



107 College Road East  
Princeton, NJ 08540  
Tel: 609.608.1246  
jcalvarez@drreddys.com

**VIA EMAIL – AGO.highcostprescriptiondrugs@vermont.gov**

February 3, 2023

Vermont Attorney General's Office  
109 State Street  
Montpelier, VT 05609

**RE: New Prescription Drug – 30-Day Notice**

Dear Sir or Madam,

In accordance with 18 V.S.A. § 4637, Dr. Reddy's Laboratories, Inc. provides the following notification:

<b>NDC:</b>	43598-0142-06
<b>Product Description:</b>	Nelarabine Inj. 250mg/50mL 6's
<b>Date of Introduction to Market:</b>	1/12/2023
<b>WAC:</b>	\$3,966.00
<b>Description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally</b>	<p>Nelarabine Injection 250mg/50mL SDV (DRL ANDA 216934) is being marketed in the generic multi-source space. Establishing the WAC price for 250mg/50mL SDV at \$3,966.00 constitutes a significant reduction in the WAC pricing of the referenced listed drug, Arranon which, upon information and belief, was \$4,849.02 at the time Dr. Reddy's introduced Nelarabine Injection 250mg/50mL SDV into the market, representing a 18% reduction in price. Dr. Reddy's WAC pricing will enable it to: i) recoup the costs it incurred in evaluating the economic landscape surrounding prospective products; ii) cover distribution costs; iii) provide rebates and discounts as required by partners in the supply chain; and iv) earn a reasonable return on investment.</p> <p>Dr. Reddy's did not develop direct-to-consumer marketing or paid advertising for the product. In addition, we do not directly promote the product to physicians. To the extent that our purchasing agents or buyers are licensed pharmacists or HCPs we may provide them with product sell sheets which include product name, product description, available pack information, and order entry details. The spend on such materials is less than \$5,000 per year.</p>

<p><b>The estimated volume of patients that may be prescribed the drug</b></p>	<p>Dr. Reddy's does not track the estimated number of patients to be prescribed a drug on a monthly basis, due, among other reasons, to the fact that this is a generic product with numerous other generics available. Dr. Reddy's lacks sufficient information to determine the total number of patients who may be prescribed its product given, among other things, (i) the unknown size of the prospective patient population meeting the relevant criteria; (ii) the current existence of numerous other prescription drugs with the same active pharmaceutical ingredient; and (iii) the existence of numerous other prescriptions drugs to treat these same conditions.</p>
<p><b>Was the drug granted breakthrough therapy designation by the federal Food and Drug Administration (FDA) prior to final approval?</b></p>	<p>N</p>
<p><b>Did the drug receive a priority review by the federal Food and Drug Administration prior to final approval?</b></p>	<p>N</p>
<p><b>The date and price of acquisition if the drug was not developed by the manufacturer</b></p>	<p>NA/NA</p>

Please do not hesitate to contact us if you have any questions.

Regards,

Juan Carlos Alvarez  
Government Contracts & Pricing  
Dr. Reddy's Laboratories, Inc.