F.No. X-11026/98/14-BD (Pt-II)
Directorate General of Health Services
Central Drugs Standard Control Organization
Biological Division

FDA Bhawan, Kotla Road,
New Delhi-110002
Date: 25 AUG 2014

To,
M/s Nichi-In Centre for Regenerative Medicine,
III floor, LICET, Loyola College Campus, (PB 1262),
Nungambakkam, Chennai-600034

Subject: Action in pursuance to the investigation carried out at facility for administration of Dendritic cells or treatment of cancer.

This is with reference to the above subject matter and to state that a complaint was received against your firm to investigate on the issue of sale of Dendritic cell cancer vaccine in the name of Dendritic cell immunotherapy. It was also mentioned in the complaint that exorbitant fees is being charged from different cancer patients for administering the Dendritic cell cancer vaccine.

Taking cognizance of the complaint, an investigation was undertaken by CDSCO officials. The investigation team in its report has observed that you are involved in collection of blood from patients which is further subject to cell regeneration which includes (cell isolation, cell culturing, centrifugation & dilution) of NATURAL KILLER CELL and T CELLS. These cells are being used in the treatment for Cancer patients as Autologous Immunotherapy. There is no approval for this activity from Competent Authorities. It is also observed that Ethics Committee of M/s Nichi-In Centre for Regenerative Medicine is not registered to Central Drugs Standard Control Organization.

As per the Informed Consent Form produced to the investigation team, it is clearly mentioned that "Hospital in which treatment to be given" whereby it is understood that treatment is given by the physician of the particular hospital to the cancer patient by using Natural killer cells and T cells which attracts the provision of Section 3(b) of Drugs and Cosmetics Act 1940.

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 cell regeneration which includes (cell isolation, cell culturing, centrifugation & dilution) of NATURAL KILLER CELL and T CELLS and no valid market authorisation obtained from the CDSCO before the commercial use of the product and that the Autologous Immune Enhancement Therapy (AIET) given to the patients without any permission. 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.

In view of above, you are directed to stop collection of blood from any new patients for processing and administration of NATURAL KILLER CELL and T CELLS with immediate effect and providing the same to patients till further orders in public interest.

Yours faithfully,

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

Copy for necessary action to:

1. The Director General, Indian Council of Medical Research (ICMR), Ansari Nagar, Post Box No. 4911, New Delhi -110029.
2. The Deputy Drugs Controller (I), Central Drug Standard Control Organisation, South Zone, Second Floor, Shastri Bhavan Annexe, 26, Haddows road, Chennai- 600 006.