

To: Office of the Vermont Attorney General
AGO.highcostprescriptiondrugs@vermont.gov

From: Sandoz Inc.
100 College Road West
Princeton, NJ 08540

Date: April 27, 2023

Re: Vermont Act 193 (18 V.S.A. §4637)

On January 10, 2023, Sandoz Inc. (“Sandoz”) notified the Office of the Vermont Attorney General (“Attorney General”) of a new prescription drug, chlorpromazine oral solution, pursuant to 18 V.S.A §4637(b).

NDC	Drug Product Description	Introduced to Market Date	WAC at Introduction
00781-4028-22	CHLORPROMAZINE 100MG/ML 240ML 1SOL BO US	3/31/2023	\$2,160.00

Sandoz hereby notifies the Attorney General of the additional information required, pursuant to 18 V.S.A §4637(c).

Statutory Requirement	Reporting Information
A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally	This launch is specific to the U.S. Sandoz Inc. is contracting within the wholesaler and/or specialty pharmacy space. The WAC is priced equal to the previous manufacturer.
The estimated volume of patients who may be prescribed the drug	Chlorpromazine Oral Solution is indicated for the treatment of multiple conditions including but not limited to the following: the management of manifestations of psychotic disorders, the treatment of schizophrenia, to control nausea and vomiting. For relief of restlessness and apprehension before surgery, for acute intermittent porphyria, as an adjunct in the treatment of tetanus. To control the manifestations of the manic type of manic-depressive illness, for relief of intractable hiccups, for the treatment of severe behavioral problems in children (1 to 12 years of age) marked by combativeness and/or explosive hyper excitable behavior (out of proportion to immediate provocations), and in the short-term treatment of hyperactive children who show excessive motor activity with accompanying conduct disorders consisting of some or all of the following symptoms: impulsivity, difficulty sustaining attention, aggressivity, mood lability and poor frustration tolerance. There is an estimated 139,710 patients treated with Chlorpromazine Oral Solution in the United States. Source: DailyMEd, FDA label
Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval	N/A
The date and price of acquisition if the drug was not developed by the manufacturer	12/22/2022 \$1,400,000.00

Sandoz Inc. provides this report consistent with its understanding and interpretation of Vermont Act 193 (18 V.S.A. § 4637) and its provisions. In providing this report, Sandoz Inc. does not waive any rights that may have at law or in equity with respect to the applicability, interpretation, or application of Vermont Act 193 (18 V.S.A. § 4637) as it may relate to Sandoz Inc. or any of its affiliates now or in the future. Sandoz Inc., on behalf of itself and affiliates, expressly reserves all such rights. We believe that all information submitted by Sandoz Inc. to the Department of Vermont Health Access or to the Attorney General under Vt. Stat. tit. 18 §§ 4635 or 4637, including all information contained in this submission, is confidential and proprietary commercial or financial information not subject to disclosure, including under the Vermont Public Records Act (Subchapter 3 of Chapter 5 of the Vermont Statutes) and applicable laws pertaining to trade secrets. We request that your company or organization maintain the confidentiality of this submission and of all Sandoz Inc.'s related information herein to the maximum extent permitted by law. To the extent that any of this designated information is requested, whether under Vermont Public Records Act (Subchapter 3 of Chapter 5 of the Vermont Statutes) or otherwise, we request that your company or organization notify us of the request and afford us the opportunity to submit objections to disclosure.

For any questions concerning this notification, please contact:
state.transparency@sandoz.com.