No.31015/5/2019-Pricing GOVERNMENT OF INDIA MINISTRY OF CHEMICALS & FERTILIZERS DEPARTMENT OF PHARMACEUTICALS

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A Wing, Shastri Bhawan, New Delhi-110 001.

<u>Order</u>

1. This is an order on an application, dated 25.02.2019 filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Cipla Limited (hereinafter called the applicant) against notification S.O.No. 1028(E) dated 26.02.2019 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of their formulations Budesonide Inhalation (DPI) 200mcg/dose, Budesonide (A) + Formoterol (B) Inhalation (DPI) 100mcg (A)/200 mcg(A)/400 mcg(A) + 6 mcg (B) and Tiotropium Inhalation (DPI) 18 mcg/dose. The review application, dated 26.03.2019, filed by the applicant for its formulations Budesonide Inhalation (MDI) 200mcg/dose and Tiotropium Inhalation (MDI) 9 mcg/dose, is also disposed of with this order as it is similar in nature to the application mentioned above.

2. The applicant company has not implemented the ceiling prices notification of the formulations before filing the review applications. The company stated that the review applications of Glenmark and Lupin for review of price of Metered Dose Inhalers (MDI)/Dry Powder Inhalers (DPI) were earlier considered by the authority even though the applicants had not implemented the notified prices. The hearings were given to Glenmark and Lupin on the ground that NPPA had not earlier fixed the ceiling price of DPI formulations and wrongfully inserted it in notification giving impact of Wholesale Price Index. Considering the merit of their cases, the Department of Pharmaceuticals had granted hearing to those companies at that time. In the instant matter, NPPA has fixed the ceiling price of DPI formulations, and therefore this case is not similar to the cases referred to by the applicant.

3. As per Para 31 of DPCO, 2013, it is mandatory for the applicant company to implement the ceiling price of the formulation before filing the review petition. Therefore, both the applications of the applicant, mentioned in paragraph 1 of this order, are not considered for review and stand rejected.

Issued on this, the 14th day of June, 2019.

(M.K. Bhardwaj) Deputy Secretary For and on behalf of the President of India Copy to :-

- 1. M/s Cipla Limited, Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai-400 013.
- 2. The Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001.
- 3. PS to Hon'ble Minister(C&F), Shastri Bhawan, New Delhi for information.
- 4. PS to MoS(C&F), Shastri Bhawan, New Delhi for information.
- 5. PSO to Secretary(Pharma), Shastri Bhawan, New Delhi for information.
- 6. Joint Secretary (Pharma), Shastri Bhawan, New Delhi for information.
- 7. T.D., NIC for uploading the order on Department's Website.