

Reg A/D

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No. 31/DFDA/4A/2017-18/ 99

Government of Goa

Dte. of Food & Drugs Admn.,

"Dhanwantari",

Opp Shrine of the Holy Cross,

Bambolim- Goa 403 202.

Dated: 05/11/19

306

To

M/s. Cipla Ltd.,

Plot No. M-61, M-62 & M-63, Verna Industrial Estate,

Verna, Salcete, Goa - 430 722

Sub: Adverse Drug reaction of ROKOFOS INFUSION

B.No – V4008 M/D Feb 2014. E/DJan 2016.

Mfgd by you.

Sir,

This has reference to your letter no. Nil dated 23/01/2018 in reply to this Directorate's show cause notice No. 31/DFDA/68B/2017-18/6844 dated 18/01/2018 and subsequent personal hearing held on 23/03/2018 on the subject mentioned above. In this connection, I am to inform you that explanation submitted by you vide above said letter is not satisfactory, as you had failed to intimate to this Directorate regarding serious Adverse Drug Reaction as required under Sub Para (2) of Para 28 of Schedule M of Drugs and Cosmetic Rules. However considering the assurance given by you that such violation will not be repeated and that on investigating the matter by the Inspecting Officer of this Directorate no adverse findings were reported in respect of quality of the product; no action is taken against you. However you are hereby warned on the matter that, if, such lapses are reported on your part in future, then strict action as per the provision of law will be taken against you.

Yours faithfully,



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

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