

**F.No. Stm-CI/27/Apac Biotech/12-BD (Pt-I)**  
**Directorate General of Health Services**  
**Central Drugs Standard Control Organization**  
**Biological Division**

FDA Bhawan, Kotla Road,  
New Delhi-110002

Date: **19 AUG 2015**

To,  
M/s Apac Biotech Pvt. Ltd.,  
69, Jacaranda Marg,  
DLF Phase II,  
Gurgaon-122002


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

With reference to the letter No. X-11026/98/14-BD dated 23.12.2014 of this office with a direction to stop the collection and sale of Autologous preparation containing mature Dendritic cell (Brand Name: APCEDEN) with immediate effect and till further orders in public interest.

The above matter was discussed in the CBBTDEC meeting held on 09.12.2014 and 03.02.2015 at ICMR, HQ, New Delhi in which the committee reviewed the data submitted by the firm & also the recommendations of the site visit expert group. The committee recommended to revoke the ban imposed by the DCGI with immediate effect to permit the company as per the provisions of Drugs & Cosmetics Act. Further the matter was discussed in the Technical Committee on 23.07.2015 and the Committee recommended that the ban on the firm shall be revoked as per recommendations of CBBTDEC. However, they shall be permitted for this product for using in particular indication only after the basis of approval and future conditions for further studies and prices to be recovered from patients are clarified by CBBTDEC.

In view of above, this Directorate revokes the order dated 15.07.2014 till further order for the purpose of conducting clinical trial, if any, as permitted and also requires the firm to distribute the product for using in particular indications only after it is permitted.

Yours faithfully,

  
(Dr. G. N. Singh)

Drugs Controller General (I)

**Copy for necessary action to:**

- 1) The Deputy. Drugs Controller (I), Central Drug Standard Control Organisation, North Zone, C.G.O., Building-I, Kamla Nehru Nagar, Hapur Chungi, Ghaziabad – 201 002 (U.P.).
- 2) The Chairman, CBBTDEC, Indian Council of Medical Research (ICMR), Ansari Nagar, Post Box No. 4911, New Delhi -110029.