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

Dated: 13-12-2016

OFFICE MEMORANDUM

Subject: Form 29 License to manufacture drugs for purposes of examination, test or analysis for biological products (Vaccines & r-DNA products)-regarding.

In order to promote research & development of new drugs, it has been decided to discontinue the practice of prior joint inspection for issuance of Form 29 licenses to vaccine & r-DNA products.

The applicant shall submit application along with self declaration (in format enclosed) to State Licensing Authority & Central Licensing Authority by hard copy and also by e-mail (dci@nic.in, testlicensebio@cdsco.nic.in and on email of the concern State Licensing Authority). The State Licensing Authority shall issue Form 29 Licenses within three working days of receipt of application.

The receipt of Form 29 License shall also be confirmed by applicant on email to CDSCO, within three working days.

The joint inspection of such applicants shall be carried out after issuance of Form 29 Licenses, using the risk based approach.

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

To:

All State/UT Drugs Controllers
All Zone/Subzone Offices of CDSCO
All CDTL/CDL

LEGAL UNDERTAKING ON NON JUDICIAL PAPER

I.....S/o.....being authorized signatory in the company at address..... do hereby solemnly affirm and state as under that:-

1. I / We undertake to state that the product.....shall be manufactured by M/s..... at.....

2. I/ We undertake to state that condition of Form 29 under Drugs and Cosmetics Rules will be followed by the undersigned & batches meant for clinical trial/study will be manufactured in compliance with Good Manufacturing Practice (GMP).

(Name & Signature of Applicant)

Date:

Place: