File no. X11026/306/11-BD

Central Drug Standard Control Organization

Directorate General of Health Services

Office of Drugs Controller General (India)

(Biological Division)

DATE: 18 JAN 2013

NOTICE

Clarification and requirements related to Post approval changes as per CDSCO Guidance for Industry for Biological Products.

This is in reference to the implementation of Guidance for Industry posted on CDSCO website for evaluation of various applications of post approval changes/variations for Biological Products.

In order to update the Quality information of already licensed products in a systemic approach it has been decided to submit the updated PPD of all approved Biological Product on yearly basis having all changes compiled in Quality information. The updated PPD for all approved Biological drug products should include following information:-

- All subsequent supplement and notifiable changes implemented after obtaining approval from this Directorate.
- All subsequent minor changes intimated to this directorate which doesnot requires approval from DCG(I).

This is further clarified that all subsequent applications made after obtaining Market Authorization from DCG(I) should be applied under Post approval changes as per requirements of Guidance for Industry (PAC/1108 ver. 1.1) and no change having impact on the quality on the Drug product should be implemented prior to approval from this directorate.

Accordingly all are advised to submit updated PPD as per Document no, PPD/71108 ver 1.1 of Guidance for Industry including Appendix section (hard and soft copy) to this directorate within 15 days of issuance of this notice.

(Dr. G.N. Singh)

Drugs Controller General (I)

To

All Manufacturers/Importers of Vaccines