

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

FDA Bhawan, Kotla Road,
New Delhi-110002

Date:

28 AUG 2014

To,
M/s Wellness Solution,
C/o Legacy Health Solution,
No. 72, 2nd Main Road Nanjappa Layout,
Behind Kethams Hospital Vidyanarayapura,
Bangalore-560097.

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 and which is transported to Institute of Cellular Therapies (ICT), Noida for the preparation of Dendritic cell vaccine and which is being used in the treatment for Cancer patients. It was observed that as per the product label claim made on the package insert, the product falls under the purview of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945.

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 the collection of blood for the processing of Dendritic cell vaccine for commercial use to be administered in patient without any permission of Competent Authority. These observations prima facie 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, packaging and administration of Dendritic cell vaccine 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.
- 3) The Deputy Drugs Controller (I), Central Drug Standard Control Organisation, Sub-Zonal office, 2nd Floor, Palace Road (Drug Controller Office), Bangalore (Karnataka).