

Pfizer Inc.  
235 East 42<sup>nd</sup> Street  
New York, NY 10017



September 7, 2018

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

Dear Office of the Vermont Attorney General,

Pfizer Inc. ("Pfizer") is issuing this notice pursuant to 18 V.S.A. § 4637(b), which requires prescription drug manufacturers to provide the Office of the Attorney General (the "Office") written notice within three calendar days of releasing 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.

18 V.S.A. § 4637 does not currently define "release of the drug in the commercial market." Further, Pfizer is not aware of any guidance issued by the Office or any Vermont regulation that defines "release of the drug in the commercial market" for the purpose of 18 V.S.A. § 4637.

As a result, Pfizer considers a drug to be "release[d] . . . in the commercial market" when Pfizer publishes a trade letter to wholesale customers announcing the introduction of the new drug and begins accepting orders for the drug.

Please note that the WAC-related information provided in this notice may be subject to change.

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,

A handwritten signature in blue ink, appearing to read "JK", written over a light blue horizontal line.

John Kennedy  
Vice President, US Biosimilars  
Pfizer Inc.

For any questions concerning this notification please contact: [StateLawReporting@Pfizer.com](mailto:StateLawReporting@Pfizer.com)