



**CENTER FOR DRUG REGULATION AND RESEARCH**

**MINOR VARIATION – STRAIN CLEARANCE (MiV-SC) OF HUMAN INFLUENZA  
VACCINES APPLICATION**

- Who May Avail** : All Manufacturers, Distributors, Importers, Exporters,  
Wholesalers, and Traders of Human Influenza Vaccines
- Fees to be Paid** : **Minor Variation – Strain Clearance (MiV-SC)**  
PHP 500.00 + LRF

**CHECKLIST OF REQUIREMENTS**

1. Integrated Application Form (with proof of payment)
2. Certifications
  - For contract manufacturing:
    - a. License of pharmaceutical industries and contract manufacturer
    - b. Contract manufacturing agreement
    - c. GMP certificate of contract manufacturer
  - For manufacturing “under-license”:
    - a. License of pharmaceutical industries
    - b. GMP certificate of the manufacturer
    - c. Copy of “under-license” agreement
  - For locally manufactured products:
    - a. Valid License to Operate (LTO) (Manufacturer/Packer/Repacker/Trader/  
Distributor/ Wholesaler)
    - b. Valid GMP certificate
  - For imported products:
    - a. Valid License to Operate (LTO) (Packer/Repacker/ Trader/Importer/  
Distributor/ Wholesaler)
    - b. Valid Foreign GMP Clearance
3. Labeling (New Strains)
4. Product Information
  - a. Package Insert
  - b. Summary of Product Characteristics (Product Data Sheet)
5. Representative Sample with corresponding Certificate of Analysis
6. Risk Management Plan
7. Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report (PBRER)
8. List of Countries where the product is already licensed and the date of approval
9. Information on the number system of the lots or batches
10. Summary Lot Protocol
11. Copy of valid Certificate of Product Registration (CPR)
12. Notarized Letter of Request for Minor Variation – Strain Clearance (refer to



Appendix 3) indicating the affected product, as well as a declaration that there is/are no other change/s. This shall be signed by the Head of Regulatory Office.

13. Adverse event following immunization report (summary of annual reports)

**Additional Requirement:**

- Data on the testing of the seed virus for extraneous agents using Polymerase Chain Reaction (PCR) (where applicable)

END