No.21013/15/2017-DC
Central Drugs Standards Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare
(Office of DCGI)
FDA Bhavan, Kotla Road,
New Delhi-110002.

Dated the 2nd February, 2017

NOTICE

For evaluation of various categories of applications of clinical trials, new drugs and new medical devices, Subject Expert Committees (SECs), have been constituted by the Ministry of Health & Family Welfare. These SECs meet regularly and submit their recommendations to DCGI. It is however, observed that in a few cases where the applicant is not satisfied with the recommendations of the SEC, he/she approaches various authorities for redressing his grievance. In order to streamline the grievance redressal mechanism, the following procedure will henceforth be adopted :

The appeal relating to the grievance, together with all details, will be submitted to the o/o DCGI within 7 days of issue of the minutes of the meeting of the SEC. DCGI shall refer the appeal to the following Committee under the chairmanship of concerned JDC(I), which shall give its recommendations within 7 days. Other members of the Committee will be :

1. DDCI concerned.
2. One DDCI from the Zone – (DDCI)–EZ or Ahemedabad for Biologics & other products and DDCI(SZ) or Hyderabad or Bangalore for Medical Devices & other products).
3. DDCI (AKP) – Coordinator.

This issues with the approval of the competent authority.

(Arun Sharma)
Director(Admn.)
Tel : 23216376

1. Officers concerned.
2. O/o DCGI/PPS to JS(R)
3. Website of CDSCO.
4. Guard file.