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

Dated: 18th July 2017

Circular

Subject:Clarification regarding submission of application for Post Approval Changes of HumanVaccines -regarding.

In continuation to this office memorandum dated 28.10.2013 for streamlining the regulatory approvals requiring examination by CDL, Kasauli and CDSCO, it has been decided that the following post approval changes the application shall be referred to CDL,Kasuali and the manufacturers shall simultaneously submit post approval application to CDL Kasauli

1. Where there is change in specifications in final product other than Pharmacopeial specifications.
2. Where there is change in the shelf life of drug substance and drug product only in case if it is proposed on the basis of stability testing method other than one used at the time of approval of product.
3. Where there is change in the testing procedure of drug substance and drug product other than Pharmacopeial method.
4. Where there is change in the critical manufacturing process i.e. change in the conjugation process, inactivation and use of new adjuvant.
5. Where there is change in the starting material.
6. Where there is a specific direction from CDSCO/other regulatory body for compliance.

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

To,

i. The Director, CDL Kasuali.
ii. All Stakeholders through website of CDSCO.