No.31015/9/2012-PI.I Government of India Ministry of Chemicals & Fertilizers Department of Pharmaceuticals

'B' Wing, 3rd Floor, Janpath Bhawan, New Delhi

<u>O R D E R</u>

Subject: Review Application of M/S Gland Pharma Limited under para 22 of the Drugs (Prices Control) Order, 1995 (DPCO, 1995) against NPPA price fixation Notification No. S.O.2734 (E) dated 16.11.2012 fixing prices of Human Insulin Injections produced domestically.

Whereas Government of India, vide price fixation Order SO No. 2734 (E) dated 16.11.2012 fixed the prices of Human Insulin Injections, i.e. Human Insulin 40 IU in 10 ml vial Human Insulin 100 IU in 3ml cartridge.

2. And whereas aggrieved by the above notification M/S Gland Pharma Limited (hereinafter referred to as Petitioners) had represented to the reviewing authority against the said price fixation. The Department of Pharmaceuticals gave personal hearing to the Petitioners on 10.12.2012. The Petitioners were represented by S/Shri Ramesh Kumar, Vice President and, P. Tribikarama, Manager. Shri S.K. Bhatt, Deputy Director, Ms. Manmohan Kaur, Deputy Director and Shri Suneel Chopra, Consultant represented on behalf of NPPA during the hearing. Shri V.K. Tyagi, DIA, Department of Pharmaceuticals was also present during the hearing as a technical expert.

3. The issues involved in the review application have been examined based on the record note of discussions of the personal hearing, other documents on record and the Government has ordered as under:

"While the ceiling price issued by the NPPA on 16.11.2012 may be maintained, which is in the public interest and also as per the spirit of DPCO, NPPA is required to follow the procedure provided under DPCO 1995. The Petitioners may be asked to provide the information in form III or form IV as the case may be within 15 days from the date of issue of the review order and NPPA may be directed to revise the ceiling price by considering the information as provided in this review order or the latest information available to them as per the provisions of DPCO, 1995 and fix the revised ceiling price within a period of 2 months as specified in the DPCO 95 for price fixation of formulations. While fixing the revised ceiling price NPPA should keep in mind that the allowed price is not evasive and should not have the potential of forcing the major manufacturers out of business thereby creating a shortage of the product in the market. In the meanwhile the Petitioners should be directed to maintain the ceiling price.

4. However, based on the review order passed earlier in similar other cases of review against the said impugned order, an opportunity was given by NPPA to all the manufacturers/importers of the drug to give presentation on insulin formulations manufactured/imported by them and considering the data/information received from them, including the Petitioners also, NPPA has already revised the prices of relevant insulin formulations vide notification No. S.O.1540(E) dated 14.6.2013 in supersession of the impugned notification S.O. No.1734(E) dated 16.11.2012. The above mentioned review application of the Petitioners against S.O. No.1734(E) dated 16.11.2012 is accordingly treated as disposed of.

Issued on this date 31st December, 2013.

(Roshan Lal) Under Secretary to the Govt. of India For and on behalf of the President of India

То

- 1. M/S Gland Pharma Limited, 6-3-865/1/2, Flat No.201, Greenland Apartments Ameerpet, Hyderabad -500016
- The Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001

Copy to :

- 1. PS to Hon'ble Minister of State (Independent Charge) in the Ministry of Chemicals and Fertilizers, Shastri Bhawan, New Delhi for information.
- 2. Sr. PPS to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
- 3. The Chairman, NPPA, YMCA Cultural Centre Building, New Delhi for information