

3131(E)

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Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals
National Pharmaceuticals Pricing Authority

New Delhi, the 20th November, 2015

ORDER

S.O.3131(E) – Whereas the National Pharmaceutical Pricing Authority (NPPA) was established vide the Resolution of the Government of India in the Ministry of Chemicals and Fertilizers No. 33/7/97-PI.I dated 29th August, 1997, inter-alia, to fix prices and notify the changes therein, if any, of bulk drugs and formulations, monitor the prices of non-scheduled drugs and formulations and oversee the implementation of the provisions of the Drugs (Price Control) Order (DPCO).

And whereas the Ministry of Chemicals and Fertilizers vide S.O.1394(E) dated the 30th May, 2013, in exercise of the powers conferred by Section 3 and 5 of Essential Commodities Act, 1955 has delegated the powers in respect of specified paras of the DPCO,2013, including para 32 of the said order to be exercised by the NPPA on behalf of the Central Government.

And whereas an application received from M/s Wockhardt Limited, Mumbai for non-application of provisions of DPCO, 2013 under para 32 (iii) of the said order in respect of (i) Insulin Human Injection, 200IU/ml (ii) Isophane Insulin Human Suspension, 200IU/ml and (iii) 70% Isophane Insulin Human Suspension and 30% Insulin Human Injection, 200IU/ml duly approved by the office of Drugs Controller General (India) as 'new drug' under Rule 122(E) of the Drugs and Cosmetics Act and Rules thereunder, was examined by the Expert Committee constituted for this purpose.

And whereas the NPPA considered the recommendations of the Expert Committee in detail at its 25th Authority Meeting held on 29.10.2015 under DPCO, 2013 and approved that (i) Insulin Human Injection, 200IU/ml (ii) Isophane Insulin Human Suspension, 200IU/ml and (iii) 70% Isophane Insulin Human Suspension and 30% Insulin Human Injection, 200IU/ml of M/s Wockhardt Limited, Mumbai qualifies for the non-application of provisions of DPCO, 2013 under para 32 (iii) of the said Order for a period of 5 years from the date of its market approval in India.

Now, therefore, in exercise of the powers delegated under para 32 of the Drugs (Prices Control) Order, 2013 vide S.O. 1394(E) dated 30th May, 2013 issued by the Government of India in the Ministry of Chemicals and Fertilizers, NPPA allows M/s Wockhardt Limited, Mumbai exemption from the provisions of DPCO, 2013 under para 32 (iii) of the said order in respect of above said drug viz. (i) Insulin Human Injection, 200IU/ml (ii) Isophane Insulin Human Suspension, 200IU/ml and (iii) 70% Isophane Insulin Human Suspension and 30% Insulin Human Injection, 200IU/ml for a period of five years with effect from 08.01.2015, which is the date of grant of marketing approval by the Drugs Controller General (India).

The company shall inform NPPA of the Maximum Retail Price fixed by the company in respect of above said formulations by issuing a price list in Form V under DPCO, 2013.

PN/157/25/2015/F

No. 8(25)/2015/ DP/Div-II/NPPA

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