



April 25, 2023

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 March 31, 2023, 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
00480-2359-56	TOPIRAMATE ER CAPSULE 200MG 30	\$1,125.24
00480-2359-01	TOPIRAMATE ER CAPSULE 200MG 100	\$3,750.75

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).
- 1. Estimated volume of patients:** Research suggests that as many as 21.3 million Americans, in total, suffer from the conditions that this product is indicated to treat.
- 2. Whether the FDA granted breakthrough therapy designation or priority review:** Yes, Priority Review.
- 2. Date and price of acquisition:** Not applicable.

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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,

Jacqueline O’Connell
Director Commercial Compliance