March 16, 2023

To Whom it May Concern,

Pursuant to 18 V.S.A. § 4637(c), please find below the required information submitted by Boehringer Ingelheim Pharmaceuticals, Inc. within 30 days of the notification pursuant to 18 V.S.A. § 4637(b) for Pradaxa Oral Pellets.

(1) a description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally	Specific Marketing and Pricing Plans for Pradaxa Oral Pellets are not in the public domain or publicly available. Boehringer Ingelheim considered several factors in determining the price of Pradaxa Oral Pellets. This included: the value of innovative medicines, investments made (including research and development), manufacturing and other costs and the risks undertaken, and the market size (patient population). Boehringer Ingelheim invests 20% of its net sales into research and development.
(2) the estimated volume of patients who may be prescribed the drug	Pradaxa Oral Pellets is an approved treatment option for venous thromboembolic events (VTE) in pediatric patients aged 3months to less than 12 years of age who have been treated with a parenteral anticoagulant for at least 5 days. The annual incidence of pediatric VTE in the US ranges from 1.4 to 11.9 per 100,000 persons aged 0 - 12 years. In the US, there are an estimated ~700 to 6000 pediatric VTE incidences, a fraction of which would be treated with Pradaxa Oral Pellets in a given year.
(3) whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval	Pradaxa Oral Pellets was granted priority review by the FDA prior to final approval.
(4) the date and price of acquisition if the drug was not developed by the manufacturer	N/A

Boehringer Ingelheim has limited information above to that which is otherwise in the public domain or publicly available. Please let me know if you have any further questions.

Sincerely,

Benjamin Yao

Benjamin Yao
Director, US Compliance Operations