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Reg A/D

Ph : (0832)-2459230/ 2459226

Fax : (0832)-2459223

Website: www.dfda.goa.gov.in

No. 31/DFDA/⁶⁸⁶2017-18/4844

Government of Goa

Dte. of Food & Drugs Admn.,

"Dhanwantari",

Opp Shrine of the Holy Cross,

Bambolim- Goa 403 202.

Dated: 18/01/18

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 – V40056. M/D Feb 2014. E/DJan 2016.

Mfgd by you.

Sir,

This has reference to the complaint received from Mr. Umeshchandra Barkur of Mumbai regarding death of his wife due to adverse drug reaction of ROKOFOS INFUSION, (B.No – V40056, M/D Feb 2014) E/DJan 2016) manufactured by you; and inspection conducted of your manufacturing premises for purpose of investigation of above mentioned complaint. It is reported that you have not conducted any investigation at your manufacturing site and that investigation is done at your drug safety department Mumbai. Also you have not reported to this Directorate regarding the serious adverse drug reaction as per requirement under sub para (2) of para 28 of Schedule M of Drugs & Cosmetic Act 1940 & Rules thereunder.

In view of above; you are directed to submit to this Directorate the details of investigation conducted by you regarding the above complaint.

Further your non reporting the serious adverse drug reaction to this Directorate is in violation of sub para (2) of para 28 of Schedule M of Drugs & Cosmetic Rules.

In view of same, I, intend to take action deemed fit without prejudice to the legal action, which may be initiated against you. However you are given an opportunity to submit your explanation in the matter, and to showcause, if any so as to why, I, should not take intended action against you; within 7 days from the receipt

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माहिती अधिकारात व सा.सा. अधिन्यायी, (व.मुं.) अन्न व औषध संस्थान, स.रा. बांनी दिलेली माहिती.	

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of this letter. Please note, that, if you fail to showcause within the stipulated time period, I, will proceed with the intended action without any further reference to you.

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.
2. Asst. Drugs Controller (I), Central Drugs Standard Control Organization, Sub Zonal Office, 3rd Floor, Customs Building, Custom House, Marmagao Goa 403803.
3. Main File.
4. Showcause File

18/01/2018 mar -shmfg

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<p>माहिती अधिकारांत त शा.मा. अधिकारी, (उ.पुं.) अन्न व औषध प्रशासन, म.रा. यांनी दिलेली माहिती.</p>	