

19314/29.04.13

File No.4-173/2006-DC (Pt. SEP)
Directorate General of Health Services
Office of Drugs Controller General (India)
(FDC Division)

Tele. No. : 011-23236965
Fax No. : 011-23236973

FDA Bhawan, Kotla Road
New Delhi-110002

Dated: 17.10.2013

To

M/s. Scott Edil Pharmacia Ltd.,
56, E.P.I.P., Phase-I, Jharmajri, Baddi, H. P.

Subject: Grant of permission to manufacture and market FDC of Cefixime 200mg +
Ofloxacin 200mg tablet-Regarding.

Sir,

Please refer to your letter no. nil dated 30.04.2013 on the subject mentioned above. You have applied initially for FDC of Cefixime + Ofloxacin in February 2012 and it was observed that you had submitted non-authentic data. A clarification was asked from you in this regard vide letter dated: 25.07.2012, however no reply was received from your side. Now you have submitted again a fresh application for the same FDC with new Treasury challan of Rs. 15000/-. On scrutiny of the documents submitted by you, it was observed that you have submitted non authentic data again to this office.

In view of above, it is to inform you that your application is hereby rejected and you are debarred for applying to any of the offices of CDSCO for any purpose for a period of 3 years.

Yours faithfully,



(Dr. G. N. Singh)

Drugs Controller General (India)

Copy to:-

1. All Zonal/Sub Zonal/ Port Offices of CDSCO.
2. All Divisions of CDSCO, HQ.
3. State Drugs Controlling Authority, Nagar Panchayat Bhawan, Sai Road, Baddi , Distt. Solan, Himachal Pradesh.