

Rotblatt, Hart

From: Catherine St. John <Catherine.StJohn@kadmon.com>
Sent: Tuesday, November 19, 2019 1:58 PM
To: AGO - High Cost Prescription Drugs
Cc: Kadmon Legal
Subject: RE: Pursuant to 18 V.S.A.§ 4637 (Notice of Introduction of New High-Cost Prescription Drugs)

To Whom It May Concern:

This is to provide information regarding the new prescription drug below as required by 18 V.S.A.§ 4637:

(1) a description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally;	Kadmon announced the product’s approval and also made a copay savings card available to eligible patients. Marketing initiatives include print and digital media, engagement at scientific meetings attended by HCPs most likely to manage patients with Wilson’s disease, materials to be used by sales representatives to share information on Clovique with prescribers, and materials to educate patients about Clovique and Wilson’s disease. Pricing methodology is based on cost (including development and manufacturing costs) and the market (including the current number of generic competitors and the number of generic competitors expected to enter the market).
(2) the estimated volume of patients who may be prescribed the drug;	The prevalence of Wilson’s disease in the US is approximately 7000-9000 patients. Reference: Ferenci P, Askari F. Whom and how to screen for Wilson disease. Expert Rev. Gastroenterol. Hepatol. 8(5), 513-520 (2014).
(3) whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval; and	No.
(4) the date and price of acquisition if the drug was not developed by the manufacture	NA.

Thank you,

Cate St. John



Catherine St. John | Senior Director, FDA Compliance & Regulatory Counsel
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From: Catherine St. John
Sent: Thursday, October 24, 2019 8:27 AM
To: 'AGO.highcostprescriptiondrugs@vermont.gov' <AGO.highcostprescriptiondrugs@vermont.gov>
Cc: Kadmon Legal <Legal@kadmon.com>
Subject: Pursuant to 18 V.S.A. § 4637 (Notice of Introduction of New High-Cost Prescription Drugs)

To Whom It May Concern:

This is to provide notice that Kadmon Pharmaceuticals, LLC has introduced a new prescription drug to market at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under Medicare Part D. The information is below:

Full trade name of the drug	Clovique™ Trientine hydrochloride capsules, USP and Trientine hydrochloride capsules, USP
11-digit National Drug Code (NDC) for the drug product	66435-700-10 and 66435-0700-20

Further required information will be provided within 30 days (November 23, 2019).

Thank you,
Cate St. John