teva | Legal Group

January 25, 2019

Via E-mail: AGO.highcostprescriptiondrugs@vermont.gov

Re: New Drug Introduction Report Pursuant to 18 V.S.A. § 4637(c)

To Whom It May Concern:

On January 5, 2019, and pursuant to 18 V.S.A. § 4637(b), Teva Pharmaceuticals USA, Inc. ("Teva") submitted a new drug introduction notice for the following (collectively, the "Product"):

NDC	Product Description
00093-7652-56	VARDENAFIL HCL TABLETS 2.5MG 30
00093-7653-56	VARDENAFIL HCL TABLETS 5MG 30
00093-7654-56	VARDENAFIL HCL TABLETS 10MG 30
00093-7655-56	VARDENAFIL HCL TABLETS 20MG 30

Teva now provides the following additional information pursuant to 18 V.S.A. § 4637(c).

1. **US and international marketing and pricing plans used at launch:** Teva declines to provide this information in accordance with 18 V.S.A. § 4637(d).

2. **Estimated volume of patients:** Projected count of 101,361 patients in 2018, based on IQVIA data.

3. **Whether the FDA granted breakthrough therapy designation or priority review:** The Product did not receive a breakthrough therapy designation or priority review.

4. **Date and price of acquisition:** Not applicable; Teva developed the Product.

* * * *

Teva provides this report consistent with its understanding and interpretation of 18 V.S.A. § 4637 and its provisions. In providing this report, Teva does not waive any rights it may have at law or in equity with respect to 18 V.S.A. § 4637, its interpretation, and/or its application to Teva or any of its affiliates, now or in the future. Teva, on behalf of itself and its affiliates, expressly reserves all such rights.

Thank you for your consideration.

Sincerely,

Brian Savage

Brian Savage
General Counsel, US Generics
Teva Pharmaceuticals USA, Inc.

Teva Pharmaceuticals
425 Privet Road | Horsham, PA 19044 | Tel. 215.293.7283 | Fax. 215.293.6499 | brian.savage@tevapharm.com | www.tevausa.com