("FDA").

Please be guided accordingly.

Yours faithfully,

**INDIES PHARMA JAMAICA**

**PER:**

**VENICE WILLIAMS**

**CORPORATE SECRETARY**

Reg Office: Unit 5 Trade Centre, Catherine Hall, Howard Cook Boulevard, Montego Bay, St. James, Jamaica, West Indies

Distribution Centre: Bioprist HQ Building, 1<sup>A</sup> Pimento Way, Freeport, Montego Bay, Jamaica, West Indies

Toll Free: 1-888-CALL-IPJ (225-5475) • Phone: (876) 940-7984-5 • Fax: (876) 940-7980 • [businessinfo@indiespharma.com](mailto:businessinfo@indiespharma.com)