May 26, 2021

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 April 30, 2021, and pursuant to 18 V.S.A. § 4637(b), Teva Pharmaceuticals USA, Inc. ("Teva") submitted a new drug introduction notice for the following (the "Product"):

NDC	Product Description	WAC
00591-2433-15	ISOTRETINOIN CAPSULE 10MG 30	$ 763.57
00591-2434-15	ISOTRETINOIN CAPSULE 20MG 30	$ 763.57
00591-2451-15	ISOTRETINOIN CAPSULE 25MG 30	$ 821.56
00591-2435-15	ISOTRETINOIN CAPSULE 30MG 30	$ 821.56
00591-2501-15	ISOTRETINOIN CAPSULE 35MG 30	$ 821.56
00591-2436-15	ISOTRETINOIN CAPSULE 40MG 30	$ 821.56

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:** Estimated average of up to 8050 prescriptions per month (across all dosage strengths), based on historic IQVIA data.

3. **Whether the FDA granted breakthrough therapy designation or priority review:** Yes, priority review was granted for this ANDA.

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

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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,

Maria Lesny
Director Commercial Compliance

Teva Pharmaceuticals
Morris Corporate Center III, Building B | 400 Interpace Parkway | Parsippany, NJ 07054
Tel. 973-658-0228 | Maria.Lesny@tevapharm.com | www.tevausa.com