

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

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

Date: June 27, 2019

Re: Vermont Act 193 (18 V.S.A. §4637)

On May 30, 2019, Sandoz Inc. ("Sandoz") notified the Office of the Vermont Attorney General ("Attorney General") of a new prescription drug, Fulvestrant, pursuant to 18 V.S.A §4637(b).

NDC	Drug Product Description	Introduced to Market Date	WAC at Introduction
00781307912	FULVESTRANT 250MG/5ML 2LISY	5/29/2019	\$ 1,745.15

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 is currently contracting within the oncology space. The WAC is priced lower than the WAC of the reference product.
The estimated volume of patients who may be prescribed the drug	Sandoz's Fulvestrant Injection is a hormonal therapy medicine used to treat breast cancer in women with: Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer, who have gone through menopause and have not been previously treated with endocrine therapy, HR-positive advanced breast cancer, who have gone through menopause and whose disease has progressed after endocrine therapy, HR-positive, HER2-negative advanced breast cancer or breast cancer that has spread to other parts of the body (metastatic), in combination with palbociclib or abemaciclib in women whose disease has progressed after endocrine therapy. According to Kantar Health, there is an estimated 187,628 patients with this condition in the United States.
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	N/A

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.