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VIA ELECTRONIC MAIL (AGO.highcostprescriptiondrugs@vermont.gov)

July 18, 2019

Office of The Attorney General
State of Vermont
Attn: TJ Donovan, Attorney General
109 State Street
Montpelier, VT 05609

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

Dear Mr. Donovan:

On June 19, 2019, GlaxoSmithKline ("GSK") issued a notice pursuant to 18 V.S.A §4637(b) to inform you that on June 17, 2019 GSK introduced two new prescription drugs to market (in the U.S. and Vermont) at a wholesale acquisition price above the threshold set for a specialty drug under the Medicare Part D program.
The two new drugs, listed below with their respective NDCs, were:

(1) NUCALA, NUCALA INJ 100MG/ML (NDC:00173089201); and
(2) NUCALA, NUCALA INJ 100MG/ML (NDC:00173089242)

This letter is to provide reporting requirements under 18 V.S.A §4637 (c).

Reporting Requirement Under 18 V.S.A §4637(c)	**Reporting Requirement Response for NUCALA (NDC:00173089201)**
(1) a description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally	GSK has not made marketing and pricing plans available in the public domain and is limiting its response to information that which is otherwise in the public domain or publicly available under 18 V.S.A §4637(d)
(2) the estimated volume of patients who may be prescribed the drug	There is no specific information regarding the estimated volume of patients who may be prescribed Nucala (NDC:00173089201) for Severe Eosinophilic Asthma available in the public domain. GSK is limiting its response to information that which is otherwise in the public domain or publicly available under 18 V.S.A §4637(d). Nucala's (NDC:00173089201) second indication is for Eosinophilic Granulomatosis with

	Polyangiitis (EGPA). Approximately five people out of every one million will be diagnosed with EGPA each year worldwide. Diagnosed patients may or may not be prescribed Nucala (NDC:00173089201) depending on their known resistance to the medicines and other patient specific factors such as allergic reactions or other medical conditions that may preclude a patient's ability to be effectively treated with Nucala (NDC:00173089201).
(3) whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval	Nucala (NDC:00173089201) was not granted breakthrough therapy designation or priority review by the FDA prior to final approval
(4) the date and price of acquisition if the drug was not developed by the manufacturer	Nucala (NDC:00173089201) was developed by GSK

Reporting Requirement Under 18 V.S.A §4637(c)	**Reporting Requirement Response for NUCALA (NDC:00173089242)**
(1) a description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally	GSK has not made marketing and pricing plans available in the public domain and is limiting its response to information that which is otherwise in the public domain or publicly available under 18 V.S.A §4637(d)
(2) the estimated volume of patients who may be prescribed the drug	There is no specific information regarding the estimated volume of patients who may be prescribed Nucala (NDC:00173089242) for Severe Eosinophilic Asthma available in the public domain. GSK is limiting its response to information that which is otherwise in the public domain or publicly available under 18 V.S.A §4637(d). Nucala's (NDC:00173089242) second indication is for Eosinophilic Granulomatosis with Polyangiitis (EGPA). Approximately five people out of every one million will be diagnosed with EGPA each year worldwide. Diagnosed patients may or may not be prescribed Nucala (NDC:00173089242) depending on their known resistance to the medicines and other patient specific factors such as allergic reactions or other medical conditions that may preclude a patient's ability to be effectively treated with Nucala (NDC:00173089242).
(3) whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval	Nucala (NDC:00173089242) was not granted breakthrough therapy designation or priority review by the FDA prior to final approval
(4) the date and price of acquisition if the drug was not developed by the manufacturer	Nucala (NDC:00173089242) was developed by GSK

Yours very truly,

Nick Vigliarolo
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