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VIA EMAIL – AGO.highcostprescriptiondrugs@vermont.gov

October 2, 2020

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

RE: New Prescription Drug – 30-Day Notice

Dear Sir or Madam,

Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's") is providing this information in accordance with 18 V.S.A. § 4637(c), which requires that prescription drug manufacturers notify the Office of the Attorney General and to provide certain information following the release of a drug in the commercial market whose Wholesale Acquisition Cost ("WAC") exceeds the threshold set for a specialty drug under the Medicare Part D Program.

NDC:	43598-0262-02
Product Description:	Fulvestrant Injection 250 mg/5 mL (50 mg/mL)
Date of Introduction to Market:	9/4/2020
WAC:	\$700.00 per pack of 2 Single Dose Pre-Filled Syringes
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.
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, according to the American Cancer Society's estimates for breast cancer in the United States for 2020 approximately 276,480 new cases of invasive breast cancer will be diagnosed in women. However, Dr. Reddy's lacks sufficient information to determine the total number of patients who may be prescribed its Fulvestrant Injection 250 mg/5 mL 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 prescription 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	N/A

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

Regards,

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