

Pfizer Inc.
235 East 42nd Street
New York, NY 10017



October 5, 2018

Office of the Vermont Attorney General

Notice of a New Prescription Drug Pursuant to 18 V.S.A. § 4637(c)

Dear Office of the Vermont Attorney General,

Pfizer Inc. ("Pfizer") 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.

Pfizer released Nivestym™ (filgrastim-aafi) injection into the commercial market on September 5, 2018. Pfizer anticipates Nivestym's™ WAC to exceed the threshold set for a specialty drug under the Medicare Part D Program.

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.	Pfizer does not believe this information is publicly available and has not released this information in the public domain. Accordingly, Pfizer is limiting its response to this item pursuant to 18 V.S.A. § 4637(d).
The estimated volume of patients that may be prescribed the drug.	Pfizer does not believe this information is publicly available and has not released this information in the public domain. Accordingly, Pfizer is limiting its response to this item pursuant to 18 V.S.A. § 4637(d).
Was the drug granted breakthrough therapy designation by the federal Food and Drug Administration (FDA) prior to final approval?	Nivestym™ (filgrastim-aafi) injection did not receive breakthrough designation by the federal FDA. ⁱ
Did the drug receive a priority review by the federal Food and Drug Administration prior to final approval?	Nivestym™ (filgrastim-aafi) injection did not receive priority review by the federal FDA. ⁱⁱ

Statutory Requirement	Reporting Information
The date and price of acquisition if the drug was not developed by the manufacturer.	<p>Hospira, Inc. acquired the worldwide rights to Nivestym™ (filgrastim-aafi) injection from PLIVA Hrvatska d.o.o. (Zagreb, Croatia) (ZSE: PLVA-R-A) on September 30, 2009.ⁱⁱⁱ Pfizer acquired Hospira, Inc. on September 3, 2015.^{iv}</p> <p>Pfizer does not believe the acquisition price of Nivestym™ (filgrastim-aafi) injection is publicly available and has not released this information in the public domain. Accordingly, Pfizer is limiting its response to this item pursuant to 18 V.S.A. § 4637(d).</p>

In the event Vermont S. 92 and the laws it implements, including 18 V.S.A. § 4637, are found invalid, Pfizer reserves all of its legal rights. In issuing this notice in an attempt to comply with 18 V.S.A. § 4637, Pfizer does not waive any legal claims or legal rights related to potential constitutional defects with Vermont S. 92.

Sincerely,



John Kennedy
Vice President, US Biosimilars
Pfizer Inc.

For any questions concerning this notification please contact: StateLawReporting@Pfizer.com

ⁱ U.S. Food and Drug Administration, Breakthrough Therapy Approvals. Available at: <https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/drugandbiologicapprovalreports/ndaandblaapprovalreports/ucm373418.htm>. Last accessed September 21, 2018.

ⁱⁱ Food and Drug Administration Application Number BLA 761080. Hospira, Inc. Available at: <https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/UCM617300.pdf>. Last accessed September 21, 2018.

ⁱⁱⁱ Hospira, Inc. (2009, September 30). *Hospira Acquires Worldwide Rights to Biogeneric Version of Filgrastim and Manufacturing Facility From PLIVA* [Press release]. Available at <http://phx.corporate-ir.net/phoenix.zhtml?c=175550&p=irol-newsArticle&ID=1336833>. Last accessed September 21, 2018.

^{iv} Pfizer Inc. (2015, September 3). *Pfizer Completes Acquisition of Hospira* [Press release]. Available at: <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-completes-acquisition-of-hospira>. Last accessed September 21, 2018.