

# UPSHER-SMITH

October 5, 2021

To: The Office of Attorney General of Vermont

Via: Electronic Mail at [AGO.highcostprescriptiondrugs@vermont.gov](mailto:AGO.highcostprescriptiondrugs@vermont.gov)

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

To Whom It May Concern:

As required by 18 V.S.A. § 4637(c), and within thirty calendar days of the initial notice provided on 9/22/2021, Upsher-Smith Laboratories, LLC is providing further information on the introduction of a new prescription drug with a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare Part D program:

Manufacturer Name	Name of Prescription Drug	NDC
Upsher-Smith Laboratories, LLC.	Isotretinoin 10 mg Capsules, USP	0245-0570-01
Upsher-Smith Laboratories, LLC.	Isotretinoin 20 mg Capsules, USP	0245-0571-01
Upsher-Smith Laboratories, LLC.	Isotretinoin 30 mg Capsules, USP	0245-0573-01

As required by 18 V.S.A. § 4637(c), Upsher-Smith Laboratories, LLC now provides the following additional information regarding the Product:

**Marketing and Pricing Plans Used in Launch:** This product is a generic medication and it will not be marketed. Upsher-Smith Laboratories, LLC intends to provide the product at a competitive price based off the current market landscape today.

**Estimated Volume of Patients:** Upsher-Smith Laboratories, LLC estimates the volume of patients at 1,800,000 based on IQVIA prescription data.

**Breakthrough Therapy Designation or Priority Review:** The product was not granted priority review and did not receive a breakthrough therapy designation from the FDA.

**Date and Price of Acquisition:** The product was not the result of an acquisition.

Sincerely,

Brent Eilefson  
VP, Legal Affairs, Chief Compliance Officer  
Upsher-Smith Laboratories, LLC

## Upsher-Smith Laboratories, LLC

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