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VIA EMAIL – AGO.highcostprescriptiondrugs@vermont.gov

April 24, 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:	43598-0235-31
Product Description:	Cycloserine Capsules 250mg, 30s
Date of Introduction to Market:	03/30/2023
WAC:	\$2,297.00
Description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally	<p>Cycloserine Capsules 250mg, 30s (ANDA 060593) is a single sourced generic product. Dr. Reddy's WAC pricing of \$2,297.00 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>The estimated volume of patients that may be prescribed the drug</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>Was the drug granted breakthrough therapy designation by the federal Food and Drug Administration (FDA) prior to final approval?</p>	<p>N</p>
<p>Did the drug receive a priority review by the federal Food and Drug Administration prior to final approval?</p>	<p>N</p>
<p>The date and price of acquisition if the drug was not developed by the manufacturer</p>	<p>Product was acquired but launched on 3/30/2023 under new Dr. Reddy's NDC. Prevailing WAC during acquisition was \$2,090.00.</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.