File No.4-165/2008-DC (Vapi)
Directorate General of Health Services
Office of Drugs Controller General (India)
(FDC Division)

FDA Bhawan, Kotla Road
New Delhi-110002

Dated: 07 FEB 2014

ORDER

Subject: Cancellation of the permission of FDC of Olmesartan Medoxomil + Amlodipine + Hydrochlorothiazide tablets-regarding.

An inspection of one of the clinical trial sites where you had conducted the trial in respect of aforesaid FDC was carried out and team recommended that GCP norms have not been addressed while conducting the clinical trial. Accordingly, a letter was written to you for explaining your position vide this office letter dated: 28.04.2012 and you submitted your reply to this office on 06.07.2012. After scrutinizing the reply and inspection report, many critical irregularities were observed. Thereafter you were show caused under Rule 122 DB by this office vide letter dated 04.12.2012 as to why your product permission shall not be cancelled. Now you vide letter dated 22.12.2012 has submitted your reply. On examining the reply it was observed that you did not submit your clarification alongwith relevant documents to justify the critical deficiencies observed during the inspection.

In view of above facts and circumstances, your permission for manufacturing and marketing FDC of Olmesartan Medoxomil + Amlodipine + Hydrochlorothiazide tablets issued by this office vide MF-553/2011 dated: 23.11.2011 was cancelled vide this office order no. 4-165/2008-DC (Vapi) dated: 17.04.2013. You were also required to surrender the permission in original to this office. However, you did not surrender the permission till date.

You were again requested by this office vide letter no. 4-165/2008-DC (Pt. Vapi) dated: 17.10.2013 to surrender the original permission issued in form 46 to this office within 7 days, otherwise it will be viewed as non-compliance to the directions and suitable action as deemed fit will be taken against you under the provisions of Drugs& Cosmetics Act and Rules thereunder. However, you still did not surrender the permission issued to you.

It was observed that you have not taken up the directions issued by this office seriously. As the permission in respect of aforesaid FDC was already cancelled by this office on 17.04.2013, it may be informed that in case you are still manufacturing and marketing this FDC in the country, the same will be treated as without license and action as deemed fit will be taken against you as per provisions of Drugs & Cosmetics Act and Rules thereunder.

Further, as you have not complied with the direction of this office, it is to inform you that you are debarred for applying to any of the offices of CDSCO for any purpose for a period of 5 years.

Yours faithfully,

(Dr. G. N. Singh)
Drugs Controller General (India)

To,
M/s. Vapi Care Pharma Pvt. Ltd., Plot no. 225/3, GIDC, Near Morarji Circle, Vapi-396195, Gujarat.

Copy for necessary action to:-
1. All State/UTs Drug Controllers
2. All Zonal/Sub Zonal offices of CDSCO.