SANDOZ A Novartis Division

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

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

Date: December 10, 2019

Re: Vermont Act 193 (18 V.S.A. §4637)

On November 13, 2019, Sandoz Inc. ("Sandoz") notified the Office of the Vermont Attorney General ("Attorney General") of a new prescription drug, Ziextenzo (pegfilgrastim-bmez), pursuant to 18 V.S.A §4637(b).

NDC	Drug Product Description	Introduced to Market Date	WAC at Introduction
61314086601	ZIEXTENZO 6MG/0.6ML 1LISY	11/12/2019	$ 3,925.53

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., however, Sandoz biosimilar pegfilgrastim has been approved and marketed in Europe as Ziextenzo (pegfilgrastim) since 2018. Sandoz Inc. 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	>650,000 patients with cancer receive chemotherapy annually in the United States. Treatment of cancer with chemotherapy may lead to bone marrow suppression, which can mask the early signs and symptoms of an infection as well as diminish the patient's capacity to fight infections. Neutropenia and subsequent infectious complications are some of the most serious treatment-related toxicities of chemotherapy for cancer and result in preventable morbidity and mortality. Previous estimates indicate that >60,000 persons with cancer are hospitalized with neutropenia and >4,000 persons die of febrile neutropenia each year in the United States. To decrease the incidence of infection to Patients with cancer receiving myelosuppressive chemotherapy . For 2012, sources identified 91,560 cancer-related neutropenia hospitalizations among adults and 16,859 cancer-related neutropenia hospitalizations among children in the NIS and KID data. According to the CDC, there is an estimated 108,419 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	N/A

not developed by the manufacturer	

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.