

25173/27.05.13

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

Tele. No. : 011-23236965  
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FDA Bhawan, Kotla Road  
 New Delhi-110002

Dated: 05 NOV 2013

To,  
 M/s. Gurufcure,  
 R.S. No. 241/1 & 241/5,  
 Kalitheerthal, Kuppam, Madagadipet (Post),  
 Puducherry.

**Subject:** Grant of permission to manufacture and market certain FDC-Regarding.

Sir,

Please refer to your letter no. nil dated 27.05.2013 on the subject mentioned above. You applied for manufacturing and marketing of certain FDCs. It was observed that the documents submitted may not be authentic. Accordingly a joint inspection was conducted by officers of CDSCO, South Zone as well as State Drugs Control, Puducherry. The investigating team concluded that all the data submitted is fabricated and not authentic. You vide this office letter dated: 14.05.2013 were asked to explain your position within 10 days. Now, you vide letter dated: 27.05.2013 have submitted your reply. After examining the reply, it was observed that you have not submitted any satisfactory reply and for most of the points, you have given clarification as "Typographical error" which is not acceptable.

Therefore, in view of the doubtful integrity of data submitted by you which was further confirmed by inspection team, your applications in respect of the following proposals pending in FDC Division are hereby rejected.

Sr. No.	Name of FDC	Diary no.
1.	Montelukast Sodium 4mg + Levocetirizine HCl 2.5 per 5ml dry syrup	48613/29.01.2013
2.	Cefixime 50mg + Ofloxacin 50mg dry syrup	15926/18.04.2012
3.	Montelukast Sodium 4mg + Levocetirizine HCl 2.5 tablet	19814/15.05.2012
4.	Cefixime 200mg + Ofloxacin 200mg tablet	22775/05.06.2012
5.	Cefixime 200mg + Azithromycin 250mg tablet	19685/14.05.2012
6.	Cefpodoxime 200mg + Azithromycin 250mg tablet	19404/11.05.2012
7.	Cefixime 100mg/200mg + Ofloxacin 100mg/200mg tablet	39581/25.09.2012

Yours faithfully,

(Dr. G. N. Singh)

Drugs Controller General (India)

**Copy to:-**

1. Deputy Drugs Controller (I), Deputy Drugs Controller (I), Central Drug Standard Control Organisation, South Zone, 2nd Floor, Shastri Bhawan, Annexe, 26, Haddows Road, Chennai - 600006.
2. The Commissioner, Food and Drugs Administration, 99A, Mission Street, Puducherry-605110.