March 16, 2023

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 Lioresal ® Intrathecal (Baclofen) 40mg/20 mL (2000mcg/mL) ("the Product") into the market on March 14, 2023, 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
70121-2503-01	Lioresal ® Intrathecal 40mg/20 mL (2000mcg/mL)	1	$945.14
70121-2505-02	Lioresal ® Intrathecal 40 mg/20 mL (2000 mcg/mL)	2	$1,890.28

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270.678.9393 main | 866.525.7271 fax | amneal.com

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 *18 V.S.A. § 4637(c)(1)*	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 *18 V.S.A. § 4637(c)(2)*	NDC 70121-2503-01: 60,168 NDC 70121-2505-02: 31,080
Was the drug granted breakthrough therapy designation or priority review by the federal Food and Drug Administration prior to final approval? *18 V.S.A. § 4637(c)(3)*	Breakthrough Therapy Designation – No Priority Review – Yes
The date and price of acquisition if the drug was not developed by the manufacturer *18 V.S.A. § 4637(c)(4)*	February 9, 2022

Sincerely,

William E Riker

William E. Riker
Senior Director, Pricing & Contracts

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