

CONFIDENTIAL & PROPRIETARY / TRADE SECRET
NOT SUBJECT TO DISCLOSURE UNDER THE FREEDOM OF INFORMATION ACT OR
VERMONT PUBLIC RECORDS LAW

VIA E-MAIL

June 23, 2020

Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404

Office of the Vermont Attorney General
Attention: Attorney General, TJ Donovan
109 State Street
Montpelier, VT 05609
AGO.highcostprescriptiondrugs@vermont.gov

Dear Attorney General Donovan:

This letter provides information, as required by Section 4637 of Vermont Act 193, as codified at Vermont Statutes Annotated, Title 18 (“Act 193”). This report is in addition to the notice Gilead Sciences, Inc. (“Gilead”) provided to the Office of the Attorney General (the “Office”) on May 29, 2020 regarding the market entry of SOVALDI® (sofosbuvir) oral pellets (NDCs 61958-1504-01 and 61958-1505-01; “SOVALDI oral pellets”) and HARVONI® (ledipasvir and sofosbuvir) oral pellets (NDCs 61958-1805-01 and 61958-1804-01; “HARVONI oral pellets”) on May 26, 2020.

This letter provides the information required by Section 4637(c) of Act 193 for both drugs, in the chart below:

Section 4637(c) Reporting Requirements	Response for SOVALDI oral pellets	Response for HARVONI oral pellets
A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally.	Consistent with Section 4637(d) of Act 193, Gilead is limiting its response to that which is otherwise in the public domain or publicly available. This information is not in the public domain or publicly available.	
The estimated volume of patients that may be prescribed the drug.	Consistent with Section 4637(d) of Act 193, Gilead is limiting its response to that which is otherwise in the public domain or publicly available. This information is not in the public domain or publicly available.	
Was the drug granted breakthrough therapy designation by the federal Food and Drug Administration prior to final approval?	Gilead did not apply for breakthrough therapy designation for this drug product.	
Did the drug receive a priority review by the federal Food and Drug Administration prior to final approval?	Yes, the drug product received a priority review by the FDA.	

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The date and price of acquisition if the drug was not developed by the manufacturer.	This information is not applicable.
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Lastly, we understand that, pursuant to Section 4637(e) of Act 193, the Office will publish information reported pursuant to Section 4637 on its website. Accordingly, we have attached a single-page version of this notice the Office can publish on its website while preserving the signatory's right to privacy, consistent with Section 317(c)(10) of Title 1 of the Vermont Statutes Annotated. We ask that the Office only publish the single-page version of this notice on its website, pursuant to Section 4637(e) of Act 193.

Sincerely,

Kristie Banks
Vice President
Managed Markets Strategy & Operations

Notice of New Drug Pursuant to Section 4637 of Vermont Act 193

This letter provides information, as required by Section 4637 of Vermont Act 193, as codified at Vermont Statutes Annotated, Title 18 (“Act 193”). This report is in addition to the notice Gilead Sciences, Inc. (“Gilead”) provided to the Office of the Attorney General (the “Office”) on May 29, 2020 regarding the market entry of SOVALDI® (sofosbuvir) oral pellets (NDCs 61958-1504-01 and 61958-1505-01; “SOVALDI oral pellets”) and HARVONI® (ledipasvir and sofosbuvir) oral pellets (NDCs 61958-1805-01 and 61958-1804-01; “HARVONI oral pellets”) on May 26, 2020.

This letter provides the information required by Section 4637(c) of Act 193 for both drugs, in the chart below:

Section 4637(c) Reporting Requirements	Response for SOVALDI oral pellets	Response for HARVONI oral pellets
A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally.	Consistent with Section 4637(d) of Act 193, Gilead is limiting its response to that which is otherwise in the public domain or publicly available. This information is not in the public domain or publicly available.	
The estimated volume of patients that may be prescribed the drug.	Consistent with Section 4637(d) of Act 193, Gilead is limiting its response to that which is otherwise in the public domain or publicly available. This information is not in the public domain or publicly available.	
Was the drug granted breakthrough therapy designation by the federal Food and Drug Administration prior to final approval?	Gilead did not apply for breakthrough therapy designation for this drug product.	
Did the drug receive a priority review by the federal Food and Drug Administration prior to final approval?	Yes, the drug product received a priority review by the FDA.	
The date and price of acquisition if the drug was not developed by the manufacturer.	This information is not applicable.	