File No: X-11026/143/16-BD
Directorate General of Health Services
Office of Drugs Controller General (India)
(Biological Division)

Dated: 20/12/2016

OFFICE MEMORANDUM

Subject: Avoiding Multiple Inspections of a facility using Risk Based Approach-Regarding

In order to avoid multiple inspections, which otherwise can be avoided based on the risk based analysis and availability of past inspection report / performance of the firm, it has been decided that all biological products (vaccine & r-DNA products) inspection for other than grant or renewal of license shall be carried out usually once in a year, unless otherwise justified based on risk based analysis of the firms, products and issue requiring inspection.

In order to facilitate, this approach, whenever inspections other than for investigation/ grant/ renewal purposes are planned, an opportunity shall be given to the firm, in writing by email and hard copy for expression of their interest to undergo such inspections or for submission of justification as why such inspections is not necessary, due to availability of earlier joint inspections report etc.

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

To:

1. Zonal/Sub-Zonal Heads of CDSCO
2. All division head of CDSCO (HQ)

Copy to: Stakeholders through CDSCO website for information