## 22. TURNED INITIAL REGISTRATION OF WATER PURIFICATION DEVICES/SYSTEM

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| **Center/Office/Division** | : | CDRRHR-LRD |
| **Classification** | : | Highly Technical |
| **Type of Transaction** | : | **G2B - Government-to-Businesses** |
| **Who May Avail** | : | Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader |
| **Fees to be Paid** | : | **Note: For renewal applications that are filed 120 days after expiry date of certificate** |

| Surcharge | Penalties 40% | Initial Fee | LRF | Total |
|---|---|---|---|---|
| 1,000 | 200 | 500 | 10 | Php1,710 |
| 2,000 | 400 | 1,000 | 10 | Php3,410 |

| CHECKLIST OF REQUIREMENTS | WHERE TO SECURE |
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| 1. Properly and completely filled-up application form<br>- Must be signed by the company representative with a date when signed.<br>- Claims should only be either for safe drinking water or purified water. Claims such as alkaline, ionized, PI, oxygenated or energized are not acceptable.<br>- Latest form should be used. | Applicant.<br><br>Form may be downloaded from the FDA website. |
| 2. Copy of SEC Articles of Incorporation or DTI Certificate of Business Registration<br>- The activity of manufacturing, importing or distributing the device should be reflected in the Articles of Incorporation<br>- The DTI Certificate of Business Registration must be valid. | Applicant |
| 3. Copy of Mayor's Permit<br>- Must be Valid<br>- Name and address in the Mayor's Permit should be the same in the application form | Applicant |

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| 4. Copy of Operation Manual<br>- Name and model number of the device in the operation manual should be the same with the application form and label | Applicant |
| . Layout of devices or flowchart of treatment process. - The lay out or flowchart should show every stage how the water is being treated.<br>○ Include a narrative description for every stage or step of the treatment process<br>○ Submit a clear and colored photo of the device.<br><br>. List of raw materials used as components of the water purification device/system.<br>○ Should have a list of the component parts with the corresponding raw material used in the device.<br><br>. Label/labelling/product insert of manufacturer's performance claim<br>○ Should be clear and readable.<br>○ Name of the product and model number in the label should be consistent with the name and model number in the application form and operation manual.<br>○ Name and address of the manufacturer, importer and distributor should be reflected<br>○ Provide provision for the registration number<br><br>. For special claims, data from scientific research and laboratory analysis supporting and proving the claims of the manufacturer of the product | Applicant |
| 5. Copy of valid License to Operate (LTO) | Applicant |

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| NOTES:<br>• Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi)<br>• The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. | |

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| *Submission schedule is every Friday from 8:00 AM to 5:00 PM.<br><br>This schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day. | |

| CLIENT STEPS | AGENCY ACTION | FEES TO BE PAID | PROCESSING TIME* | PERSON RESPONSIBLE |
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| 1. Client sends an email containing their application to cdrrhr-productregistration@fda.gov.ph following the correct schedule of application. | 1. Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment. | None | 10 working days<br><br>**Timeline starts after posting of payment** | CDRRHR Officer |
| | 2. Pre-assessment and issuance of Order of Payment or Denial Letter. | None | | Technical Evaluator |
| 2. Payment of the approved application at the Cashier | | See above table<br><br>Php1,710/ Php3,410 | | Cashier |
| | 3. Transmittal of applications to CDRRHR | None | 1 working day | FDAC Officer |
| . | 4. Decking of application | None | 2 working days | Data Controller |
| | 5. Technical evaluation of application. Issuance of a | None | 20 working days | Technical Evaluator |

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| | Notice of Deficiencies or endorsement. | | | |
| 3. Client complies with the Notice of Deficiencies<br><br>*Clients are given 30 days to comply with the NOD. Non-compliance would mean disapproval of the application. | 6. Evaluator reviews submitted compliance documents. | None | 13 working days | Technical Evaluator |
| | 7. Quality Assurance - Checking of recommendation of the Supervisor. | None | 5 working days | LRD Chief |
| | 8. Drafting and finalization of CPR. | None | 2 working days | Administrative Officer |
| | 9. Final Approval/Disapproval and E-Signature | None | 3 working days | CDRRHR Director |
| | 10. Assigning of number | None | 1 working day | Administrative Officer |
| | 11. Transmit to Record Section | None | 1 working day | Administrative Officer |
| | 12. Scanning and barcoding of CPR | None | 1 working day | Records Section Officer |
| | 13. Queuing and endorsement to the FDA Releasing Section | None | 1 working day | Releasing Section Officer |

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| | **TOTAL** | **Php1,710/ Php3,410** | **50 working days**** | |

**Day 1 commences upon the receipt of the proof of payment / posting of payment.*

***Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.*