

## 2 Research Way Suite 1A Princeton, NJ 08540

June 7, 2023

To: Office of the Vermont Attorney General

From: Analog Pharma

Subject: Compliance to Vermont state law V.S.A.§ 4637 (Notice of Introduction of New High-Cost Prescription Drugs) NITISINONE 20mg capsules.

NDC11	NDC Description
70505-0220-60	NITISINONE capsules, for oral use 20 mg.

In compliance with Vermont's state law V.S.A.§ 4637 (Notice of Introduction of New High-Cost Prescription Drugs), this letter provides additional information on NITISINONE 20mg which was available on June 5, 2023. *Responses are italicized*.

- (1) a description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally; Orphan (generic) drug, extremely rare disease with less than three hundred patients and price is below the brand. There is a website for Health Care Professionals (HCPs) and patients.
- (2) the estimated volume of patients who may be prescribed the drug; < 50 at peak sales
- (3) whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval; *No*
- (4) the date and price of acquisition if the drug was not developed by the manufacturer; N/a

If you have any questions or comments, please let me know.

Best,

John Conville

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