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Reg A/D
Ph : (0832)-2459230/ 2459226
Fax : (0832)-2459223
Website: www.dfda.goa.gov.in

No. 31/DFDA/4A/2017-18/ 883
Government of Goa
Dte, of Food & Drugs Admn
"Dhanwantari"
Opp Shrine of the Holy Cross,
Bambolim, Goa . 403 202
Dated: 15/5/18

Sr. No.

To,
The Drugs Controller (India),
Directorate General of Health Services,
Office of Drugs Controller General (India),
FDA Bhawan, Kotla Road,
New Delhi-110 002.

Dy DC(I)
2/5
Amulya M

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 Goa.

Sir.

This Directorate received above mentioned complaint on 01/01/2018 via email. The said complaint was investigated by Investigating Officer of this Directorate by visiting the premises and was reported that as per cipla's policy, all complaints related to adverse drug reaction are investigated at Drug Safety Department of Cipla at Mumbai and subsequent follow up reports are submitted to Drugs Controller General (India) as per pharmacovigilance guidelines and the said adverse drug reaction case was not reported to this Directorate.

Further firm was served with showcause notice & was personally heard in the matter.

As it is a serious adverse drug reaction case, copy of complaint and submission from cipla along with reply from complainant on explanation submitted by cipla is forwarded for information and necessary action at your end.

P - 9260 dt 29/5/18 29/5/18

Yours faithfully,

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

Copy to: 1. The. Dy .Drugs Controller,(INDIA)
CDSCO, West Zone, 4th Floor, Central FDA Bhavan, GMSD compound,
Bellasis Road, Mumbai Central, Mumbai-400 008.

14/05/2018 mar let dc stf

Communicated to IPE

4/6/18 (DCC(KMS) STDD (Switch) ~~DI(Hqs)~~).