October 18, 2019

AGO.highcostprescriptiondrugs@vermont.gov

Report Concerning a New Prescription Drug Pursuant to 18 V.S.A. § 4637(c)

Dear Office of the Vermont Attorney General,

Par Pharmaceutical, Inc. ("Par") is issuing this notice pursuant to 18 V.S.A. § 4637(c), which asks prescription drug manufacturers to report certain information to the Office of the Attorney General (the "Office") within thirty calendar days of providing initial notice to the Office that the manufacturer has released a drug in the commercial market whose wholesale acquisition cost ("WAC") exceeds the threshold set for a specialty drug under the Medicare Part D Program.

On September 20, 2019 Par informed the Office that it introduced Nitisinone into the commercial market at a WAC that exceeds the threshold set for a specialty drug under the Medicare Part D Program.

Below is the information related to Nitisinone, issued pursuant to 18 V.S.A. § 4637(c). Consistent with 18 V.S.A. § 4637(d), Par has limited the below information to what Par believes is otherwise in the public domain or publicly available.

18 V.S.A. § 4637(c) Reporting Requirement	**Response for Nitisinone**
Description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally	Par does not believe this information is otherwise in the public domain or publicly available. Accordingly, Par is limiting its response to this item pursuant to 18 V.S.A. § 4637(d).

18 V.S.A. § 4637(c) Reporting Requirement	Response for Nitisinone
Estimated volume of patients who may be prescribed the drug	This product is indicated for Tyrosinemia Type 1. Publicly available information indicates that between 100-200 cases have been diagnosed in the United States. *See, e.g.*, https://www.centerwatch.com/drug-information/fda-approved-drugs/drug/765/orfadin-nitisinone; https://www.orfadin.com/support; https://www.businesswire.com/news/home/20181119005482/en/Longer-shelf-life-NITYR-nitisinone-tablets-HT-1.
Whether the drug was granted breakthrough therapy designation by the federal Food and Drug Administration prior to final approval	No.
Whether the drug was granted priority review by the federal Food and Drug Administration prior to final approval	No.
The date and price of acquisition if the drug was not developed by the manufacturer	Not applicable. Par did not acquire this product from another manufacturer.

In the event 18 V.S.A. § 4637 is found invalid, Par reserves all of its legal rights. In issuing this notice in an attempt to comply with 18 V.S.A. § 4637, Par does not waive any legal claims or legal rights related to potential constitutional defects with 18 V.S.A. § 4637.

Sincerely,

Gregory Halen

Gregory Halen, Manager Government Contracts and Pricing