## 17. CERTIFICATE OF PRODUCT REGUSTRATION FOR PHARMACEUTICAL PRODUCTS (VARIATION-TURNED-INITIAL APPLICATIONS)

This Certificate of Product Registration is granted to Marketing Authorization Holders once the proposed post-approval changes on the quality (e.g. manufacture, controls and container closure system), safety, efficacy, and administrative information of pharmaceutical products has been substantiated.

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| **Center/Office/Division** | : | Center for Drug Regulation and Research |
| **Classification** | : | Highly Technical |
| **Type of Transaction** | : | G2B – Government-to-Businesses |
| **Who May Avail** | : | All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Drug Products |
| **Fees to be Paid** | | Refer to FDA Circular No. 2014-008, Annex D<br>Payment shall be on a per product, per change basis<br><br>Variation-turned-Initial:<br>Branded: Php 15,000.00 + 1% LRF<br>Unbranded: Php 10,000.00 + 1% LRF<br>Monitored Release Status: Php 20,000.00 + 1% LRF (for three years) + Php 20,000.00 + 1% LRF (for additional two years as per FDA Circular No. 2013-004) |

| CHECKLIST OF REQUIREMENTS | WHERE TO SECURE |
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| **LIST OF VARIATION-TURNED-INITIAL APPLICATIONS**<br>• Mav-1: Change and/or additional indication/dosing regimen/patient population/inclusion of clinical indication extending the usage of the product<br>• MaV-4: Addition or replacement of the manufacturing site of the drugs product<br>• MaV-10: Qualitative or quantitative change of excipient<br>a) For immediate release oral dosage forms (as per Level 2 and 3, Part III Components and Composition, SUPAC guideline)<br>b) For modified release oral dosage forms<br>c) For other critical dosage forms such as sterile preparations<br>• MaV-11: Quantitative change in the coating weight of tablets or weight and/or size of the capsule shell for modified release dosage form<br>• MaV-12: Change in the primary packaging material for sterile drug product | FDA Circular No. 2014-008, Annex D |

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| a) Qualitative and quantitative composition and/or<br>b) Type of container and/or<br>c) nclusion of primary packaging material<br>• MaV-13: Change or addition of pack size/fill volume and/or change of shape or dimension of container or closure for a sterile solid and liquid drug product (unless the change is dimension, i.e. wide-mouth bottles vs. narrow-mouth bottles)<br>• MiV-PA15: Qualitative or quantitative change of excipient<br>a) For immediate release oral dosage forms (as per Level 1, Part III Components and Composition, SUPAC guideline)<br>b) For other non-critical dosage forms (e.g. oral liquid, external preparation)<br>• MiV-PA16: Quantitative change in coating weight of tablets or weight and/or size of capsule shell for immediate release oral dosage form<br>• MiV-PA17: Change of the colouring/flavouring agent of the product [addition, deletion or replacement of colourant(s)/flavour(s)]<br>• MiV-PA28: Change in primary packaging for non-sterile drug product<br>a) Qualitative and quantitative composition and/or<br>b) Type of container and/or<br>c) Inclusion of the primary packaging material<br>➢ Change of manufacturing site (same subsidiary) of the drug product | |
| **CHECKLIST OF REQUIREMENTS FOR VARIATION-TURNED INITIAL APPLICATIONS**<br>FDA Circular No. 2014-008<br>Application Process and Requirements for Post-Approval Changes of Pharmaceutical Products<br><br>ASEAN Variation Guidelines<br><br>1. Complete documentary requirements based on the ASEAN Variation Guidelines and FDA Circular No. 2014-008<br>2. Annex A (A maximum of 3 proposed variations shall be made per application, consistent with those reflected on the Integrated Application Form.)<br>3. Proof of Payment based on FDA Circular No. 2014-008 Annex D | Applicant Company<br><br>Applicant Company<br>Applicant Company/ FDA Cashier/Other<br>FDA- Authorized Payment Portals or Banks |

| CLIENT STEPS | AGENCY ACTION | FEES TO BE PAID | PROCESSING TIME | PERSON RESPONSIBLE |
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| 1. Secure a schedule of appointment / submission to FDAC | 1. Sends the scheduled date of submission for pre-assessment | None | | FDAC *Personnel* |
| 2. E-mail submission:<br>Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph | 2. Pre-assesses the completeness of the application.<br><br>If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment.<br>If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN). | None | | CDRR *Personnel* |
| 3. For accepted applications,<br>pays the required fee through any of the following:<br><br>• BANCNET<br>• Landbank OnColl<br>• Landbank Link.BizPortal<br><br>Sends proof of payment to the FDAC. | 3. Upon receipt of the proof of payment, endorses the application to CDRR for evaluation. | See Table Above | Day 1<br>1 working day | FDA Cashier/ Landbank<br><br>FDAC *Personnel* |

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| | 4. Receives the application from FDAC and encodes/updates the database | None | Day 2<br>1 working day | Center for Drug Regulation and Research (CDRR) – Central |
| | 5. Queuing time of the application before decking to evaluators of Registration Section and/or Clinical Research Section | None | Day 2-21<br>20 working days | CDRR-CRR Unit *Personnel* |
| | 6. Decks/Assigns the application to the assigned evaluators of Registration Section and/or Clinical Research Section | None | Day 22<br>1 working day | CDRR *Director* |
| | 7. Evaluates the application according to requirements and prescribed standards | None | Day 23-72<br>50 working days | *Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/* |
| If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator | Prepares a worksheet and drafts Certificate of Product Registration (CPR) (from safety and efficacy evaluation, if applicable) when the approval of the application is recommended (Quality, and Safety & Efficacy received from the CRS)<br><br>Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation (Quality, and Safety & Efficacy received from the CRS) | | | |

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| | For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued<br><br>*Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication | None | | *FDRO I/II/III* |
| | 8. Reviews the evaluated application bearing the recommendation of the Junior Evaluator | None | Day 73-112<br>40 working days | *FDRO III* |
| | 9. Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III)<br><br>If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the Certificate | None | Day 113<br>1 working day | *FDRO I/II* |
| | 10. Reviews the final output document, affixes initial on the worksheet, and forwards it to the | None | Day 114<br>1 working day | *FDRO III* |
| | 11. Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief | None | Day 115<br>1 working day (per batch of applications) | *FDRO IV (Supervisor)* |

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| | 12. Checks and recommends the decision of the evaluators and supervisor by affixing signature | None | Day 116<br>1 working day (per batch of applications) | *LRD Chief* |
| | 13. Signs and approves the final decision | None | Day 117<br>1 working day (per batch of applications) | *CDRR Director* |
| | 14. Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the CDRR-Records Section | None | Day 118<br>1 working day (per batch of applications) | CDRR-CRR Unit<br>*Personnel* |
| | 15. Scans and barcodes the final output document (CPR/LOD/Letter); emails scanned copy of the final output document to the client; and endorses the final output document (hard copy) to the AFS Releasing Section. | None | Day 119<br>1 working day (per batch of applications) | CDRR-Records *Personnel* |
| 4. Receives the CPR/ LOD letter | 16. Releases the CPR/LOD/letter to the client | None | Day 120<br>1 working day | AFS Releasing Section<br>*Personnel* |
| (Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13 and Republic Act No. 7394 Article 31). | | **TOTAL:** | **120 working days** | |