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VIA EMAIL – AGO.highcostprescriptiondrugs@vermont.gov

May 14, 2021

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:	43598-0452-02
Product Description:	Albendazole tablets, 200 mg , 2 tablets
Date of Introduction to Market:	4/28/2021
WAC:	$80.00 *Based on a 30-day course of treatment, the WAC exceeds the reporting threshold.

Description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally	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. Albendazole tablets 200mg (ANDA #211034) is the generic equivalent of an existing innovator product and is being marketed in the generic multi-source space. Accordingly, establishing the WAC price at $80 constitutes a significant reduction in the WAC pricing of the referenced listed drug, Albenza which, upon information and belief, was $485.34 at the time Dr. Reddy's introduced Albendazole 200mg into the market, representing a 84% reduction in price. Dr. Reddy's WAC pricing will enable it to: i) recoup the costs it incurred in evaluating the economic and/or intellectual property landscape surrounding a prospective Albendazole 200mg product, 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.
The estimated volume of patients that may be prescribed the drug	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, based on public info, there is a total of 5,300 patients with Neurocysticercosis and Hydatid Disease. Dr. Reddy's lacks sufficient information to determine the total number of patients who may be prescribed its Albendazole 200mg 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.
Was the drug granted breakthrough therapy designation by the federal Food and Drug Administration (FDA) prior to final approval?	No
Did the drug receive a priority review by the federal Food and Drug Administration prior to final approval?	No

The date and price of acquisition if the drug was not developed by the manufacturer	NA/NA

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

Regards,

Juan Alvarez

Digitally signed by Juan Alvarez
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Date: 2021.05.14 09:55:11 -04'00'

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