



January 5, 2024

Office of the Vermont Attorney General  
109 State Street  
Montpelier, VT 05609

**RE: Notice of a New Prescription Drug Pursuant to 18 V.S.A. § 4637**

Dear Office of the Vermont Attorney General,

Amneal Pharmaceuticals, LLC (“Amneal”) is issuing this notice pursuant to 18 V.S.A. § 4637(c), which requires prescription drug manufacturers to provide the Office of the Attorney General (the “Office”) with certain information following the release of 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.

Amneal released Nitrofurantoin Oral Suspension, USP (“the Product”) into the market on January 2, 2024, at a WAC that exceeds the threshold set for a specialty drug under the Medicare Part D program. This notice provides the additional required information by 18 V.S.A. § 4637(c) regarding the Product. Amneal notes that the Office of the Attorney General has not yet set forth and released a format for submissions under this section. Furthermore, as authorized by 18 V.S.A. § 4637(d), Amneal has limited the information reported to that which is in the public domain or publicly available.

NDC	Product	Package Size	WAC
69238-2512-09	Nitrofurantoin Oral Suspension, USP	230	\$1,142.96

Statutory Requirement	Reported Information
A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally <i>18 V.S.A. § 4637(c)(1)</i>	Pursuant to 18 V.S.A. § 4637(d), Amneal has elected to limit its response to this item due to the requested information not being publicly available and in the public domain.
The estimated volume of patients that may be prescribed the drug <i>18 V.S.A. § 4637(c)(2)</i>	NDC 69238-2512-09: 10,815
Was the drug granted breakthrough therapy designation or priority review by the federal Food and Drug Administration prior to final approval? <i>18 V.S.A. § 4637(c)(3)</i>	Breakthrough Therapy Designation – No Priority Review – No
The date and price of acquisition if the drug was not developed by the manufacturer <i>18 V.S.A. § 4637(c)(4)</i>	Not Applicable

Sincerely,



William E. Riker  
Senior Director, Pricing & Contracts