F.No: X-11026/143/16-BD
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

Dated: 26.05.2017

CIRCULAR

Subject: Acknowledgement for Level –III Post approval changes (Annual Notifications) of Biological products (Vaccines & r-DNA) – Regarding.

In order to streamline the approval process of Level –III Post approval changes (Annual Notifications) of Biological products (Vaccines & r-DNA) as per the Guidance document for Industry, it is to clarify that, Level-III post approval changes needs to be notified to CDSCO (HQ) with complete details and does not require separate prior approval, except for cases of change in shelf life. In case of imported products, such changes also needs to be notified and acknowledged by NRA of country of origin.

(Dr. G. N. Singh)
Drugs Controller General (India)

Copy To:

1. All Stakeholder of Vaccine and r-DNA product manufacturers and importers.
2. Zonal/Sub-Zonal offices/Biological Division of CDSCO.
3. Director, CDL, Kasauli.
4. CDSCO Web site.