August 7, 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 July 9, 2019, pursuant to 18 V.S.A. § 4637(b), American Regent, Inc. (ARI) submitted a new drug introduction notice for the following product:

NDC	Product Description
00517-6560-25	SELENIOUS ACID INJECTION, USP 600 mcg/10mL 25

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

1. **US and international marketing and pricing plans used at launch**: This information is neither publicly available nor in the public domain. Accordingly, pursuant to 18 V.S.A. § 4637(d), which permits manufacturers to limit the information reported to that which is otherwise in the public domain or publicly available, ARI is not providing this information.

2. **Estimated volume of patients:** No information specific to the estimated number of patients that may be prescribed the ARI product is in the public domain or publicly available. Accordingly, pursuant to 18 V.S.A. § 4637(d), which permits manufacturers to limit the information reported to that which is otherwise in the public domain or publicly available, ARI is not providing this information.

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. ARI developed the product.

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A Daiichi Sankyo Group Company

ARI provides this report consistent with its understanding and interpretation of 18 V.S.A. § 4637 and its provisions. In providing this report, ARI 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 ARI or any of its affiliates, now or in the future. ARI, on behalf of itself and its affiliates, expressly reserves all such rights.

Thank you for your consideration,