F.No. X-11026/173/14-BD

Directorate General of Health Services
Central Drugs Standard Control Organization
Biological Division

FDA Bhawan, Kotla Road,
New Delhi-110002
Date: 19 DEC 2014

To,
M/s Chaitanya Hospital,
S.No. 133, 2nd Flr., Rahi Sakha Apt.,
Pune-Sinhagad road, Parvati, Pune.

Subject: Action in pursuance to the investigation carried out at your facility for misuse and unethical stem cell clinical trial malpractices.

This is with reference to the above subject matter, this office has issued a show cause notice dated 21.11.2014 with the condition to submit the explanation within 10 days of receipt of the notice however, you have failed to submit the response within stipulated timeline. It is to state that a complaint was received against your hospital to investigate the misuse and unethical stem cell clinical trial malpractices at M/s Chaitanya Hospital, Pune. It was stated that various stem cell treatments with high treatment costs such as Cerebral Palsy, Stroke, Wilson's disease and Spinal Cord injury are being offered at your hospital. It was also mentioned in the complaint that the patients are highly charged for unapproved and illegal transplants.

Taking cognizance of the complaint, an investigation was undertaken by CDSCO officials. The investigation team in its report had observed that you had not obtained the clinical trials permission from CDSCO for the clinical trials. It was observed that the patients with bone marrow derived stem cells for various diseases like Cerebral palsy, Autism, Vascular necrosis, Spinal Cord injury, Diabetes Mellitus, Hemiplegia etc. were treated. The processing of bone marrow derived mono nuclear cells was claimed to be fall under minimum manipulation category as per ICMR guidelines but in the hospital there was no instrument or equipment provided which ensures aseptic processing and no documents were maintained as required under Good Clinical Practices and moreover patients were charged heavily for the treatment for period 2013 to Sep 2014.

That the observations as made by the investigating team were examined in the CDSCO, HQ. The observations are serious in nature as there was no approval obtained for clinical trials already conducted. These observations prima facia imply that there are violations of the Drugs and Cosmetics Act, 1940 and the Drugs and the Cosmetics Rules, 1945 which has a bearing on the patient safety.

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In view of above, you are directed to stop the treatments with stem cell products to the patients in the name of clinical trial with immediate effect till further orders in public interest.

Yours faithfully,

(Dr. G. N. Singh)
Drugs Controller General (I)

Copy for necessary action to:

- The DDC(I), CDSCO, 4th floor, Zonal FDA Bhawan, GMSD Compound, Bellasis Rd, Mumbai Central, Mumbai-400 008.
- The Commissioner, Food and Drugs Admn., 341, Bandra Kulra Complex, Opp. RBI Building, Bandra (East), Mumbai- 400051.
- The Principal investigator (Dr. Anant Bagul), M/s Chaitanya Hospital, S.No. 133, 2nd Flr., Rahi Sakha Apt., Pune-Sinhagad road, Parvati, Pune.