20. INITIAL REGISTRATION OF WATER PURIFICATION DEVICES/SYSTEM

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	:	**Water Treatment Devices: Php500.00 + Php10.00 (1%) LRF per product = Php510.00** **Water Treatment System: Php1,000.00 + Php10.00 (1%) LRF per product = Php1,010.00**

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

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

NOTE: • Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) • 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. • *Submission schedule is every Friday from 8:00 AM to 5:00 PM. 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
1. Client sends an email containing the PDF of 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	CDRRHR Officer
	2. Pre-assessment and issuance of Order of Payment or Denial Letter.	None		Technical Evaluator
2. The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL).	3. FDA receives the payment from the applicant company for posting.	See above table Php510.00/ Php1,010.00	**Timeline starts after posting of payment**	FDA Cashier

*The Order of Payment will only be valid for 3 working days				
The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph through email	4. CDRRHR assigns the application to evaluator.	None	2 Working days	CDRRHR Administrative Staff
	5. Technical evaluation of application. Issuance of a Notice of Deficiencies or endorsement.	None	20 working days	Technical Evaluator
3. Client complies with the Notice of Deficiencies *Clients are given 30 days to comply with the NOD. Non-compliance would mean disapproval of the application.	6. Evaluator reviews compliance documents.	None	10 working days	Technical Evaluator
.	7. Once fully complied, endorsed to NRL for Performance Evaluation	None	1 working day	Technical Evaluator
.	8. Performance Testing	c/o NRL	**Timeline depends on the NRL procedure**	c/o EAMC-NRL
	9. Review of Performance Evaluation report	None	5 working days	Technical Evaluator
	10. Quality Assurance - Checking of recommendation of the Supervisor	None	5 working days	LRD Chief
	11. Final Approval/Disapproval and signature of the Director	None	2 working days	CDRRHR Director

	12. Printing of CPR and assigning of Number.	None	2 working days	CDRRHR Administrative Staff
	13. Transmit to Record Section	None	1 working day	CDRRHR Administrative Staff
.	14. Scanning and Barcoding of CPR	None	1 working day	AFS Records Officer / Administrative Officer
.	15. Releasing of CPR	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL	**Php510.00/ Php1,010.00**	**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.*