21. RENEWAL REGISTRATION OF WATER PURIFICATION DEVICES/SYSTEM

<table>
<tr><td>Center/Office/Division</td><td>:</td><td>CDRRHR-LRD</td></tr>
<tr><td>Classification</td><td>:</td><td>Highly Technical</td></tr>
<tr><td>Type of Transaction</td><td>:</td><td>G2B - Government-to-Businesses</td></tr>
<tr><td>Who May Avail</td><td>:</td><td>Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader</td></tr>
<tr><td>Fees to be Paid</td><td>:</td><td>Water Treatment Devices: Php500.00 + Php10.00 LRF per product
Water Treatment System: Php1,000.00 + Php10.00 LRF per product

Late Renewal
(1 Day to 1 Month)
<table>
<tr><th></th><th>Surcharge</th><th>Penalties 10%</th><th>Renewal Fee</th><th>LRF</th><th>Total</th></tr>
<tr><td>Water Treatment Devices</td><td>1,000</td><td>50</td><td>500</td><td>10</td><td>Php1,560</td></tr>
<tr><td>Water Treatment System</td><td>2,000</td><td>100</td><td>1,000</td><td>10</td><td>Php3,110</td></tr>
</table>
(1 Month to 2 Months)
<table>
<tr><th></th><th>Surcharge</th><th>Penalties 20%</th><th>Renewal Fee</th><th>LRF</th><th>Total</th></tr>
<tr><td>Water Treatment Devices</td><td>1,000</td><td>100</td><td>500</td><td>10</td><td>Php1,610</td></tr>
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Water Treatment System	2,000	200	1,000	10	Php3,210

(2 Months to 3 Months)

	Surcharge	Penalties 30%	Renewal Fee	LRF	Total
Water Treatment Devices	1,000	150	500	10	Php1,660
Water Treatment System	2,000	300	1,000	10	Php3,310

(3 Months to 4 Months)

	Surcharge	Penalties 40%	Renewal Fee	LRF	Total
Water Treatment Devices	1,000	200	500	10	Php1,710
Water Treatment System	2,000	400	1,000	10	Php3,410

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 - Use the official and latest form	Applicant. Form may be downloaded from the FDA website.
2. Affidavit of Continuous Compliance - Use the official and latest form	Applicant
3. Bacteriological, physical and chemical test report from any laboratory accredited by the DOH. - Bacteriological tests should include the following: HPC, Total Coliform and Fecal Coliform. - For safe drinking water, the physical and chemical test results should consist of the following: color, odor, turbidity, total chloride, total hardness, pH, total dissolved solids, fluoride, nitrate, nitrite, sulfate, arsenic, cadmium, chromium, iron, lead and manganese. - For purified water, the physical and chemical test results should consist of the following: color, odor, turbidity, total chloride, total hardness, pH, total dissolved solids, fluoride, nitrate, nitrite, sulfate, arsenic, cadmium, chromium, copper, iron, lead and manganese. - The sampling for laboratory testing should be performed within two (2) months upon filing of renewal or the guidelines set forth in the latest version of Philippine National Standards for Drinking Water. - For guidelines, refer to the latest version of the PNS for drinking water.	Applicant
4. Copy of old Certificate of Health-Related Device Registration - Include in the submission page 2 of old CPR and/or layout of the device	Applicant
5. Copy of valid License to Operate (LTO)	Applicant

*Performance evaluation testing is not required to be submitted given that the previous test results are still valid.	
NOTES: • 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. * Application should be filed two (2) months prior to the expiration of the validity of the CPR. Submission schedule is every Thursday 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 fdac.letters@fda.gov.ph following the correct schedule.	1. Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgment email/ order of payment to the client.	None	**Timeline starts after posting of payment**	FDAC Officer
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) *The Order of Payment will only be valid for 24 Hours.	2. The FDA will receive the payment from the applicant company for posting.	See above table		FDAC Cashier

The applicant company receives the official receipt and sends the proof of payment to FDA Action Center (FDAC) through email	3. FDAC will forward the application to CDRRHR.	None	1 working day	FDAC Officer
	4. The CDRRHR will assign the application to evaluator	None	1 working day	CDRRHR Administrative Staff
	5. Technical evaluation of application. Issuance of a Notice of Deficiencies or endorsement.	None	5 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 submitted compliance documents.	None	5 working days	Technical Evaluator
	7. Quality Assurance - Checking of recommendation of the Supervisor	None	2 working days	LRD Chief
	8. Drafting and finalization of CPR.		1 working day	CDRRHR Administrative Staff
	9. Final Approval/Disapproval and signature of the Director	None	1 working day	CDRRHR Director

	10. Assigning of number	None	1 working day	CDRRHR Administrative Staff
	11. Transmit to Record Section	None	1 working day	CDRRHR Administrative Staff
	12. Scanning and Barcoding of CPR	None	1 working day	AFS Records Officer / Administrative Officer
	13. Queuing and endorsement to the FDA Releasing Section.	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL	**Php510.00/ Php1,010.00**	**2 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.*