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: December 21, 2018

Re: 18 V.S.A § 4637

Pursuant to 18 V.S.A. § 4637, Mylan Pharmaceuticals Inc. ("Mylan") would typically provide written notice that it introduced a new prescription drug to market at a wholesale acquisition cost that is over the threshold set for a specialty drug under the Medicare Part D program. However, as described further below, a circumstance has arisen in which we do not believe the requirements of 18 V.S.A. § 4637 apply.

Due to the shortage of penicillamine titratable tablets in the U.S. market, Mylan is coordinating with the U.S. Food and Drug Administration (FDA) to temporarily import penicillamine 125 mg tablets to address a critical drug shortage of penicillamine 250 mg titratable tablets. Mylan has initiated temporary importation of D-PENAMINE (D-penicillamine) tablets, 125 mg (not scored), Bottle of 100 ("D-PENAMINE"), which are distributed in Australia by Alphapharm Pty Limited, an FDA inspected Mylan facility in Carole Park, Australia. FDA has not approved Mylan's D-PENAMINE in the United States and does not intend to initiate regulatory action for violations of applicable section 582(b) requirements of the Federal Food, Drug, and Cosmetic Act during this temporary period and only for this product lot. On December 19, 2018, Mylan began selling D-PENAMINE at a wholesale acquisition cost of $2,908.07.

Mylan does not believe that it is the intent of the statute to require notification for drugs imported on a limited basis in response to critical shortages under 18 V.S.A § 4637; therefore, in the absence of further guidance from Vermont, Mylan will not be submitting any follow-up thirty-day notice for the D-PENAMINE product and will not be submitting initial or thirty-day notices of launch for any future drugs imported on a limited basis in response to critical shortages.