braeburn

June 24, 2023

Via E-Mail: AGO.highcostprescriptiondrugs@vermont.gov

Re: New Drug Report Pursuant to 18 V.S.A. §4637(b)

To the Office of Attorney General:

On May 30, 2023, Braeburn Inc. ("Braeburn") submitted notice of the following FDA approved:

NDC	Product Name	Product Description
58284-0208-01	BRIXADI	BUPRENORPHINE 8MG/0.16 ML
58284-0216-01	BRIXADI	BUPRENORPHINE 16MG/0.32 ML
58284-0224-01	BRIXADI	BUPRENORPHINE 24MG/0.48 ML
58284-0232-01	BRIXADI	BUPRENORPHINE 32MG/0.64 ML
58284-0264-01	BRIXADI	BUPRENORPHINE 64MG/0.18 ML
58284-0296-01	BRIXADI	BUPRENORPHINE 96MG/0.27 ML
58284-0228-01	BRIXADI	BUPRENORPHINE 128MG/0.36 ML

As per 18 V.S.A. §4637(c), Braeburn is now providing additional product information for the aforementioned new drugs.

Marketing and Pricing Plans
Braeburn is not submitting a description of the marketing and pricing plans used in the launch of the aforementioned drugs in the United States and internationally because this information is not in the public domain nor is it publicly available.

Estimated Patient Volume
BRIXADI is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine. It is estimated that there are three million US citizens who have had or currently suffer from opioid use disorder (OUD).

Breakthrough Therapy/Priority Review
BRIXADI was not granted breakthrough therapy designation nor given priority review by the FDA prior to final approval.

Acquisition Date and Price
This is not applicable.

Please feel free to contact me if you have any questions and/or require any additional information.

Regards,

Carmela Crimeni
Director of Pricing and Contracting