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

DATED: 13/12/2016

Circular

<u>Subject</u>: NOC for export of biological products (Vaccine & r-DNA products) under Form 29 License to manufacture drugs for purposes of examination, test or analysis-regarding.

It is learnt that many applicants are requesting this office for issuance of export NOC for the batches manufactured under Form 29 License for commercial purpose.

In this regard, it is clarified that the product manufactured under Form 29 license can be exported only for the purpose of examination, test or analysis including clinical evaluation involving human subjects and not meant for commercial purposes as per Drugs and Cosmetics Rules.

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

To,

- i. All Stakeholder through website of CDSCO
- ii. Zonal / Sub-zonal offices of CDSCO
- iii. All officers of CDSCO (HQ)