Government of India
Ministry of Health and Family Welfare
Directorate General of Health Services
Central Drugs Standard Control Organization
(Public Grievance Cell)
FDA Bhavan, Kotla Road, New Delhi-110002

F. No. PG/90/ADR/Rokfos/2018/DCGI

Dated, 15/2/12

To,

Sh. UmeshChandra Chandu Barkur, A-IS, Neeta Apartments, Chaphhekar Bandhu Marg, Mulund East, Mulund East, Mumbai-400081

Sub: Public Grievance; in relation to conduct investigation for alleged nexus between M/s Cipla Ltd. and M/s Maruti Nursing Home's, Mulund Mumbai in sale of sub-standard drugs Rokfos i.v.;-reg. Sir,

This office has received your offline grievance dated 01/02/2018, in which you have requested to conduct an investigation for alleged nexus between M/s Cipla Ltd. and M/s Maruti Nursing Home's doctors into sale of sub-standard drugs Rokfos i.v. infusion, which resulted into untimely

and unnatural death of your wife.

In continuation of earlier reply forwarded from RTI Cell, CDSCO, vide letter no. Z-28020/541/2017-DC, dated 201.12.2017, this is for your kind information that as per Schedule M of Drug and Cosmetics Rules, all complaints thereof concerning product quality shall be carefully reviewed and recorded according to written procedures by the manufacturing companies. Each complaint shall be investigated/evaluated by the designated personnel of the company and records of investigation and remedial action taken thereof shall be maintained. There shall be written procedures describing the action to be taken, recall to be made of the defective product. Reports of serious adverse drug reactions resulting from the use of a drug along with comments and documents shall be forthwith reported to the concerned licensing authority. It is further to inform as stated by you that FDA Maharashtra has already taken action and the Drug Inspector had seized drugs valued at rupees five lakhs and eight thousand for sale without valid license as required under the Drugs and Cosmetics Act, 1940. A case was also filed with the Addl. Chief Metropolitan Magistrate 15th Court, Mazgaon, Mumbai in October 2016 on your compliant.

Therefore, in this regard you are requested to approach the (1) FDA Maharashtra (2)Medical Council Of India New Delhi and (3) Public Health Department, Govt. of Maharashtra for further necessary action in this matter.

This is being issued with the approval of the competent Authority.

Yours faithfully

(S.Basu)

Assistant Drugs Controller (India)

Copy to,

1. Chairman, Medical Council of India, Pocket- 14, Sector - 8, Dwarka Phase-1, New Delhi - 110077, India, with a kind request to examine the matter and furnish suitable reply.

2. Director, Health Services, Public Health Department, Mantralava, GT. Hospital Compound, 10th Floor, Complex Building, Mumbai: 400 001, with a kind request to examine the

matter and furnish suitable reply.

3. Commissioner, Food and Drug Administration, Survey No. 341, 2nd Floor, Bandra Kurla Complex, Opposite Reserve Bank Of India, Bandra East, Mumbai, Maharashtra 400051, with a kind request to examine the matter and to take necessary action in this matter.

4. The Dy. Drugs Controller (I), CDSCO (HZ), FDA Blavan, GHSD Compound, Bellasis Rd. Humbai Cantral, Humbai - 400008 for kind information and necessary Follow-up please,