Clarification & Amendments in guidance for industry with respect to Post Approval Changes in Biologicals Products:-

1. The provision of automatic approval of post approval change by DCG (I), if not opined within the time period (i) of 30 days for Level-I- Supplements (Major quality changes) & (ii) of 15 days for Level- II- Notifiable Changes (moderate Quality Changes), as published on the website, **www.cdsco.nic.in**, in the Guidance for Industry, post approval changes in Biological products: Quality, Safety & Efficacy Documents (No. PAC/1108, Version 1.1), **stands omitted.**

2. If the application for post approval change is for such a change which makes product, a new drug as per definition under rule 122E of Drugs & Cosmetics Rules, in such circumstances, applicants shall apply for new drug permission to DCG (I) as per requirements of Drug & Cosmetics Act & Rules thereunder with requisite fees as per usual procedures.

3. If the application for post approval change is for change in premises of manufacturing, wherein different permission under manufacturing license in form 28-D is required, in such circumstances, applicants shall apply for the said additional product permission to concerned State Licensing Authorities, Zonal Offices/ Sub-zonal Offices & CLAA as per requirements of Drug & Cosmetics Act & Rules thereunder with requisite fees as per usual procedures.

4. For adequate processing of applications:-

(A) The applicants shall submit clear statements of change about procedural, qualitative & quantitative changes in comparative table form.

(B) Similarly, the applicants shall submit clear statements & evidences about effect of change on quality, stability, validation, animal toxicity & clinical (safety & efficacy) status of the product. If, any waiver is expected or assumed in physicochemical characterization studies, stability studies, validation studies, pre-clinical (animal toxicity) studies & clinical studies, it shall be justified precisely proving the equivalence.

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare
Govt. Of India
5th August, 2010