From: Abrams, Jill
To: Abrams, Jill

Subject: Re: Edenbridge - New Drug Notice

Date: Thursday, September 3, 2020 9:29:48 AM

From: Daniel Worley Jr. <dworley@edenbridgepharma.com>

**Sent:** Thursday, September 3, 2020 7:47 AM

To: AGO - High Cost Prescription Drugs <AGO.HighCostPrescriptionDrugs@vermont.gov>

Subject: Edenbridge - New Drug Notice

## **EXTERNAL SENDER:** Do not open attachments or click on links unless you recognize and trust the sender.

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		

Daniel G. Worley Jr., PharmD, RPh, Esq. Associate General Counsel & Sr Director, Business Development Edenbridge Pharmaceuticals, LLC

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