Mylan
Better Health for a Better World

To: Office of Attorney General
AGO.highcostprescriptiondrugs@vermont.gov

From: Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Road
Morgantown, West Virginia 26505

Date: October 11, 2018

Re: 18 V.S.A § 4637

In compliance with 18 V.S.A. § 4637, on September 11, 2018 Mylan Pharmaceuticals Inc. ("Mylan") provided written notice to the Office of the Attorney General that it introduced a new prescription drug, Dalfampridine Extended-Release Tablets, 10mg ("the Product"), to the commercial market on September 10, 2018 at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare Part D program.

This letter provides the additional required information by 18 V.S.A. § 4637(c) regarding the Product. Mylan notes that the Office of the Attorney General has not yet prescribed a format for submissions under this section. Further, as authorized by 18 V.S.A. § 4637(d), Mylan has limited the information reported to that which is in the public domain or publicly available.

(1) A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally;

Dalfampridine extended-release tablets are indicated as a treatment to improve walking in adult patients with multiple sclerosis (MS). The Wholesale Acquisition Cost (WAC) for the product in the United States is below:

NDC	Product	Package Size	WAC
0378-0509-91	Dalfampridine Extended-Release Tablets, 10mg	60	$2,323.19

Discounted prices negotiated with customers are confidential. There are no marketing or pricing plans in the United States in the public domain or publicly available. The Product has not yet launched in any international jurisdiction.

(2) the estimated volume of patients who may be prescribed the drug;

No information responsive to this request is in the public domain or publicly available.

(3) whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval;

The Product was granted priority review by the FDA under the NDA for Ampyra®, which is held by Acorda Therapeutics, Inc.

(4) the date and price of acquisition if the drug was not developed by the manufacturer.

The Product is an authorized generic of the branded product, Ampyra®, an Acorda Therapeutics, Inc. product. As such, Mylan and Acorda are subject to an Authorized Generic Distribution and Supply Agreement, the terms of which are confidential and proprietary and therefore not available in the public domain or publicly available.