

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

FDA Bhawan, Kotla Road  
New Delhi-110002

Dated: 16/2/15

**ORDER**

You filed an application in this Directorate for obtaining permission to manufacture and marketed FDC of Cefixime + Ofloxacin tablets.

After examining the documents submitted by you, it appeared that data submitted by you may not be authentic. Accordingly, a joint inspection was conducted at your premises on 17.12.2013 to verify the authenticity of the data submitted by you. The inspecting team submitted its report and they opined that documents submitted by you are fictitious and forged. The same was also confirmed by Mr. Ravi Jain, Partner at the time of inspection.

After examining the inspection report and documents submitted by you as well by admission of Mr. Ravi Jain, Partner, it was observed that Mr. Ashok Khurana, Private Consultant as well as Mr. Manoj, QA Manager, Delhi have fabricated all documents submitted to this office for obtaining permission to manufacture Fixed Dose Combination (FDC) with the permission and consent of you.

You vide this office letter dated: 13.02.2014 were asked to explain as to why action should not be taken against you for submitting forged documents for obtaining approval from this office. You submitted your reply to this office on 05.03.2014. The reply submitted by you was examined by this Directorate and was not found convincing/satisfactory.

In view of facts and circumstances, it is ample clear that you have submitted forged and fabricated data in connivance with your consultant and QA Manager. Therefore, your all applications pending in FDC Division are hereby rejected and you are also 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. Arion Healthcare,  
Village-Kishanpura, Baddi, Nalagarh Highway,  
Baddi, Dsit. Solan, Himachal Pradesh.

**Copy for necessary action to:-**

1. All Zonal/Sub Zonal/Offices of CDSCO.
2. State Drugs Controlling Authority, Nagar Panchayat Bhawan, Sai Road, Baddi, Distt. Solan, Himachal Pradesh-with the request to cancel the product permissions issued to firm in respect of aforesaid products as per Annexure A.