

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: 23.07.2014

To,
M/s Denvax Clinic,
Institute of Cellular Therapies Pvt. Ltd.
J 3 Sector 41, Noida 201303, UP India


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 had observed that you had not obtained the clinical trial permission from CDSCO for the clinical trial was carried out in the year 2004-2006 and 2005-2008. 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 clinical trial already conducted and no valid market authorisation obtained from the CDSCO before the commercial use of the product and that the Denvax was administered to the patients after the trial without any permission. 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 and packaging of the product-Dendritic cell preparation 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: The Deputy Drugs Controller (I), Central Drug Standard Control Organisation, North Zone, C.G.O., Building-1, Kamla Nehru Nagar, Hapur Chungi, Ghaziabad – 201 002 (U.P.).