LICENSE TO OPERATE

1.LICENSE TO OPERATE OF ESTABLISHMENT

This process details the issuance of License to Operate (LTO) to establishments in the country. Establishments engaged in the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship of any health product are required to secure a LTO from the FDA.

1.1.LICENSE TO OPERATE – INITIAL APPLICATION FOR DRUG MANUFACTURERS

Center/Office/Division	**:**	Center for Drug Regulation and Research (CDRR)
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B - Government to Business
Who May Avail	**:**	All Manufacturers of Drug Products
Fees to be Paid	**:**	**Drug Manufacturer:** 20 Million and below - Php 10,000 +1 % LRF per year Over 20 Million but below 50 Million - Php 15,000 +1 % LRF per year 50 Million and above - Php 20,000 +1 % LRF per year **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee (LRF) Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1) Basic Requirements based on the Administrative Order No. 2020-0017:	FDA website (www.fda.gov.ph)

Accomplished e-Application Form as prescribed by FDA regulations. ● Location plan and Global Positioning System (GPS) coordinates to be filled in the eApplication Form ● Name of the Qualified Person depending on the type of health product establishment ● Self-Declaration in the e-Application Form	FDA e-Portal System
2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration (in pdf): ● For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF) ● For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF) ● For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF) ● For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter (1 Scanned copy PDF) When a business or establishment address is different from the business name registration address, the applicant shall submit a copy of the Business Permit (e.g., Mayor's Permit).	
3) Proof of income (Latest Audited Financial Statement with Balance Sheet) or Duly notarized Statement/Certification of Initial Capitalization.	
4) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
5) Site Master File (shall be presented to the FDA inspectors during inspection)	
6) Risk Management Plan (shall be presented to the FDA inspectors during inspection)	
7) Refer to FROO Inspection Agenda of this Citizen's Charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements (in PDF format) for e-LTO application Downloads and prints the generated Order of Payment through the ePortal System and email notification. Pays the assessed fee as per the system-generated Order of Payment through the existing payment channels	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective RFO. **LBP OnColl Payment: 5 wd** **Other Payment Channels: 2 wd**	See above table		FDA Cashier Administrative and Finance Service
	1.2 Conducts pre-licensing inspection *Refer to Regional Field Office (RFO) Citizen's Charter for the issuance of Certificate of Compliance /Recommendation for Disapproval/ Recommendation Letter.*	None		Regional Field Officer/ Inspector
	1.3 Evaluates completeness and veracity of the documents submitted.	None	13 working days	FDA Evaluator (Center/Licensing and Registration)
	1.4 Checks evaluation and veracity of documents submitted.	None	3 working days	Technical Officer of Center

	1.5 Quality assurance of the evaluation.	None	1 working day	Technical Officer of Center
	1.6 Finalizes decision on the LTO application If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	3 working days	Center Director
2. Receives notification and link of LTO for printing				Qualified Person
TOTAL:			**20 working days**	

1.2.LICENSE TO OPERATE – RENEWAL APPLICATION FOR DRUG MANUFACTURERS

Center/Office/Division	:	Center for Drug Regulation and Research (CDRR)
Classification	:	Complex
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	All Manufacturers of Drug Products
Fees to be Paid	:	**Drug Manufacturer:** 20 Million and below - Php 30,000 +1 % LRF over 20 Million but below 50 Million - Php 45,000 +1 % LRF 50 Million and above - Php 60,000 +1 % LRF **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-004** *Computation of Surcharge or Penalty Impossible in case of Submission of Renewal Applications Covering License of Establishments and Registration of Health Products After Their Date of Expiration Pursuant to Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implementing Rules and Regulations, and Other Purposes* **FDA Circular No. 2011-003** *Collection of Legal Research Fee (LRF) Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE

1) Basic Requirements based on the Administrative Order No. 2020-0017:	FDA website (www.fda.gov.ph)
● Accomplished e-Application Form as prescribed by FDA regulations. ● Declaration and Undertaking	FDA e-Portal (www.fda.gov.ph)
2) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
3) Refer to FROO Inspection Agenda of this Citizen's Charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal System (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements (in PDF) for e-LTO application Downloads and prints the generated Order of Payment through the ePortal and Email notification Pays the assessed fee as per the system-generated Order of Payment through the existing payment channels	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective Center/Office **LBP OnColl Payment : 5 wd** **Other Payment Channels : 2 wd**	See above table		FDA Cashier Administrative and Finance Service
	1.2 Conducts inspection (if necessary)	None		Regional Field Officer/ Inspector

	Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/ Recommendation for Disapproval/ Recommendation Letter			
	1.3 Evaluates completeness and veracity of the documents submitted	None	3 working days	FDA Evaluator (Center/Licensing and Registration
	1.4 Checks evaluation and veracity of documents submitted.	None	1 working day	Technical Officer of Center
	1.5 Quality assurance of the evaluation.	None	1 working day	Technical Officer of Center
	1.6 Finalizes decision on the Approval of LTO If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	2 working days	Center Director
2. Receives notification and link of LTO for printing		None		Qualified Person
TOTAL:			**7 Working Days**	

1.3.LICENSE TO OPERATE – MAJOR VARIATION APPLICATION FOR DRUG ESTABLISHMENT (MANUFACTURERS)

Center/Office/Division	**:**	Center for Drug Regulation and Research (CDRR)
Classification	**:**	Complex
Type of Transaction	**:**	G2B – Government to Business
Who May Avail	**:**	All Drug Manufacturers
Fees to be Paid	**:**	Major Variation: Php 500 + 1% LRF **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS (based on Administrative Order No. 2020-0017)	WHERE TO SECURE
Major Variation	FDA ePortal System (www.fda.gov.ph)
Transfer of Location of Manufacturing Plant - Accomplished e-Application Form - Business permit reflecting the new address - Updated Site Master File to be presented upon inspection - Payment of fees	
Expansion of Manufacturer and/or Additional Product Line; or Change of Manufacturing Activity - Accomplished e-Application Form - Updated Site Master File to be presented upon inspection	

- Payment of fees	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements (in PDF format) for e-LTO application Downloads and prints the generated Order of Payment through the ePortal System and email notification. Pays the assessed fee as per the system-generated Order of Payment through the existing payment channels	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective RFO. **LBP OnColl Payment: 5 wd** **Other Payment Channels:** **2 wd**	See above table		FDA Cashier Administrative and Finance Service
	1.2 Conducts inspection *Refer to Regional Field Office (RFO) Citizen's Charter for the issuance of Certificate of Compliance /Recommendation for Disapproval/ Recommendation Letter.*	None		Regional Field Officer/ Inspector
	1.3 Evaluates completeness and	None	13 working days	FDA Evaluator (Center/Licensing and Registration)

	veracity of the documents submitted.			
	1.4 Checks evaluation and veracity of documents submitted.	None	3 working days	Technical Officer of Center
	1.5 Quality assurance of the evaluation.	None	1 working day	Technical Officer of Center
	1.6 Finalizes decision on the LTO application If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	3 working days	Center Director
2. Receives notification and link of LTO for printing				Qualified Person
TOTAL:			**20 working days**	

1.4.LICENSE TO OPERATE – INITIAL APPLICATION FOR DRUG TRADERS, DRUG DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER), DRUGSTORES, RETAIL OUTLETS FOR NON-PRESCRIPTION DRUGS (RONPD), CLINICAL RESEARCH ORGANIZATIONS AND SPONSORS

Center/Office/Division	:	Center for Drug Regulation and Research (CDRR)
Classification	:	Complex
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Drug Traders, Drug Distributors (Importer, Exporter, Wholesaler), Drugstores/Retail Outlets for Non-Prescription Drugs, Clinical Research Organizations and Sponsors
Fees to be Paid	:	**Drug Traders:** 20 Million and below – Php 3,000 + 1% LRF per year over 20 Million but below 50 Million – Php 5,000 + 1% LRF per year 50 Million and above – Php 7,000 + 1% LRF per year **Drug Distributors:** Importer, Exporter, Wholesaler- Php 5,000 + 1% LRF per year **Drug Outlets:** Drugstore and Retail Outlet for Non-Prescription Drugs - Php 1,000 + 1% LRF per year **Clinical Research Organizations and Sponsors :** 20 Million and below – Php 3,000 + 1% LRF per year over 20 Million but below 50 Million – Php 5,000 + 1% LRF per year 50 Million and above – Php 7,000 + 1% LRF per year

		Administrative Order 50 s. 2001 *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1)Basic Requirements based on the Administrative Order No. 2020-0017:	FDA website (www.fda.gov.ph)
Accomplished e-Application Form as prescribed by FDA regulations. ● Location plan and Global Positioning System (GPS) coordinates to be filled in the e-Application Form ● Name of the Qualified Person depending on the type of health product establishment Self-Declaration in the e-Application Form	FDA eServices (www.fda.gov.ph)
2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration (in pdf): ● For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF) ● For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF) ● For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF) ● For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter (1 Scanned copy PDF)	

When a business or establishment address is different from the business name registration address, the applicant shall submit a copy of the Business Permit (e.g., Mayor's Permit).	
3) Proof of income (for Trader) - Latest Audited Financial Statement with Balance Sheet or Duly notarized Statement/Certification of Initial Capitalization.	
4) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
5) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through http://eservices.fda.gov.ph and click **"Applications"** found on the upper right corner of the system. Selects the product category (Drug) and the type of business establishment (Drug Trader, Drug Distributor, Drugstores, RONPD, CRO, Sponsor) before clicking "**Initial"** Application Fills-out all necessary information. All fields mark with asterisk (*) are required to be filled-out. Uploads the required documents as indicated on the Checklist of Requirements in pdf format. Reviews the duly filled out form in the **Self-Assessment Review**. Once reviewed, click on **"Confirm"** to submit the application.	1. Conducts pre-assessment on the submitted application and documentary requirements with regards to completeness and correctness. If the application passed the pre-assessment step, the applicant shall receive the Order of Payment with Reference Number via email. If not, the FDA shall notify the client the reason/s for non-acceptance and prompt the	None		FDA Evaluator (Center/Licensing and Registration)

	applicant to apply again through the eServices Portal.			
2. Prints the Order of Payment with Reference Number sent through the declared e-mail address Pays the application fee through existing payment channels	2. Posts payment in eServices Portal System for confirmed payments. This will prompt automatic decking of application to respective Center. **LBP OnColl Payment: 5 wd** **Other Payment Channels: 2 wd** **Note**: Acknowledgement Receipt will automatically be sent to the client once payment is posted and will signify the start of processing time of the application.	See above table		FDA Cashier Administrative and Finance Service (AFS)
3. Receives Acknowledgement Receipt through email	3.1 Checks and quality assurance of the documents provided	None	4 working days	Technical Officer of Center
	3.2 Finalizes decision on the LTO application If application is approved, the FDA shall send the LTO to the	None	3 working days	Center Director

	registered email address of the applicant. If application is disapproved, the FDA shall inform the applicant through its registered email address of the reason for such action on the application.			
4. Receives notification and prints LTO if application is approved				Qualified Person
TOTAL:			**7 working days**	

1.5.LICENSE TO OPERATE – RENEWAL APPLICATION FOR DRUG TRADERS, DRUG DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER), DRUGSTORES, RETAIL OUTLETS FOR NON-PRESCRIPTION DRUGS (RONPD), CLINICAL RESEARCH ORGANIZATIONS AND SPONSORS

Center/Office/Division	:	Center for Drug Regulation and Research (CDRR)
Classification	:	Complex
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	All Drug Traders, Drug Distributors (Importer, Exporter, Wholesaler), Drugstores/Retail Outlets for Non-Prescription Drugs, Clinical Research Organizations and Sponsors
Fees to be Paid	:	**Drug Traders:** 20 Million and below – Php 9,000 + 1% LRF over 20 Million but below 50 Million – Php 15,000 + 1% LRF 50 Million and above – Php 21,000 + 1% LRF **Drug Distributors:** Importer, Exporter, Wholesaler- Php 15,000 + 1% LRF **Drug Outlets:** Drugstore and Retail Outlet for Non-Prescription Drugs - Php 3,000 + 1% LRF **Clinical Research Organizations and Sponsors :** 20 Million and below – Php 9,000 + 1% LRF over 20 Million but below 50 Million – Php 15,000 + 1% LRF 50 Million and above – Php 21,000 + 1% LRF **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of*

		Food and Drugs **FDA Circular No. 2011-004** *Computation of Surcharge or Penalty Impossible in case of Submission of Renewal Applications Covering License of Establishments and Registration of Health Products After Their Date of Expiration Pursuant to Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implementing Rules and Regulations, and Other Purposes* **FDA Circular No. 2011-003** *Collection of Legal Research Fee (LRF) Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1) Basic Requirements based on the Administrative Order No. 2020-0017:	FDA Website (www.fda.gov.ph)
• Accomplished e-Application Form as prescribed by FDA regulations. • Declaration and Undertaking	FDA eServices (www.fda.gov.ph
2) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
3) Refer to FROO Inspection Agenda of this Citizen's Charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through https://eservices.fda.gov.ph and click **"Applications"** found on the upper right corner of the system.	1. Posts confirmed payments. This will prompt automatic routing of application to Center **LBP OnColl Payment: 5 wd**	None		FDA Cashier Administrative and Finance Service

Selects the product category (Drug) and the type of business establishment (Drug Trader, Drug Distributor, Drugstore, RONPD, CRO, Sponsor) before clicking **"Renewal"** application Reads the **"Declaration and Undertaking"** before proceeding with the application process. Check the box *"I agree to the Declaration and Undertaking"* and click on **"Start Application".** Fills-out all necessary information. All fields mark with asterisk (8*) are required to be filled-out. Updates contact numbers if necessary. Click **"Next"** to proceed to Self – Assessment Review Reviews all details in the **"Self-Assessment Review"**. Once reviewed, click on **"Confirm"** to submit application. Prints the Order of Payment with Reference Number sent through the declared email address Pays the application fee through existing payment channels	**LBP Linkbiz: auto posting** **Other Payment Channels: 2 wd** **Note**: Acknowledgement Receipt will automatically be sent to the client once payment is posted and will signify the start of processing time of the application.			
2. Receives Acknowledgement Receipt through email	2. Finalizes decision on the LTO application	None	3 working days	Center Director

	If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial			
3. Receives notification and link of LTO for Printing		None		
TOTAL:			**3 working days**	

1.6.LICENSE TO OPERATE – MINOR VARIATION APPLICATION FOR DRUG TRADERS, DRUG DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER), DRUGSTORES, RETAIL OUTLETS FOR NON-PRESCRIPTION DRUGS (RONPD), CLINICAL RESEARCH ORGANIZATIONS AND SPONSORS

Center/Office/Division	:	Center for Drug Regulation and Research (CDRR)
Classification	:	Complex
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Drug Traders, Drug Distributors (Importer, Exporter, Wholesaler), Drugstores/Retail Outlets for Non-Prescription Drugs, Clinical Research Organizations and Sponsors
Fees to be Paid	:	Minor Variation: Php 500 + 1% LRF **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS (based on Administrative Order No. 2020-0017)	WHERE TO SECURE
Minor Variation	FDA website (www.fda.gov.ph)
Transfer of Location of Offices - Accomplished e-Application Form - Business permit reflecting new location of office - Payment of fees	

Transfer of Location of Drug Retailers - Accomplished e-Application Form - Business permit reflecting new address - Payment of fees	
Change of Distributor Activity - Accomplished e-Application Form - Contract Agreements showing change in activity - Payment of fees	
Transfer/Addition of Warehouse - Accomplished e-Application Form - Business Permit reflecting new warehouse location - Payment of fees	
Additional Drugstore Activities - Accomplished e-Application Form - Additional credentials of pharmacist (as applicable) - Other documents related or specific to the additional activity, such as but not limited to: • Adult Vaccination – Standard Operating Procedure • Dispense Vaccines and Biologicals – Standard Operating Procedure • Mobile Pharmacy – Standard Operating Procedure • Online Ordering and Delivery – Standard Operating Procedure and Website Screenshot • Sterile Compounding and Non-Sterile Complex Compounding – Standard Operating Procedure • Other additional activities that may require appropriate regulation - Payment of fees	
Expansion of Office Establishments and Drug Retailers - Accomplished e-Application Form - Expansion floor plan - Payment of fees	

Change of Ownership - Accomplished e-Application Form - Business name registration reflecting new ownership - Any proof on the transfer of ownership such as any of the following • Deed of Sale or assignment or transfer of rights/ownership • Memorandum of Agreement • Notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the transfer - Payment of fees	
Change of Business Name - Accomplished e-Application Form - Business permit reflecting the new name - Payment of fees	
Zonal Change in Address - Accomplished e-application Form - Certificate of Zonal Change - Payment of fees	
Change of Qualified Person - Accomplished e-Application Form - Name of new qualified person - Applicable requirements as specified in ANNEX B of AO 2020-0017 - Payment of fees	
Change of Authorized Person - Accomplished e-Application Form - Name of new authorized person - Updated contact details - Payment of fees	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through http://eservices.fda.gov.ph and click **"Applications** "found on the upper right corner of the system. Selects the product category (Drug) and the type of business establishment (Drug Trader, Drug Distributor, Drugstores, RONPD, CRO, Sponsor) before clicking "**Variations"** Reads the **"Declaration and Undertaking "**before proceeding with the application process. Check the box *"I agree to the Declaration and Undertaking"* and click on **"Start Application".** Fills-out all necessary information. All fields mark with asterisk (*) are required to be filled-out. Uploads the required documents as indicated on the Checklist of Requirements in pdf format. Reviews the duly filled out form in the **Self-Assessment Review**. Once reviewed, click on **"Confirm"** to submit the application.	1. Conducts pre-assessment on the submitted application and documentary requirements with regards to completeness and correctness. If the application passed the pre-assessment step, the applicant shall receive the Order of Payment with Reference Number via email. If not, the FDA shall notify the client the reason/s for non-acceptance and prompt the applicant to apply again through the eServices Portal.	None		CDRR Personnel

2. Prints the Order of Payment form with Reference Number sent through the declared e-mail address Pays the application fee through existing payment channels	2. Posts payment in eServices Portal System for confirmed payments. This will prompt automatic decking of application to respective Center. **LBP OnColl Payment:** **5 wd** **Other Payment Channels:** **2 wd** **Note**: Acknowledgement Receipt will automatically be sent to the client once payment is posted and will signify the start of processing time of the application.	See above table		FDA Cashier Administrative and Finance Service (AFS)
3. Receives Acknowledgement Receipt through email	3.1 Checks and quality assurance of the documents provided	None	4 working days	Technical Officer of Center
	3.2 Finalizes decision on the LTO application If application is approved, the FDA shall send the LTO to the registered email address of the applicant.	None	3 working days	Center Director

	If application is disapproved, the FDA shall inform the applicant through its registered email address of the reason for such action on the application.			
4. Receives notification and prints LTO if application is approved				Qualified Person
TOTAL:			**7 working days**	

1.7.LICENSE TO OPERATE – INITIAL APPLICATION FOR FOOD MANUFACTURERS

Center/Office/Division	**:**	Center for Food Regulation and Research (CFRR)
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B - Government to Business
Who May Avail	**:**	All Manufacturers of Drug Products
Fees to be Paid	**:**	**Food Manufacturer:** **250K and below- Php 1,000 + 1% LRF** **Over 250K but not more than 500K- Php 1,500 + 1% LRF** **Over 500K but not more than 1 Million- Php 2,000 + 1% LRF** Over 1 Million but below 5 Million – **Php 4,000 + 1% LRF** 5 Million but below 10 Million - **Php 6,000 + 1% LRF** 10 Million but below 20 Million – **Php 10,000 + 1% LRF** 20 Million but below 50 Million – **Php 20,000 + 1% LRF** 50 Million and above - **Php 30,000 + 1% LRF** **Iodized Salt Manufacturer:** **Large Manufacturer (exceeding 2,000 m.t/year)- Php 2,000 + 1% LRF** **Medium Manufacturer (>300 m.t to 2000 m.t/year)- Php 1000 + 1% LRF** **Small Manufacturer (>200 m.t to 300 m.t/year- Php 400 + 1% LRF** **Bottled Water Processor: Php 3,000 + 1% LRF** **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee (LRF) Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1) Basic Requirements based on the Administrative Order No. 2020-0017:	
Accomplished e-Application Form as prescribed by FDA regulations. ● Location plan and Global Positioning System (GPS) coordinates to be filled in the eApplication Form ● Name of the Qualified Person depending on the type of health product establishment ● Self-Declaration in the e-Application Form	FDA e-Portal System
2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration (in pdf): ● For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF) ● For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF) ● For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF) ● For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter (1 Scanned copy PDF) When a business or establishment address is different from the business name registration address, the applicant shall submit a copy of the Business Permit (e.g., Mayor's Permit).	
3) Proof of income (Latest Audited Financial Statement with Balance Sheet) or Duly notarized Statement/Certification of Initial Capitalization.	
4) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
5) Site Master File (shall be presented to the FDA inspectors during inspection)	
6) Risk Management Plan (shall be presented to the FDA inspectors during inspection)	

7) Refer to FROO Inspection Agenda of this Citizen's Charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements (in PDF format) for e-LTO application Downloads and prints the generated Order of Payment through the ePortal System and email notification. Pays the assessed fee as per the system-generated Order of Payment through the existing payment channels	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective RFO. **LBP OnColl Payment : 5 wd** **Other Payment Channels: 2 wd**	See above table		FDA Cashier Administrative and Finance Service
	1.2 Conducts pre-licensing inspection *Refer to Regional Field Office (RFO) Citizen's Charter for the issuance of Certificate of Compliance /Recommendation for Disapproval/ Recommendation Letter.*	None		Regional Field Officer/ Inspector

	1.3 Evaluates completeness and veracity of the documents submitted.	None	13 working days	FDA Evaluator (Center/Licensing and Registration)
	1.4 Checks evaluation and veracity of documents submitted.	None	3 working days	Technical Officer of Center
	1.5 Quality assurance of the evaluation.	None	1 working day	Technical Officer of Center
	1.6 Finalizes decision on the LTO application If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	3 working days	Center Director
2. Receives notification and link of LTO for sprinting				Qualified Person
TOTAL:			**20 working days**	

1.8.LICENSE TO OPERATE – RENEWAL APPLICATION FOR FOOD MANUFACTURERS

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	:	Complex
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	All Manufacturers of Food Products
Fees to be Paid	:	**Food Manufacturer:** **250K and below- Php 1,000 + 1% LRF** **Over 250K but not more than 500K- Php 1,500 + 1% LRF** **Over 500K but not more than 1 Million- Php 2,000 + 1% LRF** Over 1 Million but below 5 Million – **Php 4,000 + 1% LRF** 5 Million but below 10 Million - **Php 6,000 + 1% LRF** 10 Million but below 20 Million – **Php 10,000 + 1% LRF** 20 Million but below 50 Million – **Php 20,000 + 1% LRF** 50 Million and above - **Php 30,000 + 1% LRF** **Iodized Salt Manufacturer:** **Large Manufacturer (exceeding 2,000 m.t/year)- Php 2,000 + 1% LRF** **Medium Manufacturer (>300 m.t to 2000 m.t/year)- Php 1000 + 1% LRF** **Small Manufacturer (>200 m.t to 300 m.t/year- Php 400 + 1% LRF** **Bottled Water Processor: Php 3,000 + 1% LRF** **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-004** *Computation of Surcharge or Penalty Impossible in case of Submission of Renewal Applications Covering License of Establishments and Registration of Health Products After Their Date of Expiration Pursuant to Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implementing*

		Rules and Regulations, and Other Purposes **FDA Circular No. 2011-003** *Collection of Legal Research Fee (LRF) Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1) Basic Requirements based on the Administrative Order No. 2020-0017:	
• Accomplished e-Application Form as prescribed by FDA regulations. • Declaration and Undertaking	FDA e-Portal (www.fda.gov.ph)
2) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
3) Refer to FROO Inspection Agenda of this Citizen's Charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal System (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements (in PDF) for e-LTO application Downloads and prints the generated Order of Payment through the ePortal and Email notification Pays the assessed fee as per the system- generated Order of Payment through the existing payment channels	1. Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective Center/Office **LBP OnColl Payment: 5 wd** **Other Payment Channels: 2 wd**	See above table		FDA Cashier Administrative and Finance Service

	1.2 Conducts inspection (if necessary) *Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/ Recommendation for Disapproval/ Recommendation Letter*	None		Regional Field Officer/ Inspector
	1.3 Evaluates completeness and veracity of the documents submitted	None	3 working days	FDA Evaluator (Center/Licensing and Registration
	1.4 Checks evaluation and veracity of documents submitted.	None	1 working day	Technical Officer of Center
	1.5 Quality assurance of the evaluation.	None	1 working day	Technical Officer of Center
	1.6 Finalizes decision on the Approval of LTO If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	2 working days	Center Director

2. Receives notification and link of LTO for printing		None		Qualified Person
TOTAL:			**7 working days**	

1.9.LICENSE TO OPERATE – MAJOR VARIATION APPLICATION FOR FOOD ESTABLISHMENT (MANUFACTURERS)

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	:	Complex
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Food Manufacturers
Fees to be Paid	:	**Major Variation: Php 500 + 1% LRF** **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS (based on Administrative Order No. 2020-0017)	WHERE TO SECURE
Major Variation	FDA ePortal System (www.fda.gov.ph)
Transfer of Location of Manufacturing Plant - Accomplished e-Application Form - Business permit reflecting the new address - Updated Site Master File to be presented upon inspection - Payment of fees	
Expansion of Manufacturer and/or Additional Product Line ; or Change of Manufacturing Activity - Accomplished e-Application Form - Updated Site Master File to be presented upon inspection	

- Payment of fees	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements (in PDF format) for e-LTO application Downloads and prints the generated Order of Payment through the ePortal System and email notification. Pays the assessed fee as per the system-generated Order of Payment through the existing payment channels	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective RFO. **LBP OnColl Payment : 5 wd** **Other Payment Channels : 2 wd**	See above table		FDA Cashier Administrative and Finance Service
	1.2 Conducts inspection *Refer to Regional Field Office (RFO) Citizen's Charter for the issuance of Certificate of Compliance /Recommendation for Disapproval/ Recommendation Letter.*	None		Regional Field Officer/ Inspector
	1.3 Evaluates completeness and veracity of the documents submitted.	None	13 working days	FDA Evaluator (Center/Licensing and Registration)

	1.4 Checks evaluation and veracity of documents submitted.	None	3 working days	Technical Officer of Center
	1.5 Quality assurance of the evaluation.	None	1 working day	Technical Officer of Center
	1.6 Finalizes decision on the LTO application If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	3 working days	Center Director
2. Receives notification and link of LTO for printing				Qualified Person
TOTAL:			**20 working days**	

1.10.LICENSE TO OPERATE – INITIAL APPLICATION FOR FOOD TRADERS AND DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER)

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	:	Complex
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Food Traders and Food Distributors (Importer, Exporter, Wholesaler)
Fees to be Paid	:	**Food Traders:** **250K and below- Php 1,000 + 1% LRF** **Over 250K but not more than 500K- Php 1,500 + 1% LRF** **Over 500K but not more than 1 Million- Php 2,000 + 1% LRF** Over 1 Million but below 5 Million – **Php 4,000 + 1% LRF** 5 Million but below 10 Million - **Php 6,000 + 1% LRF** 10 Million but below 20 Million – **Php 10,000 + 1% LRF** 20 Million but below 50 Million – **Php 20,000 + 1% LRF** 50 Million and above - **Php 30,000 + 1% LRF** **Food Distributors:** Importer, Exporter, Wholesaler – Php 8,000 + 1% LRF Iodized Salt Importer – Php 1,000 + 1% LRF **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1)Basic Requirements based on the Administrative Order No. 2020-0017:	
Accomplished e-Application Form as prescribed by FDA regulations. . ● Location plan and Global Positioning System (GPS) coordinates to be filled in the e-Application Form ● Name of the Qualified Person depending on the type of health product establishment Self-Declaration in the e-Application Form	FDA eServices (www.fda.gov.ph)
2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration (in pdf): ● For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF) ● For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF) ● For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF) ● For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter (1 Scanned copy PDF) When a business or establishment address is different from the business name registration address, the applicant shall submit a copy of the Business Permit (e.g. Mayor's Permit).	
3) Proof of income (for Trader) - Latest Audited Financial Statement with Balance Sheet or Duly notarized Statement/Certification of Initial Capitalization.	
4) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
5) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through http://eservices.fda.gov.ph and click **"Applications** "found on the upper right corner of the system. Selects the product category (Food) and the type of business establishment (Food Trader, Food Distributor) before clicking "**Initial"** Application Reads the **"Declaration and Undertaking "**before proceeding with the application process. Check the box *"I agree to the Declaration and Undertaking"* and click on **"Start Application".** Fills-out all necessary information. All fields mark with asterisk (*) are required to be filled-out. Uploads the required documents as indicated on the Checklist of Requirements in pdf format. Reviews the duly filled out form in the **Self-Assessment Review**. Once reviewed, click on **"Confirm"** to submit the application.	1. Conducts pre-assessment on the submitted application and documentary requirements with regards to completeness and correctness. If the application passed the pre-assessment step, the applicant shall receive the Order of Payment with Reference Number via email. If not, the FDA shall notify the client the reason/s for non-acceptance and prompt the applicant to apply again through the eServices Portal.	None		FDA Evaluator (Center/Licensing and Registration)
2. Prints the Order of Payment form with Reference Number sent through the declared e-mail address Pays the application fee through existing payment channels	2. Posts payment in eServices Portal System for confirmed payments. This will prompt automatic decking of application to respective Center.	See above table		FDA Cashier Administrative and Finance Service (AFS)

	LBP OnColl Payment: 5 wd **Other Payment Channels: 2 wd** **Note**: Acknowledgement Receipt will automatically be sent to the client once payment is posted and will signify the start of processing time of the application.			
1. Receives Acknowledgement Receipt through email	3.1 Checks and quality assurance of the documents provided	None	11 working days	Technical Officer of Center
	3.2 Finalizes decision on the LTO application If application is approved, the FDA shall send the LTO to the registered email address of the applicant. If application is disapproved, the FDA shall inform the applicant through its registered email address of the reason for such action on the application.	None	3 working days	Center Director
2. Receives notification and prints LTO if application is approved				Qualified Person
TOTAL:			**14 working days**	

1.11.LICENSE TO OPERATE – RENEWAL APPLICATION FOR FOOD TRADERS AND FOOD DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER)

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	:	Complex
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	All Food Traders and Food Distributors (Importer, Exporter, Wholesaler)
Fees to be Paid	:	**Food Traders:** **250K and below- Php 1,000 + 1% LRF** **Over 250K but not more than 500K- Php 1,500 + 1% LRF** **Over 500K but not more than 1 Million- Php 2,000 + 1% LRF** Over 1 Million but below 5 Million – **Php 4,000 + 1% LRF** 5 Million but below 10 Million - **Php 6,000 + 1% LRF** 10 Million but below 20 Million – **Php 10,000 + 1% LRF** 20 Million but below 50 Million – **Php 20,000 + 1% LRF** 50 Million and above - **Php 30,000 + 1% LRF** **Food Distributors:** Importer, Exporter, Wholesaler – Php 8,000 + 1% LRF Iodized Salt Importer – Php 1,000 + 1% LRF **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-004**

		Computation of Surcharge or Penalty Impossible in case of Submission of Renewal Applications Covering License of Establishments and Registration of Health Products After Their Date of Expiration Pursuant to Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implementing Rules and Regulations, and Other Purposes **FDA Circular No. 2011-003** *Collection of Legal Research Fee (LRF) Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1) Basic Requirements based on the Administrative Order No. 2020-0017:	FDA Website (www.fda.gov.ph)
• Accomplished e-Application Form as prescribed by FDA regulations. • Declaration and Undertaking	
2) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
3) Refer to FROO Inspection Agenda of this Citizen's Charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through https://eservices.fda.gov.ph and click **"Applications"** found on the upper right corner of the system. Selects the product category (Drug) and the type of business establishment (Drug Trader, Drug Distributor, Drugstore, RONPD, CRO, Sponsor) before clicking **"Renewal"** application	1. Posts confirmed payments. This will prompt automatic routing of application to Center **LBP OnColl Payment: 5 wd** **LBP Linkbiz: auto posting** **Other Payment Channels: 2 wd**	None		FDA Cashier Administrative and Finance Service

Reads the **"Declaration and Undertaking"** before proceeding with the application process. Check the box *"I agree to the Declaration and Undertaking"* and click on **"Start Application".** Fills-out all necessary information. All fields mark with asterisk (8*) are required to be filled-out. Updates contact numbers if necessary. Click **"Next"** to proceed to Self – Assessment Review Reviews all details in the **"Self-Assessment Review"**. Once reviewed, click on **"Confirm"** to submit application. Prints the Order of Payment with Reference Number sent through the declared email address Pays the application fee through existing payment channels	**Note**: Acknowledgement Receipt will automatically be sent to the client once payment is posted and will signify the start of processing time of the application.			
2. Receives Acknowledgement Receipt through email				
3. Receives notification and link of LTO for Printing		None		
TOTAL:	**The LTO shall be automatically generated by the system once the payment has been posted by the FDA Cashier**			

1.12.LICENSE TO OPERATE – MINOR VARIATION APPLICATION FOR FOOD TRADERS AND FOOD DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER)

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	:	Complex
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Food Traders and Food Distributors (Importer, Exporter, Wholesaler)
Fees to be Paid	:	**Minor Variation: Php 500 + 1% LRF** **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS (based on Administrative Order No. 2020-0017)	WHERE TO SECURE
Minor Variation	FDA eServices (www.fda.gov.ph)
Transfer of Location of Offices - Accomplished e-Application Form - Business permit reflecting new location of office - Payment of fees	
Change of Distributor Activity - Accomplished e-Application Form	

- Contract Agreements showing change in activity - Payment of fees	
Transfer/Addition of Warehouse - Accomplished e-Application Form - Business Permit reflecting new warehouse location - Payment of fees	
Expansion of Office Establishments and Drug Retailers - Accomplished e-Application Form - Expansion floor plan - Payment of fees	
Change of Ownership - Accomplished e-Application Form - Business name registration reflecting new ownership - Any proof on the transfer of ownership such as any of the following • Deed of Sale or assignment or transfer of rights/ownership • Memorandum of Agreement • Notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the transfer - Payment of fees	
Change of Business Name - Accomplished e-Application Form - Business permit reflecting the new name - Payment of fees	
Zonal Change in Address - Accomplished e-application Form - Certificate of Zonal Change - Payment of fees	

Change of Qualified Person - Accomplished e-Application Form - Name of new qualified person - Applicable requirements as specified in ANNEX B of AO 2020-0017 - Payment of fees	
Change of Authorized Person - Accomplished e-Application Form - Name of new authorized person - Updated contact details - Payment of fees	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through http://eservices.fda.gov.ph and click **"Applications** "found on the upper right corner of the system. Selects the product category (Food) and the type of business establishment (Food Trader, Food Distributor) before clicking "**Variations"** Reads the **"Declaration and Undertaking "**before proceeding with the application process. Check the box *"I agree to the Declaration and Undertaking"* and click on **"Start Application".** Fills-out all necessary information. All fields mark with asterisk (*) are required to be filled-out.	1. Conducts pre-assessment on the submitted application and documentary requirements with regards to completeness and correctness. If the application passed the pre-assessment step, the applicant shall receive the Order of Payment with Reference Number via email. If not, the FDA shall notify the client the reason/s for non-acceptance and	None		FDA Evaluator (Center/Licensing and Registration)

Uploads the required documents as indicated on the Checklist of Requirements in pdf format. Reviews the duly filled out form in the **Self-Assessment Review**. Once reviewed, click on **"Confirm"** to submit the application.	prompt the applicant to apply again through the eServices Portal.			
2. Prints the Order of Payment form with Reference Number sent through the declared e-mail address Pays the application fee through existing payment channels	2. Posts payment in eServices Portal System for confirmed payments. This will prompt automatic decking of application to respective Center. **LBP OnColl Payment: 5 wd** **Other Payment Channels: 2 wd** **Note**: Acknowledgement Receipt will automatically be sent to the client once payment is posted and will signify the start of processing time of the application.	See above table		FDA Cashier Administrative and Finance Service (AFS)
3. Receives Acknowledgement Receipt through email	3.1 Checks and quality assurance of the documents provided	None	4 working days	Technical Officer of Center

	3.2 Finalizes decision on the LTO application If application is approved, the FDA shall send the LTO to the registered email address of the applicant. If application is disapproved, the FDA shall inform the applicant through its registered email address of the reason for such action on the application.	None	3 working days	Center Director
4. Receives notification and prints LTO if application is approved				Qualified Person
TOTAL:			**7 working days**	

1.13.LICENSE TO OPERATE – INITIAL APPLICATION FOR MEDICAL DEVICE MANUFACTURERS

Center/Office/Division	**:**	Center for Device Regulation, Radiation and Health Research (CDRRHR)
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B - Government to Business
Who May Avail	**:**	All Manufacturers of Medical Device Products
Fees to be Paid	**:**	**Medical Device Manufacturer:** 20 Million and below – Php 5,000 +1% LRF over 20 Million but below 50 Million – Php 7,000 +1% LRF 50 Million and above – Php 10,000 +1% LRF **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee (LRF) Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1) Basic Requirements based on the Administrative Order No. 2020-0017:	
Accomplished e-Application Form as prescribed by FDA regulations. ● Location plan and Global Positioning System (GPS) coordinates to be filled in the eApplication Form ● Name of the Qualified Person depending on the type of health product establishment ● Self-Declaration in the e-Application Form	FDA e-Portal System

2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration (in pdf): ● For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF) ● For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF) ● For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF) ● For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter (1 Scanned copy PDF) When a business or establishment address is different from the business name registration address, the applicant shall submit a copy of the Business Permit (e.g., Mayor's Permit).	
3) Proof of income (Latest Audited Financial Statement with Balance Sheet) or Duly notarized Statement/Certification of Initial Capitalization.	
4) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
5) Site Master File (shall be presented to the FDA inspectors during inspection)	
6) Risk Management Plan (shall be presented to the FDA inspectors during inspection)	
7) Refer to FROO Inspection Agenda of this Citizen's Charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal (http://eportal.fda.gov.ph) using the issued username and password, and	1.1 Posts payment in ePortal for confirmed payments. This will	See above table		FDA Cashier

uploads the required documentary requirements (in PDF format) for e-LTO application Downloads and prints the generated Order of Payment through the ePortal System and email notification. Pays the assessed fee as per the system-generated Order of Payment through the existing payment channels	prompt automatic decking of application to respective RFO. **LBP OnColl Payment: 5 wd** **Other Payment Channels: 2 wd**			Administrative and Finance Service
	1.2 Conducts pre-licensing inspection *Refer to Regional Field Office (RFO) Citizen's Charter for the issuance of Certificate of Compliance /Recommendation for Disapproval/ Recommendation Letter.*	None		Regional Field Officer/ Inspector
	1.3 Evaluates completeness and veracity of the documents submitted.	None	13 working days	FDA Evaluator (Center/Licensing and Registration)
	1.4 Checks evaluation and veracity of documents submitted.	None	3 working days	Technical Officer of Center
	1.5 Quality assurance of the evaluation.	None	1 working day	Technical Officer of Center

	1.6 Finalizes decision on the LTO application If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	3 working days	Center Director
2. Receives notification and link of LTO for printing				Qualified Person
TOTAL:			**20 working days**	

1.14.LICENSE TO OPERATE – RENEWAL APPLICATION FOR MEDICAL DEVICE MANUFACTURERS

Center/Office/Division	:	Center for Device Regulation, Radiation and Health Research (CDRRHR)
Classification	:	Complex
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	All Manufacturers of Medical Device Products
Fees to be Paid	:	**Medical Device Manufacturer:** 20 Million and below – Php 5,000 +1% LRF over 20 Million but below 50 Million – Php 7,000 +1% LRF 50 Million and above – Php 10,000 +1% LRF **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-004** *Computation of Surcharge or Penalty Impossible in case of Submission of Renewal Applications Covering License of Establishments and Registration of Health Products After Their Date of Expiration Pursuant to Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implementing Rules and Regulations, and Other Purposes* **FDA Circular No. 2011-003** *Collection of Legal Research Fee (LRF) Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1) Basic Requirements based on the Administrative Order No. 2020-0017:	
● Accomplished e-Application Form as prescribed by FDA regulations. ● Declaration and Undertaking	FDA e-Portal (www.fda.gov.ph)

2) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
3) Refer to FROO Inspection Agenda of this Citizen's Charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal System (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements (in PDF) for e-LTO application Downloads and prints the generated Order of Payment through the ePortal and Email notification Pays the assessed fee as per the system- generated Order of Payment through the existing payment channels	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective Center/Office **LBP OnColl Payment: 5 wd** **Other Payment Channels:** 1. **2 wd**	See above table		FDA Cashier Administrative and Finance Service
	1.2 Conducts inspection (if necessary) *Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/*	None		Regional Field Officer/ Inspector

	Recommendation for Disapproval/ Recommendation Letter			
	1.3 Evaluates completeness and veracity of the documents submitted	None	3 working days	FDA Evaluator (Center/Licensing and Registration
	1.4 Checks evaluation and veracity of documents submitted.	None	1 working day	Technical Officer of Center
	1.5 Quality assurance of the evaluation.	None	1 working day	Technical Officer of Center
	1.6 Finalizes decision on the Approval of LTO If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	2 working days	Center Director
2. Receives notification and link of LTO for printing		None		Qualified Person
TOTAL:			**7 working days**	

1.15..LICENSE TO OPERATE – MAJOR VARIATION APPLICATION FOR MEDICAL DEVICE ESTABLISHMENT (MANUFACTURERS)

Center/Office/Division	:	Center for Device Regulation, Radiation, and Health Research (CDRRHR)
Classification	:	Complex
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Medical Device Manufacturers
Fees to be Paid	:	**Major Variation: Php 500 + 1% LRF** **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS (based on Administrative Order No. 2020-0017)	WHERE TO SECURE
Major Variation	FDA ePortal System (www.fda.gov.ph)
Transfer of Location of Manufacturing Plant - Accomplished e-Application Form - Business permit reflecting the new address - Updated Site Master File to be presented upon inspection - Payment of fees	
Expansion of Manufacturer and/or Additional Product Line; or Change of Manufacturing Activity - Accomplished e-Application Form - Updated Site Master File to be presented upon inspection	

- Payment of fees	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements (in PDF format) for e-LTO application Downloads and prints the generated Order of Payment through the ePortal System and email notification. Pays the assessed fee as per the system-generated Order of Payment through the existing payment channels	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective RFO. **LBP OnColl Payment: 5 wd** **Other Payment Channels: 2 wd**	See above table		Qualified Person FDA Cashier Administrative and Finance Service
	1.2 Conducts inspection *Refer to Regional Field Office (RFO) Citizen's Charter for the issuance of Certificate of Compliance /Recommendation for Disapproval/ Recommendation Letter.*	None		Regional Field Officer/ Inspector

	1.3 Evaluates completeness and veracity of the document submitted.	None	13 working days	FDA Evaluator (Center/Licensing and Registration)
	Checks evaluation and veracity of documents submitted.	None	3 working days	Technical Officer of Center
	1.4 Quality assurance of the evaluation.	None	1 working day	Technical Officer of Center
	1.5 Finalizes decision on the LTO application 1.6 If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	3 working days	Center Director
2. Receives notification and link of LTO for printing				Qualified Person
TOTAL:			**20 working days**	

1.16.LICENSE TO OPERATE – INITIAL APPLICATION FOR MEDICAL DEVICE TRADERS AND DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER)

Center/Office/Division	:	Center for Device Regulation, Radiation and Health Research (CDRRHR)
Classification	:	Complex
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Medical Device Traders and Distributors (Importer, Exporter, Wholesaler)

Fees to be Paid	:	**Medical Device Trader:** 20 million and below – Php 3,000 + 1% LRF Over 20 million but below 50 million – Php 5,000 + 1% LRF 50 million and above – Php 7,000 + 1% LRF **Medical Device Distributors (Importer, Exporter, Wholesaler) :** Php 4,000 + 1% LRF **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1)Basic Requirements based on the Administrative Order No. 2020-0017:	FDA website (www.fda.gov.ph)

Accomplished e-Application Form as prescribed by FDA regulations. ● Location plan and Global Positioning System (GPS) coordinates to be filled in the e-Application Form ● Name of the Qualified Person depending on the type of health product establishment Self-Declaration in the e-Application Form	FDA eServices (www.fda.gov.ph)
2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration (in pdf): ● For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF) ● For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF) ● For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF) ● For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter (1 Scanned copy PDF) When a business or establishment address is different from the business name registration address, the applicant shall submit a copy of the Business Permit (e.g., Mayor's Permit).	
3) Proof of income (for Trader) - Latest Audited Financial Statement with Balance Sheet or Duly notarized Statement/Certification of Initial Capitalization.	
4) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
5) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through http://eservices.fda.gov.ph and click **"Applications"** found on the upper right corner of the system. Selects the product category (Medical Device) and the type of business establishment (Medical Device Trader, Medical Device Distributor) before clicking "**Initial"** Application Reads the **"Declaration and Undertaking "**before proceeding with the application process. Check the box *"I agree to the Declaration and Undertaking"* and click on **"Start Application".** Fills-out all necessary information. All fields mark with asterisk (*) are required to be filled-out. Uploads the required documents as indicated on the Checklist of Requirements in pdf format. Reviews the duly filled out form in the **Self-Assessment Review**. Once reviewed, click on **"Confirm"** to submit the application. Prints the Order of Payment form with Reference Number sent through the declared e-mail address	1.1 Conducts pre-assessment on the submitted application and documentary requirements with regards to completeness and correctness. If the application passed the pre-assessment step, the applicant shall receive the Order of Payment with Reference Number via email. If not, the FDA shall notify the client the reason/s for non-acceptance and prompt the applicant to apply again through the eServices Portal.	None		FDA Evaluator (Center/Licensing and Registration)

2. Pays the application fee through existing payment channels Receives Acknowledgement Receipt through email	2.1 Posts payment in eServices Portal System for confirmed payments. This will prompt automatic decking of application to respective Center. **LBP OnColl Payment: 5 wd** **Other Payment Channels: 2 wd** **Note**: Acknowledgement Receipt will automatically be sent to the client once payment is posted and will signify the start of processing time of the application.	See above table	0	Qualified Person FDA Cashier Administrative and Finance Service (AFS)
	2.2 Checks and quality assurance of the documents provided	None	11 working days	Technical Officer of Center
	2.3 Finalizes decision on the LTO application If application is approved, the FDA shall send the LTO to the registered email address of the applicant. If application is disapproved, the FDA shall inform the	None	3 working days	Center Director

	applicant through its registered email address of the reason for such action on the application.			
3. Receives notification and prints LTO if application is approved				Qualified Person
TOTAL:			**14 working days**	

1.17.LICENSE TO OPERATE – RENEWAL APPLICATION FOR MEDICAL DEVICE TRADERS AND MEDICAL DEVICE DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER)

Center/Office/Division	:	Center for Device Regulation, Radiation and Health Research (CDRRHR)
Classification	:	Complex
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	All Medical Device Traders and Medical Device Distributors (Importer, Exporter, Wholesaler)
Fees to be Paid	:	**Medical Device Trader :** 20 million and below – Php 3,000 + 1% LRF Over 20 million but below 50 million – Php 5,000 + 1% LRF 50 million and above – Php 7,000 + 1% LRF **Medical Device Distributors (Importer, Exporter, Wholesaler) :** Php 4,000 + 1% LRF **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-004** *Computation of Surcharge or Penalty Impossible in case of Submission of Renewal Applications Covering License of Establishments and Registration of Health Products After Their Date of Expiration Pursuant to Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implementing Rules and Regulations, and Other Purposes* **FDA Circular No. 2011-003** *Collection of Legal Research Fee (LRF) Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1) Basic Requirements based on the Administrative Order No. 2020-0017:	FDA Website (www.fda.gov.ph)
• Accomplished e-Application Form as prescribed by FDA regulations. • Declaration and Undertaking	
2) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
3) Refer to FROO Inspection Agenda of this Citizen's Charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through https://eservices.fda.gov.ph and click **"Applications"** found on the upper right corner of the system. Selects the product category (Drug) and the type of business establishment (Drug Trader, Drug Distributor, Drugstore, RONPD, CRO, Sponsor) before clicking **"Renewal"** application Reads the **"Declaration and Undertaking"** before proceeding with the application process. Check the box *"I agree to the Declaration and Undertaking"* and click on **"Start Application".** Fills-out all necessary information. All fields mark with asterisk (8*) are required to be filled-out.	1. System sends the Order of Payment after receipt of the application	None	0	Qualified Person

Updates contact numbers if necessary. Click **"Next"** to proceed to Self – Assessment Review Reviews all details in the **"Self-Assessment Review"**. Once reviewed, click on **"Confirm"** to submit application. Prints the Order of Payment with Reference Number sent through the declared email address				
2. Pays the application fee through existing payment channels Receives Acknowledgement Receipt through email	2. Posts confirmed payments. This will prompt automatic routing of application to Center **LBP OnColl Payment: 5 wd** **LBP Linkbiz: auto posting** **Other Payment Channels: 2 wd** **Note**: Acknowledgement Receipt will automatically be sent to the client once payment is posted and will signify the start of processing time of the application.	None		FDA Cashier Administrative and Finance Service

1.6.1.1 Receives notification and link of LTO for Printing		None		
TOTAL:	**The LTO shall be automatically generated by the system once the payment has been posted by the FDA Cashier**			

1.18.LICENSE TO OPERATE – MINOR VARIATION APPLICATION FOR MEDICAL DEVICE TRADERS AND MEDICAL DEVICE DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER)

Center/Office/Division	:	Center for Device Regulation, Radiation, and Health Research (CDRRHR)
Classification	:	Complex
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Medical Device Traders and Medical Device Distributors (Importer, Exporter, Wholesaler)
Fees to be Paid	:	**Minor Variation: Php 500 + 1% LRF** **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS (based on Administrative Order No. 2020-0017)	WHERE TO SECURE
Minor Variation	FDA eServices (www.fda.gov.ph)
Transfer of Location of Offices - Accomplished e-Application Form - Business permit reflecting new location of office - Payment of fees	
Change of Distributor Activity	

- Accomplished e-Application Form - Contract Agreements showing change in activity - Payment of fees	
Transfer/Addition of Warehouse - Accomplished e-Application Form - Business Permit reflecting new warehouse location - Payment of fees	
Expansion of Office Establishments and Drug Retailers - Accomplished e-Application Form - Expansion floor plan - Payment of fees	
Change of Ownership - Accomplished e-Application Form - Business name registration reflecting new ownership - Any proof on the transfer of ownership such as any of the following • Deed of Sale or assignment or transfer of rights/ownership • Memorandum of Agreement • Notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the transfer - Payment of fees	
Change of Business Name - Accomplished e-Application Form - Business permit reflecting the new name - Payment of fees	
Zonal Change in Address - Accomplished e-application Form - Certificate of Zonal Change	

- Payment of fees	
Change of Qualified Person - Accomplished e-Application Form - Name of new qualified person - Applicable requirements as specified in ANNEX B of AO 2020-0017 - Payment of fees	
Change of Authorized Person - Accomplished e-Application Form - Name of new authorized person - Updated contact details - Payment of fees	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through http://eservices.fda.gov.ph and click **"Applications"** found on the upper right corner of the system. Selects the product category (Food) and the type of business establishment (Food Trader, Food Distributor) before clicking "**Variations"** Reads the **"Declaration and Undertaking"** before proceeding with the application process. Check the box *"I agree to the Declaration and Undertaking"* and click on **"Start Application".**	1. Conducts pre-assessment on the submitted application and documentary requirements with regards to completeness and correctness. If the application passed the pre-assessment step, the applicant shall receive the Order of Payment with Reference Number via email.	None		FDA Evaluator (Center/Licensing and Registration)

Fills-out all necessary information. All fields mark with asterisk (*) are required to be filled-out. Uploads the required documents as indicated on the Checklist of Requirements in pdf format. Reviews the duly filled out form in the **Self-Assessment Review**. Once reviewed, click on **"Confirm"** to submit the application. Prints the Order of Payment form with Reference Number sent through the declared e-mail address	If not, the FDA shall notify the client the reason/s for non-acceptance and prompt the applicant to apply again through the eServices Portal.			
2. Pays the application fee through existing payment channels Receives Acknowledgement Receipt through email	2.1 Posts payment in eServices Portal System for confirmed payments. This will prompt automatic decking of application to respective Center. **LBP OnColl Payment: 5 wd** **Other Payment Channels: 2 wd** **Note**: Acknowledgement Receipt will automatically be sent to the client once payment is posted and will	See above table	0	FDA Cashier Administrative and Finance Service (AFS)

	signify the start of processing time of the application.			
	2.2 Checks and quality assurance of the documents provided	None	4 working days	Technical Officer of Center
	2.3 Finalizes decision on the LTO application If application is approved, the FDA shall send the LTO to the registered email address of the applicant. If application is disapproved, the FDA shall inform the applicant through its registered email address of the reason for such action on the application.	None	3 working days	Center Director
3. Receives notification and prints LTO if application is approved				Qualified Person
TOTAL:			**7 working days**	

1.19. LICENSE TO OPERATE – INITIAL APPLICATION FOR MANUFACTURERS OF COSMETICS, TOYS AND CHILD CARE ARTICLES (TCCAS) AND HOUSEHOLD URBAN PESTICIDES (HUPS)

Center/Office/Division	:	Center for Cosmetic and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR)
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	Manufacturers of Cosmetics, Toys and Child Care Articles and Household Urban Pesticides
Fees to be Paid	:	**Cosmetics Manufacturer:** 20 Million and below - Php 5,000 +1 % LRF over 20 Million but below 50 Million - Php 10,000 + 1 % LRF 50 Million and above - Php 15,000 + 1 % LRF **Household Hazardous Substance Manufacturer:** 1 Million and below - Php 1,000 + 1 % LRF over 1 Million but below 5 Million - Php 2,000 + 1 % LRF 5 Million but below 10 Million - Php 3,000 + 1 % LRF 10 Million but below 20 Million - Php 5,000 + 1 % LRF` 20 Million but below 50 Million - Php 10,000 + 1 % LRF 50 Million and above - Php 15,000 + 1 % LRF **Administrative Order 50 s. 2001*** Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs **FDA Circular No. 2011-003**

		Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1) Basic Requirements based on the Administrative Order No. 2020-0017:	
Accomplished e-Application Form as prescribed by FDA regulations. ● Location plan and Global Positioning System (GPS) coordinates to be filled in the eApplication Form ● Name of the Qualified Person depending on the type of health product establishment ● Self-Declaration in the e-Application Form	FDA e-Portal System (www.fda.gov.ph)
2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration (in pdf): ● For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF) ● For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF) ● For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF) ● For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter (1 Scanned copy PDF) When a business or establishment address is different from the business name registration address, the applicant shall submit a copy of the Business Permit (e.g. Mayor's Permit).	
3) Proof of income (Latest Audited Financial Statement with Balance Sheet) or Duly notarized Statement/Certification of Initial Capitalization.	

4) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
5) Site Master File (shall be presented to the FDA inspectors during inspection)	
6) Risk Management Plan (shall be presented to the FDA inspectors during inspection)	
7) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION1	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements (in PDF format) for e-LTO application Downloads and prints the generated Order of Payment through the ePortal and Email notification. Pays the assessed fee as per the system-generated Order of Payment Form through the existing payment channels	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective RFO. **LBP OnColl Payment: 5 wd** **Other Payment Channels: 3 wd**	See above table	0	Qualified Person FDA Cashier Administrative and Finance Service
	1.2 Conducts pre-licensing inspection. *Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/Recommendation for*	None	0	Regional Field Officer/Inspector

	Disapproval/ Recommendation Letter.			
	1.3 Evaluates completeness and veracity of the documents submitted.	None	13 working days	FDA Evaluator (Center/Licensing and Registration)
	1.4 Checks evaluation and veracity of the documents submitted.	None	3 working days	Technical Office of Center
	1.5 Quality assurance of the evaluation.	None	1 working day	Technical Officer of Center
	1.6 Finalizes decision on the application. If application is disapproved, the applicant will be notified through email ad will receive the Letter of Denial	None	3 working days	Center Director
2. Receives notification and link of LTO for printing				Qualified Person
TOTAL:			**20 working days**	

1.20.LICENSE TO OPERATE – RENEWAL APPLICATION FOR MANUFACTURERS OF COSMETICS, TOYS AND CHILD CARE ARTICLES (TCCAS) AND HOUSEHOLD URBAN PESTICIDES (HUPS)

Center/Office/Division	:	Center for Cosmetic and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR)
Classification	:	Complex
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	Manufacturers of Cosmetics, Toys and Childcare Articles and Household Urban Pesticides
Fees to be Paid	:	**Cosmetics Manufacturer:** 20 Million and below - Php 10,000 + 1 % LRF over 20 Million but below 50 Million - Php 20,000 + 1 % LRF 50 Million and above - Php 15,000 + 1 % LRF **Household Hazardous Substance Manufacturer:** 1 Million and below - Php 2,000 + 10 % LRF over 1 Million but below 5 Million - Php 4,000 + 1 % LRF 5 Million but below 10 Million - Php 6,000 + 1 % LRF 10 Million but below 20 Million - Php 10,000 + 1 % LRF 20 Million but below 50 Million - Php 20,000 + 1% LRF 50 Million and above - Php 30,000 + 1% LRF **Administrative Order 50 s. 2001*** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-004** *Computation of Surcharge or Penalty Impossible in case of Submission of Renewal Applications Covering License of Establishments and Registration of Health Products After Their Date of Expiration Pursuant to Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implementing*

		Rules and Regulations, and Other Purposes **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1)Basic Requirements based on the Administrative Order No. 2020-0017:	
• Accomplished e-Application Form as prescribed by FDA regulations. • Declaration and Undertaking	FDA e-Portal (www.fda.gov.ph) Applicant /Qualified Person
2) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	FDA Cashier/Other FDA Authorized Payment Portals or Banks
3) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	Applicant/Qualified person

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements (in PDF) for e-LTO application Downloads and prints the generated Order of Payment through the ePortal and Email notification Pay the assessed fee as per the system generated Order of Payment Form through the existing payment channels	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective Center/Office.	See above table	0	FDA Cashier Administrative and Finance Service

	1.2 Conducts inspection *Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/Recommendation for Disapproval/ Recommendation Letter*	None		Regional Field Officer/ Inspector
	1.3 Evaluates completeness and veracity of the documents submitted	None	3 working days	FDA Evaluator (Center/Licensing and Registration)
	1.4 Checks evaluation and veracity of documents submitted.	None	2 working day	Technical Officer of Center
	1.5 Quality assurance of the evaluation.	None	1 working day	Technical Officer of Center
	1.6 Finalizes decision on the Approval of LTO If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	1 working day	Center Director
2. Receives notification and link of LTO for printing		None		Qualified Person
TOTAL:			**7 working days**	

1.21.LICENSE TO OPERATE – MAJOR VARIATION APPLICATION

Center/Office/Division	**:**	Center for Cosmetic and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR)
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B - Government to Business
Who May Avail	**:**	Manufacturers of Cosmetics, Toys and Childcare Articles, and Household Urban Pesticides
Fees to be Paid	**:**	**Major Variation – Php 500 +1% LRF** **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS **(Based on Administrative Order No. 2020-0017)**	**WHERE TO SECURE**
Major Variation	
A. Transfer of Location of Manufacturing Plant 1. Accomplished e-Application Form 2. Business permit reflecting the new address 3. Updated Site Master File to be presented upon inspection 4. Payment of fees	Qualified Person

B. Expansion of Manufacturer and/or Additional Product Line; or Change of Manufacturing Activity 1. Accomplished e-Application Form 2. Updated Site Master File to be presented upon inspection 3. Payment of fees	
1) Proof of payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	FDA Cashier/Other FDA Authorized Payment Portals or Banks
2) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	Applicant/Qualified person

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements for e-LTO application Downloads and prints the generated Order of Payment through the ePortal and Email notification Pays the assessed fee as per the system-generated Order of Payment Form through the existing payment channels	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective RFO. **LBP OnColl Payment: 5wd** **Other Payment Channels: 2 wd**	See above table	0	FDA Cashier Administrative and Finance Service

	1.2 Conducts inspection Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/Recommendation for Disapproval/ Recommendation Letter	None	0	Regional Field Officer/ Inspector
	1.3 Evaluates completeness and veracity of the documents submitted.	None	12 working days	FDA Evaluator (Center/Licensing and Registration)
	1.4 Checks evaluation and veracity of documents submitted.	None	4 working days	Technical Officer of Center
	1.4 Quality assurance of the evaluation.	None	2 working day	Technical Officer of Center
	1.5 Finalizes decision on the LTO application If the application is disapproved, the applicant will be notified through email and will receive the letter of Denial	None	2 working days	Center Director
2. Receives notification and link of LTO for printing				Qualified Person
TOTAL:			**20 working days**	

1.22.LICENSE TO OPERATE – INITIAL APPLICATION FOR TRADERS, DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER) OF COSMETICS, TOYS AND CHILD CARE ARTICLES (TCCAS) AND HOUSEHOLD URBAN PESTICIDES (HUPS)

Center/Division	:	Center for Cosmetic and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR)
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Traders, Distributors (Importer, Exporter, Wholesaler) Cosmetics, Toys and Child Care Articles (TCCAs) and Household Urban Pesticides (HUPs)
Fees to be Paid	:	**Cosmetics Trader:** 20 Million and below -Php 3,000+ 1 % LRF over 20 Million but below 50 Million- Php 5,000+ 1% LRF 50 Million and above - Php 7,000+ 1 % LRF **Cosmetics Distributors:** Importer, Exporter, Wholesaler - Php 3,000+ 1 % LRF **Household Hazardous Substances:** Importer, Exporter, Wholesaler- Php 3,000+ 1 % LRF **Administrative Order 50 s. 2001*** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1)Basic Requirements based on the Administrative Order No. 2020-0017: ● Accomplished e-Application Form as prescribed by FDA regulations. ● Location plan and Global Positioning System (GPS) to be filled in the eApplication Form ● Name of the Qualified Person Self-Declaration in the e-Application Form	FDA e-Portal (www.fda.gov.ph)
2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration: ● For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF) ● For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF) ● For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF) ● For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter include Mayor's Permit or Barangay Clearance provision (1 Scanned copy PDF) A copy of Business permit (i.e., Mayor's Permit or Barangay Clearance provision) will be submitted for business or establishment address with different business name registration address.	
3) Proof of income (Latest Audited Financial Statement with Balance Sheet) or Duly notarized Statement/Certification of Initial Capitalization.	
4) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
5) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements for e-LTO application Downloads and prints the generated Order of Payment through the ePortal and Email notification. Pays the assessed fee as per the system-generated Order of Payment Form through the existing payment channels	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective Center. **LBP OnColl Payment : 5wd** **Other Payment Channels : 3 wd**	See above table	0	FDA Cashier Administrative and Finance Service (AFS)
	1.2 Evaluates completeness and correctness of the documents submitted.	None	5 working days	FDA Evaluator (Center/Licensing and Registration Division)
	1.3 Checks the veracity of documents provided	None	4 working days	Technical Officer of Center
	1.4 Quality assurance of the documents provided and compliance	None	3 working days	Technical Officer of Center
	1.6 Finalizes decision on the LTO application	None	2 working days	Center Director

	If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial			
3. Receives notification and link of LTO for printing		None		Qualified Person
TOTAL:			**14 working days**	

1.23.LICENSE TO OPERATE – RENEWAL APPLICATION LICENSE TO OPERATE FOR TRADERS, DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER) OF COSMETICS, TOYS AND CHILD CARE ARTICLES (TCCAS) AND HOUSEHOLD URBAN PESTICIDES (HUPS)

Center/Office/Division	:	Center for Cosmetic and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR)
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Traders, Distributors (Importer, Exporter, Wholesaler) Cosmetics, Toys and Child Care Articles (TCCAs) and Household Urban Pesticides (HUPs)
Fees to be Paid	:	**Cosmetics Trader:** 20 Million and below - Php 6,000 + 1 % LRF over 20 Million but below 50 Million - Php 10,000 + 1 % LRF 50 Million and above - Php14,000 + 1 % LRF **Cosmetics Distributors:** Importer, Exporter, Wholesaler Php 6,000 + 1 % LRF **Household Hazardous Substances:** Importer, Exporter, Wholesaler - Php 6,000 + 1 % LRF **Administrative Order 50 s. 2001*** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856* **FDA Circular No. 2011-004**

		Computation of Surcharge or Penalty Impossible in case of Submission of Renewal Applications Covering License of Establishments and Registration of Health Products After Their Date of Expiration Pursuant to Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implementing Rules and Regulations, and Other Purposes

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1) Basic Requirements based on the Administrative Order No. 2020-0017: ● Accomplished e-Application Form as prescribed by FDA regulations. ● Declaration and Undertaking	 FDA e-Portal (www.fda.gov.ph) Applicant / Qualified Person
2) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	FDA Cashier/Other FDA Authorized Payment Portals or Banks
3) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	Applicant/Qualified person

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-portal (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements for e-LTO application Downloads and prints the generated Order of Payment through the ePortal and Email notification	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective Center/Office.	See above table		FDA Cashier Administrative and Finance Service (AFS)

Pays the assessed fee as per the system-generated Order of Payment Form through				
	1.2 Evaluates completeness and correctness of documents submitted.	None	5 working days	FDA Evaluator (Center/Licensing and Registration Division)
	1.3 Checks and quality assurance of the documents provided and compliance	None	4 working days	Technical Officer of Center
	1.4 Quality assurance of the evaluation	None	3 working days	Technical Officer of Center
	1.5 Finalizes decision on LTO application If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	2 working days	Center Director
2. Receives notification and link of LTO for printing				Qualified person
TOTAL:			**14 working days**	

1.24.LICENSE TO OPERATE – MINOR VARIATION APPLICATION FOR COSMETICS, TOYS AND CHILD CARE ARTICLES (TCCAS) AND HOUSEHOLD URBAN PESTICIDES (HUPS)

Center/Office/Division	:	Center for Cosmetic and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR)
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	All Traders, Distributors (Importer, Exporter, Wholesaler of Cosmetics, Toys and Child Care Articles (TCCAs) and Household Urban Pesticides (HUPs)
Fees to be Paid	:	**Minor Variation: Php 500 +1% LRF** **Administrative Order 50 s. 2001*** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS (based on Administrative Order No. 2020-0017)	**WHERE TO SECURE**
Minor Variation	**FDA website (www.fda.gov.ph)**
A. Transfer of Location Offices - Accomplished e-Application Form - Business permit reflecting new location of office - Payment of fees B. Change of Distributor Activity - Accomplished e-Application Form - Contract Agreements showing change in activity	Qualified Person

- Payment of fees C. Transfer or Addition of Warehouse - Accomplished e-Application Form - Business Permit reflecting new warehouse location - Payment of fees D. Expansion of Office Establishment - Accomplished e-Application Form - Current floor plan and Expansion floor plan - Payment of fees E. Change of Ownership - Accomplished e-Application Form - Business name registration reflecting new ownership - Any proof on the transfer of ownership ● Deed of sale or assignment or transfer of rights/ownership; ● Memorandum of Agreement; or ● Notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the transfer - Payment of fees F. Change of Business Name - Accomplished e-Application Form - Business permit reflecting the new name - Payment of fees G. Zonal Change in Address	

- Accomplished e-Application Form - Certificate of Zonal Address - Payment of Fees H. Change of Qualified Person - Accomplished e-Application Form - Name of new qualified person, with credentials when applicable - Applicable requirements as specified in ANNEX B of AO 2020-0017 - Payment of fees I. Change of Authorized Person - Accomplished e-Application Form - Name of new authorized person - Updated contact details - Payment of fees	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-portal (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements for e-LTO application Downloads and prints the generated Order of Payment through the ePortal and Email notification.	1.1 Posts payment in ePortal for confirmed payments. This will automatic decking of application to respective Center.	See above table		FDA Cashier Administrative and Finance Service (AFS)

Pays the assessed fee as per the system generated Order of Payment Form through the existing payment channels				
	1.2 Evaluates completeness and correctness of submitted documentary requirements.	None	5 working days	FDA Evaluator (Center/Licensing and Registration Division)
	1.3 Checks evaluation and veracity of documents submitted.	None	4 working days	Technical Officer of Center
	1.4 ality assurance of the evaluation.	None	3 working days	Technical Officer of Center
	1.5 Finalizes decision on the LTO application If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	2 working days	Center Director
2. Receives notification and link of LTO for printing		None		Qualified Person
TOTAL:			**14 working days**	

1.25.LICENSE TO OPERATE – INITIAL APPLICATION FOR MANUFACTURERS OF HOUSEHOLD URBAN HAZARDOUS SUBSTANCES (HUHS) BASED ON ADMINISTRATIVE ORDER NO. 2019-0019 AND FDA CIRCULAR 2020-025

Issuance of Electronic Portal (E-Portal) Ver.2.0 User Account

Center/Office/Division	:	Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	:	Simple
Type of Transaction	:	G2B - Government to Business
Who may Avail	:	Manufacturers of Household/Urban Hazardous Substances (under Categories III and IV) based on AO 2019-0019 and FDA Circular No. 2020-025
Fees to be paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1.Proof of Ownership of Establishment (refer to Annex B and B.1 of FDA Circular No. 2020-025)	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1.1 Requests User Account credentials by accomplishing the Online User's Registration Form through the link: bit.ly/ePortal2 (refer to Annex B.1)	1. Checks for the completeness and appropriateness of the request	None	15 Minutes	CCHUHSRR Admin. Staff
2. Receives username and password	2. Issues user account (username and password) to the client	None	Next Working Day	CCHUHSRR Admin. Staff
	TOTAL:	**None**	**1 Working Day and 15 minutes**	

Center/Office/Division	:	Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	All Manufacturers of Household/Urban Hazardous Substances (under Categories III and IV) based on Administrative Order No. 2019-0019 and FDA Circular No. 2020-025
Fees to be Paid	:	**Household Hazardous Substance Manufacturer:** 1 Million and below - Php 1,000 + 1 % LRF over 1 Million but below 5 Million - Php 2,000 + 1 % LRF 5 Million but below 10 Million - Php 3,000 + 1 % LRF 10 Million but below 20 Million - Php 5,000 + 1 % LRF` 20 Million but below 50 Million - Php 10,000 + 1 % LRF 50 Million and above - Php 15,000 + 1 % LRF Administrative Order 50 s. 2001* Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs FDA Circular No. 2011-003 Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1) Basic Requirements based on the Administrative Order No. 2020-0017 and FDA Circular No. 2020-025:	FDA website (www.fda.gov.ph
Accomplished e-Application Form as prescribed by FDA regulations. ● Location plan and Global Positioning System (GPS) coordinates to be filled in the e-Application Form	FDA e-Portalv2 (https://eportal2.fda.gov.ph)

• Personnel information of the Authorized Person and Qualified Person of the establishment • Self-Declaration in the e-Application Form	
2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration (in pdf): • For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF) • For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF) • For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF) • For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter (1 Scanned copy PDF) When a business or establishment address is different from the business name registration address, the applicant shall submit a copy of the Business Permit (e.g. Mayor's Permit).	
3) Proof of income (Latest Audited Financial Statement with Balance Sheet) or Duly notarized Statement/Certification of Initial Capitalization.	
4) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
5) Site Master File (shall be presented to the FDA inspectors during inspection).	
6) Risk Management Plan (shall be presented to the FDA inspectors during inspection)	
7) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE

1. Access the FDA e-Portal V2 at (https://eportal2.fda.gov.ph). Log in by entering the issued username and password In the Home tab, select New Application in the navigation pane and click e-License to Operate (Initial Application) to proceed to the LTO application form. Accomplish the application form as provided in parts by the application wizard. Fill-in the fields as completely as possible. Fields marked with a red asterisk (*) are required to be filled-in. Mark required fields with N/A, if not applicable. Upload Documents in PDF format. ● Proof of Business Name Registration, Proof of Income.Tick the box to certify all information is true and correct, then "Next". Applicants may upload documents simultaneously.	1. Pre-assessment on the completeness of application and documentary requirements submitted	None		FDA Evaluator
2. Pay the assessed fee as per the system generated Order of Payment Form, through existing payment channels	2.1 Post payment in ePortalv2 for confirmed payments. This will prompt automatic decking of application to respective RFO	See above table		Qualified Person FDA Cashier

	Posting of bank payment: LBP OnColl Payment – 5 wd Bancnet – 2 wd			Administrative and Finance Service
	2.2 Pre-license Inspection by Regional Field Offices (RFO) Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/ Recommendation for Disapproval/ Recommendation Letter	None		Regional Field Officer/ Inspector **Not currently required since HUHS manufacturer shall also undergo PLI (based on FDA Advisory 2020-2035)*
	2.3 Evaluation on the completeness and veracity of the documents submitted.	None	15 working days	FDA Evaluator (Center/Licensing and Registration)
	2.4 Checking of the evaluation and veracity of documents submitted.	None	3 working days	Technical Officer of specific Center of jurisdiction
	2.5 Final Decision on the Approval of LTO If application is disapproved, the applicant will be notified through	None	2 working days	Center Director

	email and will receive the Letter of Denial.			
3 Receive notification and copy of e-LTO for printing				Qualified person
TOTAL:			**20 working days**	

1.26.LICENSE TO OPERATE – RENEWAL APPLICATION FOR MANUFACTURERS OF HOUSEHOLD URBAN HAZARDOUS SUBSTANCES (HUHS) BASED ON ADMINISTRATIVE ORDER NO. 2019-0019 AND FDA CIRCULAR 2020-025

Issuance of Electronic Portal (E-Portal) Ver.2.0 User Account

Center/Office/Division	:	Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	:	Simple
Type of Transaction	:	G2B - Government to Business
Who may Avail	:	All Manufacturers of Household/Urban Hazardous Substances (under Categories III and IV) based on AO 2019-0019 and FDA Circular No. 2020-025
Fees to be paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1.Proof of Ownership of Establishment (refer to Annex B and B.1 of FDA Circular No. 2020-025)	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Request User Account credentials by accomplishing the Online User's Registration Form through the link: bit.ly/ePortal2 (refer to Annex B.1)	1. Check for the completeness and appropriateness of the request	None	15 Minutes	CCHUHSRR Admin. Staff
2. Receive username and password	2. Issue user account (username and password) to the client	None	Next Working Day	CCHUHSRR Admin. Staff
	TOTAL:	**None**	**1 Working Day and 15 minutes**	

Center/Office/Division	**:**	Center for Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	**:**	Complex
Type of Transaction	**:**	G2B - Government to Business
Who May Avail	**:**	All Manufacturers Household Urban Hazardous Substances f Household/Urban Hazardous Substances (under Categories III and IV) based on AO 2019-0019 and FDA Circular No. 2020-025
Fees to be Paid	**:**	**Household Hazardous Substance Manufacturer:** 1 Million and below - Php 2,000 + 10 % LRF over 1 Million but below 5 Million - Php 4,000 + 1 % LRF 5 Million but below 10 Million - Php 6,000 + 1 % LRF 10 Million but below 20 Million - Php 10,000 + 1 % LRF 20 Million but below 50 Million - Php 20,000 + 1% LRF 50 Million and above - Php 30,000 + 1% LRF **Administrative Order 50 s. 2001*** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856* **FDA Circular No. 2011-004** *Computation of Surcharge or Penalty Impossible in case of Submission of Renewal Applications Covering License of Establishments and Registration of Health Products After Their Date of Expiration Pursuant to Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implementing Rules and Regulations, and Other Purposes*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1)Basic Requirements based on the Administrative Order No. 2020-0017 and FDA Circular No. 2020-025:	

• Accomplished e-Application Form as prescribed by FDA regulations. • Declaration and Undertaking	FDA e-Portal V.2 (www.fda.gov.ph) Applicant / Qualified Person
2) Proof of payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	FDA Cashier/Other FDA Authorized Payment Portals or Banks
3) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	Applicant/Qualified person

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the FDA e-Portal V2 at (https://eportal2.fda.gov.ph). Log in by entering the issued username and password. Accomplish the LTO renewal application form Download and print the generated Order of Payment through the ePortal and Email notification.	1. Pre-assessment on the completeness of application and documentary requirements submitted	None		CCHUHSRR Personnel
2. Pay the assessed fee as per the system generated Order of Payment Form through existing payment channels.	2. Post payment in ePortalv2 for confirmed payments. This will prompt automatic decking of application to respective Center.	See above table		Qualified Person and FDA Cashier Administrative and Finance Service
	2.1 Pre-Inspection by the Regional Field Office (RFO)	None		Regional Field

	Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/ Recommendation for Disapproval/ Recommendation Letter			Officer/ Inspector
	2.2 Evaluation on the completeness and veracity of the documents submitted.	None	3 working days	FDA Evaluator (Center/Licensing and Registration)
	2.3 Checking of the evaluation and veracity of documents submitted.	None	2 working day	Technical Officer of specific Center of jurisdiction
	2.4 Final Decision on the Approval of LTO If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	2 working days	Center Director of jurisdiction
3. Receive notification and copy of e-LTO for printing		None		Qualified person
TOTAL:			**7 working days**	

1.27.LICENSE TO OPERATE – MAJOR VARIATION FOR MANUFACTURERS OF HOUSEHOLD URBAN HAZARDOUS SUBSTANCES (HUHS) BASED ON ADMINISTRATIVE ORDER NO. 2019-0019 AND FDA CIRCULAR 2020-025

Issuance of Electronic Portal (E-Portal) Ver.2.0 User Account

Center/Office/Division	:	Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	:	Simple
Type of Transaction	:	G2B - Government to Business
Who may Avail	:	Manufacturers of Household/Urban Hazardous Substances (under Categories III and IV) based on AO 2019-0019 and FDA Circular No. 2020-025
Fees to be paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1.Proof of Ownership of Establishment (refer to Annex B and B.1 of FDA Circular No. 2020-025)	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1.1 Request User Account credentials by accomplishing the Online User's Registration Form through the link: bit.ly/ePortal2 (refer to Annex B.1)	1. Check for the completeness and appropriateness of the request	None	15 Minutes	CCHUHSRR Admin. Staff
1.2 Receive username and password	2. Issue user account (username and password) to the client	None	Next Working Day	CCHUHSRR Admin. Staff
	TOTAL:	**None**	**1 Working Day and 15 minutes**	

Center/Office/Division	**:**	Center for Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B - Government to Business
Who May Avail	**:**	All Manufacturers of Household/Urban Hazardous Substances (HUHS)
Fees to be Paid	**:**	Amendment of LTO or Re-issuance (if lost) – Php 500 +1% LRF Administrative Order 50 s. 2001* Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs FDA Circular No. 2011-003 Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1) List of Requirements for Specific Variation based on Administrative Order No. 2020-0017: A. Transfer of Location of Manufacturing Plant Documentary Requirement: 1. Business permit reflecting the new address 2. Updated Site Master File to be presented upon inspection B. Expansion of Manufacturer and/or Additional Product Line; or Change of Manufacturing Activity Documentary Requirement: 1.Updated Site Master File to be presented upon inspection	Qualified Person

2 Proof of payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	FDA Cashier/Other FDA Authorized Payment Portals or Banks
3 Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	Applicant/Qualified person

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the FDA e-Portal V2 at (https://eportal2.fda.gov.ph). Log in by entering the issued username and password. In the Home tab, select New Application in the navigation pane and click e-License to Operate (Variation Application) to proceed to the LTO application form. Accomplish the application form as provided in parts by the application wizard. Fill-in the fields as completely as possible. Fields marked with a red asterisk (*) are required to be filled-in. Mark required fields with N/A, if not applicable. Upload Documents in PDF format. ● Proof of Business Name Registration, Proof of Income. Tick the box to certify all information is true and correct, then "Next".	1. Pre-assessment on the completeness of application and documentary requirements submitted	None	0	Qualified Person

Applicants may upload documents simultaneously. Order of payment- A computer generated document will appear reflecting the appropriate fees and charges. Applicant should save and print a copy of document as reference for payment				
2. Pay the assessed fee as per the system generated Order of Payment Form through existing payment channels.	2.1 Post payment in ePortal V.2 for confirmed payments. This will prompt automatic decking of application to respective Center	See above table	0	Qualified Person/ FDA Cashier Administrative and Finance Service (AFS)
	2.2 Pre-Inspection by Regional Field Office (RFO) Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/ Recommendation for Disapproval/ Recommendation Letter	None		Regional Field Officer/ Inspector
	2.3 Evaluation of the correctness of submitted documentary requirements.	None	15 working days	FDA Evaluator (Center/Licensing and Registration Division)

	2.4 Checking of the evaluation and veracity of documents submitted.	None	3 working days	Technical Officer of specific Center of jurisdiction
	2.5 Approval of LTO If the application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	2 working days	Center Director of jurisdiction
3. Receives notification and copy of e-LTO for printing		None		Qualified Person
TOTAL:			**20 working days**	

1.28.LICENSE TO OPERATE – INITIAL APPLICATION FOR TRADERS, DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER) OF HOUSEHOLD URBAN HAZARDOUS SUBSTANCES (HUHS) BASED ON ADMINISTRATIVE ORDER NO. 2019-0019 AND FDA CIRCULAR 2020-025

Issuance of Electronic Portal (E-Portal) Ver.2.0 User Account

Center/Office/Division	:	Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	:	Simple
Type of Transaction	:	G2B - Government to Business
Who may Avail	:	All Traders, Distributors (Importer, Exporter, Wholesaler) of Household/Urban Hazardous Substances (under Categories III and IV) based on AO 2019-0019 and FDA Circular No. 2020-025
Fees to be paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1.Proof of Ownership of Establishment (refer to Annex B and B.1 of FDA Circular No. 2020-025)	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Requests User Account credentials by accomplishing the Online User's Registration Form through the link: bit.ly/ePortal2 (refer to Annex B.1)	1. Check for the completeness and appropriateness of the request	None	15 Minutes	CCHUHSRR Admin. Staff
2. Receives username and password	2. Issue user account (username and password) to the client	None	Next Working Day	CCHUHSRR Admin. Staff

TOTAL:	**None**	**1 Working Day and 15 minutes**

Center/Division	:	Center for Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Traders, Distributors (Importer, Exporter, Wholesaler) of Household Urban Hazardous Substances (under Categories III and IV) based on AO 2019-0019 and FDA Circular No. 2020-025
Fees to be Paid	:	**Household Hazardous Substances:** Importer, Exporter, Wholesaler- Php 3,000+ 1 % LRF Note: The fees charged for the manufacturers and traders of products regulated by BFAD are based **Administrative Order 50 s. 2001*** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856* **FDA Circular No. 2011-004** *Computation of Surcharge or Penalty Impossible in case of Submission of Renewal Applications Covering License of Establishments and Registration of Health Products After Their Date of Expiration Pursuant to Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implementing Rules and Regulations, and Other Purposes*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1)Basic Requirements based on the Administrative Order No. 2020-0017 and FDA Circular No. 2020-025: ● Location plan and Global Positioning System (GPS) coordinates to be filled in the e-Application Form	FDA e-Portalv2 (https://eportal2.fda.gov.ph) Authorized Person Qualified Person

• Personnel information of the Authorized Person and Qualified Person of the establishment • Self-Declaration in the e-Application Form	
2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration: • For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF) • For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF) • For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF) • For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter include Mayor's Permit or Barangay Clearance provision (1 Scanned copy PDF) A copy of Business permit (i.e., Mayor's Permit or Barangay Clearance provision) will be submitted for business or establishment address with different business name registration address.	Applicant/Qualified Person
3) Proof of income (Latest Audited Financial Statement with Balance Sheet) or Duly notarized Statement/Certification of Initial Capitalization.	Applicant/Qualified person
4) Proof of payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	FDA Cashier/Other FDA Authorized Payment Portals or Banks
5) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	Applicant/Qualified person

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE

1. Access the FDA e-Portal V2 at (https://eportal2.fda.gov.ph). Log in by entering the issued username and password In the Home tab, select New Application in the navigation pane and click e-License to Operate (Initial Application) to proceed to the LTO application form. Accomplish the application form as provided in parts by the application wizard. Fill-in the fields as completely as possible. Fields marked with a red asterisk (*) are required to be filled-in. Mark required fields with N/A, if not applicable. Upload Documents in PDF format. ● Proof of Business Name Registration, Proof of Income. Tick the box to certify all information is true and correct, then "Next". Applicants may upload documents simultaneously.	Pre-assessment on the completeness of application and documentary requirements submitted	None		FDA Evaluator
2. Pay the assessed fee as per the system generated Order of Payment Form, through existing payment channels	2.1 Post payment in ePortalv2 for confirmed payments. This will prompt automatic decking of application to respective Center.	See above table		Qualified Person FDA Cashier

	Posting of Bank payment: LBP OnColl Payment – 5 wd Bancnet – 2 wd			Administrative and Finance Service
	2.2 Evaluation on the completeness and veracity of the documents submitted.	None	8 working days	FDA Evaluator (Center/Licensing and Registration)
	2.3 Checking of the evaluation and veracity of documents submitted.	None	3 working days	Technical Officer of specific Center of jurisdiction
	2.4 Final Decision on the Approval of LTO If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial.	None	3 working days	Center Director of jurisdiction
3. Receive notification and copy of e-LTO for printing				Qualified person
TOTAL:			**14 working days**	

1.29.LICENSE TO OPERATE- RENEWAL APPLICATION FOR TRADERS, DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER) HOUSEHOLD URBAN HAZARDOUS SUBSTANCES (HUHS) BASED ON ADMINISTRATIVE ORDER NO. 2019-0019 AND FDA CIRCULAR 2020-025

Issuance of Electronic Portal (E-Portal) Ver.2.0 User Account

Center/Office/Division	:	Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	:	Simple
Type of Transaction	:	G2B - Government to Business
Who may Avail	:	All Traders, Distributors (Importer, Exporter, Wholesaler) of Household/Urban Hazardous Substances (under Categories III and IV) based on AO 2019-0019 and FDA Circular No. 2020-025
Fees to be paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1.Proof of Ownership of Establishment (refer to Annex B and B.1 of FDA Circular No. 2020-025)	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
.1 Request User Account credentials by accomplishing the Online User's Registration Form through the link: bit.ly/ePortal2 (refer to Annex B.1)	1. Check for the completeness and appropriateness of the request	None	15 Minutes	CCHUHSRR Admin. Staff
.2 Receive username and password	2. Issue user account (username and password) to the client	None	Next Working Day	CCHUHSRR Admin. Staff
	TOTAL:	**None**	**1 Working Day and 15 minutes**	

Center/Division	:	Center for Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Traders, Distributors (Importer, Exporter, Wholesaler) Household Urban Hazardous Substances (under Categories III and IV) based on AO 2019-0019 and FDA Circular No. 2020-025
Fees to be Paid	:	**Household Hazardous Substances:** Importer, Exporter, Wholesaler - Php 6,000 + 1 % LRF **Administrative Order 50 s. 2001*** Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs **FDA Circular No. 2011-003** Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856 **FDA Circular No. 2011-004** Computation of Surcharge or Penalty Impossible in case of Submission of Renewal Applications Covering License of Establishments and Registration of Health Products After Their Date of Expiration Pursuant to Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implementing Rules and Regulations, and Other Purposes

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1)Basic Requirements based on the Administrative Order No. 2020-0017 and FDA Circular No. 2020-025:	
● Accomplished e-Application Form as prescribed by FDA regulations. ● Declaration and Undertaking	FDA e-Portal V.2 (www.fda.gov.ph) Applicant / Qualified Person

2) Proof of payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	FDA Cashier/Other FDA Authorized Payment Portals or Banks
3) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	Applicant/Qualified person

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the FDA e-Portal V2 at (https://eportal2.fda.gov.ph). Log in by entering the issued username and password. Accomplish the LTO renewal application form Download and print the generated Order of Payment through the ePortal and Email notification.	1. Pre-assessment on the completeness of application and documentary requirements submitted	None	0	FDA Evaluator
2. Pay the assessed fee as per the system-generated Order of Payment Form through existing payment channels.	2.1 Post payment in ePortalv2 for confirmed payments. This will prompt automatic decking of application to respective Center.	See above table	0	Qualified Person and FDA Cashier Administrative and Finance Service
	2.2 Pre-Inspection by the Regional Field Office (RFO) Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/	None		Regional Field Officer/ Inspector

	Recommendation for Disapproval/ Recommendation Letter			
	2.3 Evaluation on the completeness and veracity of the documents submitted.	None	3 working days	FDA Evaluator (Center/Licensing and Registration)
	2.4 Checking of the evaluation and veracity of documents submitted.	None	2 working day	Technical Officer of specific Center of jurisdiction
	2.5 Final Decision on the Approval of LTO If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	2 working days	Center Director of jurisdiction
3. Receive notification and copy of e-LTO for printing		None		Qualified person
TOTAL:			**7 working days**	

1.30.LICENSE TO OPERATE – MINOR VARIATION APPLICATION FOR HOUSEHOLD URBAN HAZARDOUS SUBSTANCES (HUHS) BASED ON ADMINISTRATIVE ORDER NO. 2019-0019 AND FDA CIRCULAR 2020-025

Issuance of Electronic Portal (E-Portal) Ver.2.0 User Account

Center/Office/Division	:	Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	:	Simple
Type of Transaction	:	G2B - Government to Business
Who may Avail	:	All Manufacturers, Traders, Distributors (Importer, Exporter, Wholesaler) of Household/Urban Hazardous Substances (under Categories III and IV) based on AO 2019-0019 and FDA Circular No. 2020-025
Fees to be paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1.Proof of Ownership of Establishment (refer to Annex B and B.1 of FDA Circular No. 2020-025)	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
2.5.1.1 Request User Account credentials by accomplishing the Online User's Registration Form through the link: bit.ly/ePortal2 (refer to Annex B.1)	1. Check for the completeness and appropriateness of the request	None	15 Minutes	CCHUHSRR Admin. Staff
2.5.1.2 Receive username and password	2. Issue user account (username and password) to the client	None	Next Working Day	CCHUHSRR Admin. Staff
	TOTAL:	**None**	**1 Working Day and 15 minutes**	

Center/Office/Division	:	Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	:	Complex
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	All Manufacturers, Traders, Distributors (Importer, Exporter, Wholesaler) of Household Urban Hazardous Substances (under Categories III and IV) based on AO 2019-0019 and FDA Circular No. 2020-025
Fees to be Paid	:	Amendment of LTO or Re-issuance (if lost) – Php 500 +1% LRF **Administrative Order 50 s. 2001*** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1)List of Requirements for Specific Variation based on Administrative Order No. 2020-0017: A. Transfer of Location Offices - Physical transfer of the office of the establishment Documentary Requirement: 1. Business permit reflecting new location of office - Physical transfer of the office of the establishment ● For Single Proprietorship: Business Permit/ Mayor's Permit or Barangay Business Permit/ Clearance reflecting the new office location; ● For SEC-registered establishments: a) Amended Articles of Incorporation (if transferred from one city/ municipality/province); or	Qualified Person

b) Updated General Information Sheet (GIS) from SEC (if transferred within the same city/municipality/province) ● If the establishment address is different from the address indicated in the SEC Registration, provide LGU/Mayor's Permit or Barangay Business Permit/Clearance reflecting new office location B. Change of Distributor Activity -additional/deletion or change in activity that the distributor is currently engaged Documentary Requirement: 1. Contract Agreements showing change in activity C. Transfer or Addition of Warehouse -Physical transfer and addition of warehouse of the establishment Documentary Requirement: 1. Mayor's Permit or Barangay Business Permit/Clearance reflecting new warehouse location D. Expansion of Office Establishment - expansion made which is adjacent to the existing location of the establishment Documentary Requirement: a) Current floor plan b) Expansion floor plan E. Change of Ownership	

-Change in ownership of the licensed establishment Documentary Requirement: 1. Business name registration reflecting new ownership 2. Any proof on the transfer of ownership ● Deed of sale or assignment or transfer of rights/ownership; ● Memorandum of Agreement; or ● Notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the transfer F. Change of Business Name -Change only in the business name of the establishment Documentary Requirement: 1. Business name registration reflecting new business name. G. Zonal Change in Address -Change of the name/number of the street/building without physical transfer of the establishment Documentary Requirement: 1. Certificate of Zonal Address 2. Certification from Local Government Unit (City/Municipality) stating no physical transfer of the establishment H. Change of Qualified Person -Change in the identified qualified person initially registered with the FDA Documentary Requirement:	

1. Name of new qualified person, with credentials when applicable 2. Valid Professional Regulation Commission (PRC) ID 3. Signed Letter of Resignation duly noted by the former employer, if previously connected with another pharmacy/establishment I. Change of Authorized Person -Change in the authorized person initially registered with the FDA Documentary Requirement: 1. Name of new qualified person 2. Valid Government ID	
2) Proof of payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	FDA Cashier/Other FDA Authorized Payment Portals or Banks

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the FDA e-Portal V2 at (https://eportal2.fda.gov.ph). Log in by entering the issued username and password. In the Home tab, select New Application in the navigation pane and click e-License to Operate (Variation Application) to proceed to the LTO application form. Accomplish the application form as provided in parts by the application wizard. Fill-in the fields as completely as possible. Fields marked with a red	1. Pre-assessment on the completeness of application and documentary requirements submitted	None		Qualified Person

asterisk (*) are required to be filled-in. Mark required fields with N/A, if not applicable. Upload Documents in PDF format. ● Proof of Business Name Registration, Proof of Income. Tick the box to certify all information is true and correct, then "Next". Applicants may upload documents simultaneously Order of payment- A computer generated document will appear reflecting the appropriate fees and charges. Applicant should save and print a copy of document as reference for payment				
2. Pay the assessed fee as per the system generated Order of Payment Form through existing payment channels	2.1 Post payment in ePortal V.2 for confirmed payments. This will prompt automatic decking of application to respective Center	See above table		Qualified Person and FDA Cashier Administrative and Finance Service (AFS)
	2.2 Evaluation of correctness of submitted documentary requirements.	None	3 working days	FDA Evaluator (Center/Licensing and Registration Division)
	2.3 Checking of the evaluation and veracity of documents submitted.	None	2 working days	Technical Officer of specific Center of jurisdiction
	2.4 Approval of LTO	None	2 working days	Center Director of jurisdiction

	If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial			
3. Receive notification and copy of e-LTO for printing		None		Qualified Person
TOTAL:			**7 working days**	

Note:

1. The fees charged for manufacturers and traders of products regulated by FDA are based on the capital invested.
2. Renewal of HUHS LTO shall be valid for a maximum period of five (5) years.
3. Application for renewal shall be done within three (3) months prior to validity date of the LTO. Applications filed after the validity date of the LTO shall be subject to surcharge as prescribed in RA 9711 and its IRR.

1.31.LICENSE TO OPERATE – INITIAL APPLICATION FOR HOUSEHOLD/URBAN PEST CONTROL OPERATORS (PCO)

Center/Office/Division	:	Cosmetic and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR)
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	Pest Control Operators engaged in commercial, in-house, and government service application of Household/Urban Pesticide Products
Fees to be Paid	:	**Administrative Order No. 2019 – 0010, Annex E** Initial application – 6,000.00 php Renewal application – 3,000.00 php Variation application – 1,000.00 php The above fees are subject to a legal research fund (LRF) equivalent to Php 10.00 or 1% of the application fee, whichever is higher, as imposed by RA 3870, as amended by PD 200 and further amended by PD1856, and surcharges and penalties for renewal applications filed beyond the validity date in accordance with RA 9711

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1)Basic Requirements based on the Administrative Order No. 2019-0010 Annex B:	
Accomplished e-Application Form as prescribed by FDA regulations. • Declaration and undertaking of the responsibilities of the applicant as a condition for the processing and approval of the LTO; • The location plan and global position system (GPS) coordinates of the establishment; • The name and credentials of the FDA-certified supervising pesticide handler	FDA eServices (www.fda.gov.ph) Applicant/Qualified person Applicant/Qualified person Applicant/Qualified person
2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration (in pdf): ● For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF)	Applicant/Qualified person

• For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF) • For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF) In cases of inconsistencies with the business name and/or address, the following supporting documents must be submitted: - If the Business Name is different from the Corporate Name, the SEC Certificate must reflect: "Doing business under the name and style of (Name of Establishment)" - Valid Mayor's Business Permit or Barangay Business Permit, if the business name and address is different from the registered name and address in the DTI or SEC	
3) Notarized Agreement with a DOH-accredited health facility that will conduct annual medical check-up for its supervising pesticide handlers, pesticide handlers and other personnel	Applicant/Qualified person
4) Risk Management Plan (contingency plan) and procedures for handling accidents and emergencies, and referrals to hospitals in case of accidents or casualties	Applicant/Qualified person
5) Safety training plan for supervising pesticide handlers, pesticide handlers and other personnel	Applicant/Qualified person
6.) Names and ID of the FDA-certified supervising pesticide handlers, pesticide handlers and other personnel (per branch or office) [1]	Applicant/Qualified person

[1] In the absence of availability of FDA-accredited trainings for SPH and PH, the PCO establishment shall submit copies of any proof of attendance to training/s of their SPH and PH related to household/urban pest management issued by: (1) the Fertilizer and Pesticide Authority (FPA) following FDA Circular No. 2016-008; or (2) any reputable organizations within the last five (5) years, in lieu of the required copy of ID of FDA-certified SPH and PH.

7.) If the owner/manager is not the FDA-certified supervising pesticide handler, submit written authorization from the appointed FDA-certified supervising pesticide handler and Certificate of Employment	Applicant/Qualified person
8.) Payment of prescribed fee	FDA Cashier/Other FDA Authorized Payment Portals or Banks
9.) In cases when less than the required number of certified supervising pesticide handler is employed by the pest control operator, the Standard Operating Procedure on the conduct of in-person and remote supervision of pest control activities in multiple branches.	Applicant/Qualified person

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through (http://eservices.fda.gov.ph) and click "Applications " found at the upper right corner of the system. Proceeds to the Initial Application Reads the **"Declaration and Undertaking"** before proceeding with the application process. Check the box *"I agree to the Declaration and Undertaking"* and click on **"Start Application".** Uploads the required documents as indicated on the Checklist of Requirements (ex. Proof of Business Name Registration with DTI/SEC) in pdf format. File size should not be more than 2MB (per document requirement)	1. Conducts pre-assessment on the submitted application based on the completeness of the documents submitted in accordance with the requirements If complete, an Order of Payment will be generated and will be given to the client thru the eServices and Email notification. If incomplete, the application will not be received and will be returned to the client. A Pre-assessment Letter of Disapproval	None		FDA Pre-Assessor (Center/ Licensing and Registration)

Reviews the duly filled out form in the **Self-Assessment Review**. By agreeing to the Terms and Conditions, the applicant confirm the completeness, correctness, and accuracy of the information given. Click on **"Confirm"** to submit the application. Prints the Order of Payment with Reference Number sent through the declared e-mail address	will be given to the client thru eServices and Email notification.			
2. Pays the application fee through existing payment channels. Receives Acknowledgment Receipt through email	2.1 Posts payment in eServices Portal System for confirmed payments. This will prompt automatic decking of application to respective Center. **LBP OnColl Payment: 5 wd** **Other Payment Channels: 2 wd** **Note:** Acknowledgement Receipt will automatically be sent to the client once payment is posted and will signify the start of processing time of the application.	See above table		FDA Cashier Administrative and Finance Service (AFS)
	2.2 Evaluates the correctness of the documents	None	12 working days	Food-Drug Regulation Officer

	2.3 Checks the evaluation and veracity of the documents submitted.		5 working days	Food-Drug Regulation Officer
3. Receives an application status through e-mail confirming that the application has been evaluated and queued for final decision.	3. Approval of LTO If the application is disapproved, the applicant will be notified through email and will receive the Letter of Disapproval	None	3 working days	Center Director
4. Receives an email notification containing the system-generated LTO through the declared e-mail address for printing.				Qualified Person
TOTAL:			**20 working days**	