From: <u>James Giuliano</u>

To: AGO - High Cost Prescription Drugs
Cc: Wanda Agrinsoni; Carmela Crimeni

Subject: New Drug Introduction Report- Ascend Laboratories

Date: Monday, September 9, 2019 11:45:44 AM

To the Office of Attorney General:

On July 8, 2019, Ascend Laboratories, LLC ("Ascend") introduced the following drugs into the market:

NDC Number	Drug Product Description
67877-0503-30	Cinacalcet 30mg 30 Tabs
67877-0504-30	Cinacalcet 60mg 30 Tabs
67877-0505-30	Cinacalcet 90mg 30 Tabs

Pursuant to 18 V.S.A. §4637(c), Ascend provides the following additional product information listed below.

- 1. US and international marketing and pricing plans used at launch
 - a. Because this information is not in the public domain or publicly available and is confidential, Ascend declines to provide this information in accordance with 18 V.S.A. §4637(d).
- 2. Estimated volume of patients
 - a. The estimated number of patients who may be prescribed Cinacalcet is not in the public domain, not publicly available, and is confidential. Additionally, Ascend does not have any information on the estimated volume of patients.
- 3. Whether the FDA granted breakthrough therapy designation or priority review
 - a. Neither breakthrough therapy designation nor priority review was granted by the FDA.
- 4. Date and price of acquisition
 - a. This is inapplicable Ascend did not acquire the product from another manufacturer.

Please feel free to contact me if you have any questions and/or require any additional information.

Thanks,

Jim Giuliano