June 16, 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 May 17, 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 PRICE |
|---|---|---|
| 00093-7909-01 | TIOPRONIN ORAL TABLETS 100MG 100CT | $ 2,437.27 |

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:** Research suggests that approximately 13,200 patients in the US suffer from severe homozygous cystinuria, and thus are candidates to take this product.

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.

* * * *

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