****

***APPLICATION FOR WAIVER OF REGISTRATION- BORDERLINE PRODUCTS***

For Government Institution

For private Institution

|  |  |  |
| --- | --- | --- |
| 1. | **Applicant Details** | |
|  | 1.1 Name of the applicant |  |
| 1.2 Address of the applicant |  |
| 1.3 Telephone number |  |
| 1.4 E-mail |  |
| 2 | **Details of the product** | |
|  | 2.1 Product Name |  |
| 2.2 Brand Name |  |
| 2.3 Pack Type (If applicable) |  |
| 2.4 Pack size (If applicable) |  |
| 2,5 Shelf life (If applicable) |  |
| 2,6 Storage condition (If applicable) |  |
| 2,7 Invoiced Quantity |  |
| 2,8 Unit price |  |
| 2,9 Total cost (USD) |  |
| 3 | **Details of the manufacturer** | |
|  | 3.1 Name of the legal manufacturer and country |  |
|  | 3.2 Name of physical manufacturer and country (if applicable) |  |
| 4 | **Details of the local agent / Importer (If applicable)** | |
|  | 4.1 Name and address |  |
|  | 4.2 Telephone number and E-mail |  |
| 5 | **Past history of issued Waiver of Registration of particular item** | |
|  | 5.1 WOR No (Letter No) |  |
| 5.2 Date of issue |  |
| 6 | **Reason for requesting Waiver of Registration** | |
|  | 6.1 Delay NMRA Registration / Short expiry of NMRA registration | |
| 6,2 Registered sources not quoted | |
| 6.3 Lowest price than registered item | |
| 6.4 Short shelf life | |
| 6,5 Manufacturer’s name changed | |
| 6.6 Out of stock situation Island wise | |
| 6.7 Epidemic situation | |
| 6.8 Government to Government agreement | |
| 6.9 No registered sources | |
| 6.10 Short shelf life of the product | |
| 6.11 Research | |
| 6.12 Other (Specify below)  Reason: | |
| 7. | **NMRA Registration Status (If available please tick “√”)** | |
| 7.1 Classification Application No | |
| 7.2 Date of Submission for Product Classification Application | |
| 7.3 Date of Payment | |
| 7.4 Has the product been classified as a Borderline Product ? Yes No | |
| 7.5 Issuing date of Classification Report (Preliminary Evaluation Sheet) by NMRA | |
| 7. 6 Validity period of the Classification Report | |
| 7.7 Registration Application No | |
| 7.8 Date of submission for Registration Application | |
| 7.9 Registration Certificate No | |
| 7.10 Validity period of the Registration Certificate | |
| 7.11 Any other NMRA documents/ Reference No (Acknowledgement) | |
| 8. | **Remarks (if any)** | |
|  |  | |
| **9.** | **Declaration** | |
|  | I,……………………………………………………………………..the undersigned, hereby declare that all the information submitted with this application is true and correct and certify that all documents uploaded/submitted in support of this application are accurate and most recent as per to date.  Signature :  Designation :  Date : | |
| **Document required for Waiver of Registration (Tick “√” if submitted with application)**  **Note: The NMRA may demand additional documents +/- data** | | |
| 1 | Approval letter from Secretary / Ministry of Health | |
| 2 | Classification Report issued by NMRA | |
| 3 | Sample Import License issued by NMRA | |
| 4 | Registration Certificate issued by NMRA | |
| 5 | Agency transfer letter issued by NMRA | |
| 6 | Letter of Authorization from the manufacturer | |
| 7 | Free sale Certificate issued by Government regulatory body/ Any other organization | |
| 8 | ISO certificate for quality management system or GMP report | |
| 9 | Labels of the product | |
| 10 | Product Information Leaflet | |
| 11 | Purchase order / Indent/Commercial invoice | |
| 12 | Approval of Procurement Committee | |
| 13 | Ethic review committee approval (Applicable for research items) | |
| 14 | Research proposal (Applicable for research items) | |
| 15 | No Objection Letter (NOL) from local agent | |
| 16 | Sri Lanka Custom Detained Document | |
| 17 | Recommendation of Professional bodies (Colleges/Institutions) | |
| 18 | Request of Professional bodies (Colleges/Institutions) | |