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VIA EMAIL – AGO.highcostprescriptiondrugs@vermont.gov

January 17, 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:

NDC:	43598-0162-30
Product Description:	Sapropterin Dihydrochloride Sachets, 500 mg (Javygtor), 30 Sachets
Date of Introduction to Market:	12/22/2022
WAC:	\$6,300.00
Description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally	<p>Sapropterin dihydrochloride Javygtor powder 500 mg sachets is the branded generic equivalent of an existing innovator product and is being marketed in the generic multi-source space. Accordingly, establishing the WAC price constitutes parity WAC pricing with the referenced listed drug, Kuvan, which, upon information and belief, was \$6,300.00 at the time. Cycle Pharma will market this product. The WAC pricing will enable Dr. Reddy's to: i) recoup the costs it incurred in evaluating the economic and/or intellectual property landscape surrounding prospective products, sourcing the active pharmaceutical ingredient (API), sourcing excipients, conducting R&D to achieve the acceptable formulation of the product, conducting biostudies, conducting stability studies, developing analytical methods, paying GDUFA and facility fees, submitting the ANDA and responding to FDA deficiencies and inquiries; ii) cover its manufacturing costs; iii) cover the cost of any associated patent litigation, including legal and expert witness fees, if any; iv) cover distribution costs; v) provide rebates and discounts as required by partners in the supply chain; vi) compete with numerous other available generics; and vii) 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>

The estimated volume of patients that may be prescribed the drug	<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. Notwithstanding, according to the National Organization for Rare Disorders, the reported incidence of Phenylketonuria (PKU) from newborn screening programs ranges from one in 13,500 to 19,000 newborns in the United States. However, Dr. Reddy's lacks sufficient information to determine the total number of patients who may be prescribed its Sapropterin dihydrochloride sachets 500mg 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>
Was the drug granted breakthrough therapy designation by the federal Food and Drug Administration (FDA) prior to final approval?	<p>N</p>
Did the drug receive a priority review by the federal Food and Drug Administration prior to final approval?	<p>N</p>
The date and price of acquisition if the drug was not developed by the manufacturer	<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.