F.No. XII026/204/10-BD
Directorate General of Health services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan, New Delhi
Dated: 8 DEC 2010

NOTICE

As you are aware guidance for submission of biological applications concerning with market authorization, clinical trial, post approval changes has already been uploaded in Dec 2008 in CDSCO website and same is being enforced by this Directorate.

As an endeavour towards the fast review of the regulatory documents of the biological application (Vaccine), this Directorate has further prepared checklist for the preliminary scrutiny of the documents pertaining to the following application:

1. Permission for conducting Clinical Trial (Phase I, II and III).
2. Global Clinical Trial.
3. Market authorization / New Drug approval.
4. Import license (Form 10).
5. Registration certificate (Form 41).
6. Post approval changes.
7. Test license for import of drugs under Form11.
8. NOC for manufacturing of test batches for test and analysis under Form 29.

Accordingly, you are directed to submit all the documents as per the sequence prescribed in the individual checklist as per the enclosed Annexure I to VIII. The same have also been uploaded on CDSCO website.

The above checklist will be utilized for review purpose by the office of DCG(I) w.e.f. 01.01.2011.

Dr. Surinder Singh
Drugs Controller General of India