

Waylis Therapeutics LLC
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June 11, 2021

Office of the Vermont Attorney General
Notice of Introduction of New High-Cost Prescription Drugs

RE: Humatin Oral Capsule, 250mg

Dear Sir:

Pursuant to 18 V.S.A. § 4637, this is to notify the Office of Attorney General that Waylis Therapeutics LLC is introducing a new prescription drug to the market at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare Part D program. As required, we submit the following information:

- (1) a description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally. **Marketing and pricing plans were based on therapy.**
- (2) the estimated volume of patients who may be prescribed the drug; approximately **3,500**
- (3) whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval. **This drug was not granted breakthrough therapy designation.**
- (4) the date and price of acquisition if the drug was not developed by the manufacturer. **N/A**

If there are any questions or comments regarding this submission, please contact me via at (813) 927-9302 or through email mgoodhead@pharmaprojectsolutions.com

Sincerely,

Melissa L. Goodhead, MSc., RAC
US Regulatory Agent for
Waylis Therapeutics LLC