From: <u>Daniel Worley Jr.</u>

To: AGO - High Cost Prescription Drugs
Subject: Edenbridge - New Drug Notice

Date: Thursday, September 3, 2020 7:47:29 AM

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To Whom It May Concern:

I write to report the launch of a new generic product for Edenbridge Pharmaceuticals, LLC. The NDC is 42799-0708-15, a 15 count box of miglustat capsules, 100mg. The WAC price is \$4018.53 as of our launch on 9/1/2020. Pursuant to 18 V.S.A.§ 4637, we report the following:

- This product is distributed via specialty pharmacy and is priced based on a reduction to the brand product for which Edenbridge's product is a generic (the brand product is Zavesca. As stated above, the WAC for 42799-0708-15 is \$4,018.53 as of September 1, 2020.
- We estimate 100 patients per year across the United States will be prescribed our product. We do not have an estimate on the number of patients in Vermont.
- Our ANDA for this product was not granted breakthrough therapy designation or priority review.
- We developed this product (i.e., it was not an acquisition)

If any other information is needed, please let me know.

Regards,	
Dan	

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