No.8/26/09-PI.I Government of India Ministry of Chemicals & Fertilizers Department of Pharmaceuticals

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

<u>ORDER</u>

Subject: Review Application of M/s USV Ltd. under DPCO, 1995 against NPPA price fixation Notification No. S.O.2923(E) dated 17.11.2009 fixing prices of Vitamin A Injection.

Whereas Government of India, vide price fixation Order No. S.O.2923(E) dated 17.11.2009 fixed a ceiling price for Vitamin A Injection.

2. And whereas aggrieved by the above notification USV Ltd. (hereinafter referred to as Petitioners) had represented to the reviewing authority against the said price fixation. Personal hearing was granted to the Petitioners by the Department of Pharmaceuticals on 02.7.2010. The Petitioners were represented by Shri Kirit B. Mehta, Cost Accountant and Dileep A. Pandit, Asso. Vice President. On behalf of NPPPA Shri Jagdish Kumar, the then Deputy Director(Tech) and Shri Manish Goswami, Deputy Director(C) were present during the hearing.

3. The Reviewing Authority has passed the following order:-

(a) Price of Vitamin A Palmitate

Company has claimed a price of Rs.4747/kg while Rs.4565/kg has been allowed to them. NPPA has mentioned that the price of Rs.4250 per kg was claimed by the company through the invoice on which NPPA had also allowed the actual incidental charges incurred by the company which comes to 3.14%. While the company cannot be granted more price than what is claimed by them in their invoice, NPPA may inform about the date on which the price for the bulk drug was notified and why the notified price is about 7% more than the actual price.

(b) Cold Storage Charges

As per guideline No.1/99 "incidental allowable expenses" are defined as:

"Incidental Allowable Expenses: To cover expenses like transportation charges, insurance, octroi, sales tax, etc. incidental charges are restricted to 8% on the notified price rate of a scheduled bulk drug manufactured indigenously or its actual whichever is lower."

Since cold storage charges have not been provided in the Incidental Allowable Expenses, the same has not been allowed.

(c) Injectable Grade Polysorbate 80

As per technical advice received from NIPER, Mohali the injectable Grade Polysorbate is costlier than usual pharma grade polysorbate 80. Thus the action of NPPA to provide the normal grade of polysorbate rates to injectable form is not in order and needs to be modified by NPPA.

(d) Amber Colour Ampoules

As against the claim of company Rs.1.08 per pack NPPA has allowed Rs.0.97 per pack as per the existing norms. Since the norms are already notified, the request of the company to revise the norms cannot be acceded to.

(e) Extractable Volume

The company claimed that as per Pharmacopeial standards they are supposed to provide 2.6 ml for a patient who requires 2.5 ml. NPPA has rejected this on the ground that this is taken care of in the process loss. NPPA has informed that the process loss notified at the rate of 10.49% is considered in respect of raw-materials in the case of injectable ampoules. The claim of the company thus cannot be allowed.

Issued on this date 2nd April, 2013.

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

То

- The Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building
 Jai Singh Road, New Delhi-110001
- M/s USV Ltd. Arvind Vithal Gandhi Chowk, B.S.D. Marg, Govandi, Mumbai-400088

Copy to:

- 1. PS to Hon'ble Minister of State(Independent Charge) of the Ministry of Chemicals & Fertilizers, Shastri Bhawan, New Delhi for information.
- 2. Sr. PPS to Secretary (Pharma), Shastri Bhawan, New Delhi for information.