AGO.highcostprescriptiondrugs@vermont.gov

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

Dear Office of the Vermont Attorney General,

Fresenius Kabi USA, LLC ("Fresenius Kabi") is issuing this notice pursuant to 18 V.S.A. § 4637(b), which asks 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 cst ("WAC") exceeds the threshold set for a specialty drug under the Medicare Part D Program.

On March 7, 2023, Fresenius Kabi informed potential customers the following drug products are available for order:

NDC	Description	WAC
65219-0566-20	mitoMYcin Intravenous Solution	\$631.98
	Reconstituted 20 MG	

The WAC for the drug product(s) identified above exceeds the threshold set for a specialty drug under the Medicare Part D Program. Please note that the WAC-related information provided in this notice may be subject to change.

18 V.S.A. § 4637 does not currently define "release of the drug in the commercial market." Further, Fresenius Kabi 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. Fresenius Kabi interprets "release of the drug in the commercial market" to mean when it is available for purchase by the channel.

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

Sincerely,
Sanjida F. Chowdhury
Vice President, Government Pricing and Compliance
Chief Compliance Officer, North America
(847) 550-2300