

No. 31015/30/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

B Wing, Janpath Bhavan,
New Delhi 110 001

Subject: Review application of M/s FDC Limited against price fixation of “Oral Rehydration Salts” vide NPPA order No. S.O. 1816(E) dated 18.05.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 23.05.2016
2) NPPA notification under review S.O. No.1816(E) dated 18.05.2016
3) Record Note of discussions held in the personal hearing held in the matter on 30.6.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s FDC Limited (hereinafter called the petitioner) against notification S.O. No.1816(E) dated 18.05.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Oral Rehydration Salts (ORS).

2. The petitioner has contended as under:

- (i) Company refer to the S.O.No.1816 (E) dated 18/05/2016 Sr. No. 19 fixing Ceiling Price at Rs. 0.71 per Gm of Oral Rehydration Salts;
- (ii) They also refer to the NPPA website “Working Sheet Related to Price Notified on 18th May, 2016”. MRP of their ELECTRAL branded ORS pack of 21.8 gm was Rs. 17.65 and after WPI reduction of 2.71% under the NPPA Notification S.O. 644(E) dated 2/3/16, it was reduced to Rs. 17.17. If they apply the above Ceiling Price Rs. 0.71 per gm to their ELECTRAL branded ORS 21.8 gm, the MRP works out to Rs. 16.25. It means MRP reduction from Rs.17.17 to Rs. 16.25.
- (iii) As per the NPPA published worksheet, Company’s ELECTRAL branded ORS is Market Leader in the Oral Rehydration Salts market with market share of 57.69%;
- (iv) Oral Rehydration Salts is life saving essential medicine prescribed by doctors for restoration of fluid & electrolyte loss due to diarrhoea or other reasons and our ELECTRAL branded ORS is WHO recommended formula manufactured under Drug License no. 461.
- (v) They also produce and market ENERZAL branded health supplement food product which is an energy drink. Their ENERZAL is manufactured under licence from the Foods Safety Standards Authority of India (FSSAI licence No. P15025/716/2012-PA/FSSAI/955 dated 30/7/2013). They attached ENERZAL powder packs of 50 gm & 100 gm of both Orange & Lime flavours for ready reference. They also attached a photocopy of FSSAI licence in respect of ENERZAL (which is not a drug formulation but food product);

- (vi) In the worksheet referred to above for Oral Rehydration Salts, Their **ENERZAL** too is added by mistake alongwith **ELECTRAL**. In the worksheet, it is also mentioned against ENERZAL that it is Energy Drink unlike ORS in all other cases. As ENERZAL is a health supplement energy drink (food product), it cannot be considered / should not be considered in Ceiling Price working of DPCO Schedule 1 essential medicines;
- (vii) If they remove **ENERZAL** listed at Sr. nos. 30 to 34 (both included) from the above worksheet, number of packs considered for price fixation will be reduced from 31 to 26. So also sum of PTR per unit (Gm) considered for price fixation will be reduced from Rs. 19.60 to Rs. 18.46. Accordingly, Average PTR per Gm will increase from Rs. 0.63 to Rs. 0.71. After adding 16% Retailer's Margin, Ceiling Price (without Local Tax) per Gm would increase from Rs. 0.73 to Rs. 0.82.
- (viii) As mentioned earlier, current MRP of their ELECTRAL ORS pack of 21.8 gm is Rs. 17.17 (i.e. after WPI reduction of 2.71% under the NPPA notification S.O. 644(E) dated 2/3/16). Therefore, if they apply correct and proper Price Rs. 0.82 per Gm to ELECTRAL 21.8 gm ORS, MRP works out to Rs. 18.76 (inclusive of VAT 5%). Therefore, as per para (a) of the Notification S.O. 1816 (E) referred to above, they need not reduce MRP of their ELECTRAL ORS 21.8 gm pack and ought not to give effect to the modified Ceiling Price pending disposal of their this Review under Paragraph 31 of the DPCO 2013.
- (ix) They further stated that such erroneous working would cause grave, irretrievable & irrecoverable loss to their Company as we annually sell over 9.54 Crore sachets of ELECTRAL branded ORS (both 21.8gm & 4.4 gm). Besides, heavy loss would be caused due to avoidable recall from the market leading to acute shortage of this essential medicine in peak summer season;
- (x) **They further requested that immediate withdrawal of entry no. 19 from the above Ceiling Price Notification No. 1816 (E) dated 18/5/16.** In view of irretrievable and irrecoverable loss to their Company, they have decided to put on hold the implementation of the erroneous Ceiling Price till a new Ceiling Price for ORS is notified.
- (xi) It will not be out of place here to **mention that Enerzal is not a medicine but a food product. By letter dated 6 April 2016, the NPPA has confirmed the same.**

3. Comments of NPPA:

- (i) NPPA has fixed the ceiling price Rs. 0.71 per gram for **Oral Rehydration Salts** vide S.O. 1816(E) dated 18.5.2016 under para 4, 10, 11, 14, 16, 17 & 18 of DPCO, 2013 based on the data submitted by Pharma Trac as per existing practice.
- (ii) Representation of company is under examination by NPPA.

4. In the personal hearing held on 30th June, 2016, the petitioner company

submitted that the ceiling price of Oral Rehydration Salts (ORS) should be based on average Price to Retailer (PTR) only of ORS medicines. In this notification, the NPPA has considered even food product, namely, Enerzal (another brand of our company meant as energy drink) for ceiling price fixation. In recent past, in April, 2016, NPPA had closed their alleged price increase over 10% taking into consideration the fact that Enerzal was a food product. Similarly, in 2013, there was error in ORS pricing which was rectified after filing review petition.

NPPA representative submitted that price for this pack was fixed based on the data submitted by Pharma Trac. The representation of the petitioner company is under examination.

The petitioner in their review application, dated 23.5.2016 has admitted that in view of irretrievable and irrecoverable loss to the company, they have decided to put on hold the implementation of the erroneous ceiling price till a new ceiling for ORS is notified.

5. **Examination:**

The company made its submission that while calculating ceiling price NPPA had taken wrong product with ORS salt. M/s FDC Ltd. is manufacturing and marketing ORS salts and its brand name is ELECTRAL. Company also manufactures and markets energy drink products under brand name ENERZAL which is a health supplement food product and manufactured under license from the FSSAI and it is not a drug. NPPA while calculating the ceiling price of ORS had combined both the products in one place.

NPPA has admitted that they have included the PTR of Enerzal (which is only a health supplement food product) while calculating the ceiling price for ORS, which comes under 'drug' category. NPPA has stated that the representation of the company, in this regard, is under examination.

The petitioner company further mentioned that the ceiling price fixation of Oral Rehydration Salts (ORS) should be based on average price to retailer of only ORS medicines and not of food supplements like Enerzal. In the recent past, in April, 2016, NPPA has closed their alleged price increase over 10% taking into consideration the fact that Enerzal was a food product. Similarly, in 2013, there was an error in ORS pricing which was rectified after filing review petition.

It is observed that NPPA has erred in including food supplement, i.e. Enerzal, for arriving at a ceiling price of the product of the petitioner company. NPPA is directed to rectify the erroneous calculation for fixing the ceiling price of the product expeditiously taking into consideration all relevant data, furnished by the petitioner company and any other source, on merit.

6. **Government Decision:**

The NPPA's price fixation was deficient in so much that a non-pharmaceutical item was included in their calculation sheet in arriving at the ceiling price. Therefore, the NPPA notification, fixing the ceiling price of the aforesaid product of the petitioner company is stayed. The ceiling price of the product category should be fixed afresh with correct calculation within a period of one month of the decision in this regard.

The petitioner's prayer is allowed.

Issued on this date, the 14th day of September, 2016.

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

To

1. **M/s. FDC Limited**
142-48, S.V. Road,
Jogeshwari (W),
MUMBAI-400 102.
2. **The Member Secretary,**
National Pharmaceutical Pricing Authority,
YMCA Cultural Centre Building, New Delhi-110001

Copy to :

1. **PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.**
2. **PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.**
3. **T.D., NIC for uploading the order on Department's Website**