

No.31015/13/2019-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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

Order

1. This is an order on an application, dated 11.09.2019 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. 2944(E) dated 14.08.2019 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the retail price of their formulation "Formoteraol Fumarate Dihydrate 6mcg + Beclomethasone Dipropionate IP 100MCG Inhaler (MDI)".
2. The company has launched the product without complying with the notified price. Para 31 of DPCO, 2013 states that "*.....pending a decision by the Government on the application submitted under the above paragraph, no manufacturer shall sell a scheduled formulation or a new drug, as the case may be, at a price exceeding the ceiling price or retail price, as the case may be, fixed by the Government of which a review has been applied for.*"
3. As per Para 31 of DPCO, 2013, it is mandatory for the applicant company to implement the ceiling/retail price of the formulation before filing the review petition. The product Formoterol Fumarate Dihydrate 6mcg + Beclomethasone Dipropionate 100 mcg inhaler (MDI) has been launched by the company without complying with the price notified vide SO 2944(E), dated 14.08.2019. Hence, as per provisions contained in para 31 of DPCO, the review application dated 11.09.2019 stands rejected.

Issued on this, the 8th day of January, 2020.

(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.