

Reg A/D  
Ph : (0832)-2459230/ 2459226  
Fax : (0832)-2459223  
Website: www.dfda.goa.gov.in  
Email id: [off-dfda.goa@nic.in](mailto:off-dfda.goa@nic.in)

No. 31/DFDA/68B/2017-18/1006  
Government of Goa  
Dte. of Food & Drugs Admn.,  
"Dhanwantari",  
Opp Shrine of the Holy Cross,  
Bambolim- Goa 403 202.  
Dated: 15/5/19

307

To,  
Mr. Umeshchandra Barkur,  
A-15, Neeta Apartments,  
Chaphekar Bandhu Marg,  
Mulund, East Mumbai 400081.

Sub: Adverse Drug reaction of ROKFOS INFUSION  
B.No – V40056. M/D Feb 2014. E/DJan 2016.  
Mfgd by M/s. Cipla Ltd., Plot No. M-61, M-62 & M-63,  
Verna Industrial Estate, Verna, Salcete, Goa - 430 722

Sir,  
This has reference to your complaint No Nil dated 2/01/2017 on the subject mentioned above. In this regards, the matter was investigated by the Inspecting Officers of this Directorate, and it was reported that; there are no lapses on the part of firm as regards the quality of the drug of batch in question; however, the firm had failed to intimate this Directorate regards the serious adverse event; hence, the firm was issued Showcause notice, explanation was called; and thereafter warning was issued as they had failed to intimate this Directorate regarding serious Adverse drug reaction as per requirement of Drugs & Cosmetic Rules 1945. (Copy of warning letter is enclosed)

This is for your information

Yours faithfully,



(Jyoti J. Sardesai)  
Director, Food & Drugs Admn.

Enclosed: As above

13/05/2019 lett mar