

### **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.	FDA e-Portal System
• 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	
2) Proof of Business Registration	
Any one of the following shall be submitted as proof of business name registration (in pdf):	
<ul> <li>For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF)</li> </ul>	
• 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)	
<ul> <li>For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF)</li> </ul>	
• 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	PROCESSING	PERSON
		BE PAID	TIME	RESPONSIBLE
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	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective RFO.      LBP OnColl Payment: 5 wd	See above table		FDA Cashier Administrative and Finance Service
notification.  Pays the assessed fee as per the system- generated Order of Payment through the existing payment channels	Other Payment Channels: 2 wd	lable		
	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		0 d	Center Director
	If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	3 working days	
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 Food and Drugs	Services Rendered by the Bureau of			
		, ,				
		Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implements and Regulations, and Other Purposes	nts and Registration of Health Products After Their Date of Expiration Pursuant to Section 3, (2) and (B)(2) of Article I of Book II of the RA 9711 Implementing			
		FDA Circular No. 2011-003				
		Collection of Legal Research Fee (LRF) Imposed by Republic Act No Amended by PD 1856	o. 3870, as amended by PD 200 and further			
		CHECKLIST OF BEOLIDEMENTS	WHERE TO SECURE			
		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.	FDA e-Portal (www.fda.gov.ph)
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.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	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
Downloads and prints the generated Order of Payment through the ePortal and Email notification	LBP OnColl Payment : 5 wd Other Payment Channels : 2 wd			
Pays the assessed fee as per the system- generated Order of Payment through the existing payment channels				
	1.2Conducts 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			
	1.3Evaluates completeness and	None	3 working	FDA Evaluator
	veracity of the documents		days	(Center/Licensing
	submitted			and Registration
	1.4 Checks evaluation and veracity of	None	1 working day	Technical Officer
	documents submitted.			of Center
	1.5Quality assurance of the	None	1 working day	Technical Officer
		None	1 working day	of Center
	evaluation.			of Center
	1.6 Finalizes decision on the	None	2 working	Center Director
	Approval of LTO		days	
	If application is disapproved, the			
	applicant will be notified through			
	email and will receive the Letter of			
	Denial			
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	PROCESSING	PERSON
		BE PAID	TIME	RESPONSIBLE
1. Logs in to the e-Portal (http://eportal.fda.gov.ph)	1.1 Posts payment in ePortal for			FDA Cashier
using the issued username and password, and	confirmed payments. This will			Administrative
uploads the required documentary requirements (in	prompt automatic decking of			and Finance
PDF format) for e-LTO application	application to respective RFO.			Service
Downloads and prints the generated Order of Payment through the ePortal System and email notification.	LBP OnColl Payment: 5 wd Other Payment Channels: 2 wd	See above table		
Pays the assessed fee as per the system- generated Order of Payment through the existing payment channels				
	1.2 Conducts inspection			Regional Field Officer/
	Refer to Regional Field Office			Inspector
	(RFO) Citizen's Charter for the			eposto.
	issuance of Certificate of	None		
	Compliance /Recommendation			
	for Disapproval/			
	Recommendation Letter.			
	1.3 Evaluates completeness and			FDA Evaluator
		None	13 working days	(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
	1.6Finalizes decision on the LTO application			Center Director
	If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	3 working days	
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				
		rug Distributors:				
		porter, Exporter, Wholesaler- Php 5,000 + 1% LRF per year				
		ig 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.	FDA eServices
<ul> <li>Location plan and Global Positioning System (GPS) coordinates to be filled in the e-Application Form</li> </ul>	(www.fda.gov.ph)
<ul> <li>Name of the Qualified Person depending on the type of health product establishment Self-Declaration in the e-Application Form</li> </ul>	
2) Proof of Business Registration	
<ul> <li>Any one of the following shall be submitted as proof of business name registration (in pdf):</li> <li>For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF)</li> </ul>	
<ul> <li>For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and</li> </ul>	
Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF)	
<ul> <li>For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF)</li> </ul>	
<ul> <li>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)</li> </ul>	



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	PROCESSING	PERSON
		BE PAID	TIME	RESPONSIBLE
Access the online application portal through <a href="http://eservices.fda.gov.ph">http://eservices.fda.gov.ph</a> and click "Applications" found on the upper right corner of the system.	Conducts pre-assessment on the submitted application and documentary requirements with regards to completeness and			FDA Evaluator (Center/Licensing and Registration)
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	If the application passed the pre- assessment step, the applicant shall receive the Order of Payment with Reference	None		
with asterisk (*) are required to be filled-out.  Uploads the required documents as indicated on	Payment with Reference Number via email.			
the Checklist of Requirements in pdf format.	If not, the FDA shall notify the			
Reviews the duly filled out form in the <b>Self-Assessment Review</b> . Once reviewed, click on " <b>Confirm</b> " to submit the application.	client the reason/s for non- acceptance and prompt the			



	applicant to apply again the second			1
	applicant to apply again through			
	the eServices Portal.			
2. Prints the Order of Payment with Reference	2. Posts payment in eServices			FDA Cashier
Number sent through the declared e-mail address	Portal System for confirmed			Administrative
	payments. This will prompt			and Finance
Pays the application fee through existing payment	automatic decking of			Service (AFS)
channels	application to respective			OCIVICE (AI O)
	Center.			
	LBP OnColl Payment:			
	5 wd	See above		
	Other Payment Channels:	table		
	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.			
3. Receives Acknowledgement Receipt through	3.1 Checks and quality assurance	None		Technical Officer
email	of the documents provided	None	4 working days	of Center
	3.2Finalizes decision on the LTO			
	application			
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		None	3 working days	Center Director
	If application is approved, the			
	FDA shall send the LTO to the			



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



# 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				



	PHILIPPINES
Food and Drugs	
FDA Circular No. 2011-004	
Computation of Surcharge or Penalty Impossible in case of Submote of Establishments and Registration of Health Products After The Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 971 Rules and Regulations, and Other Purposes	Their Date of Expiration Pursuant to Section 3,
FDA Circular No. 2011-003	
Collection of Legal Research Fee (LRF) Imposed by Republic A	ct 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.	FDA eServices (www.fda.gov.ph
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	PROCESSING	PERSON
		BE PAID	TIME	RESPONSIBLE
1. Access the online application portal through	1. Posts confirmed payments.	None		FDA Cashier
https://eservices.fda.gov.ph and click	This will prompt automatic			Administrative
"Applications" found on the upper right corner	routing of application to			and Finance
of the system.	Center			Service
	LBP OnColl Payment: 5 wd			



			T	T	PHILIPPINE2
	Selects the product category (Drug) and the type of business establishment (Drug Trader, Drug Distributor, Drugstore, RONPD, CRO, Sponsor) before clicking "Renewal" application	LBP Linkbiz: auto posting Other Payment Channels: 2 wd			
	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 filledout.	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.			
	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				
2.	Receives Acknowledgement Receipt through email	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		None		
	Printing				
	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 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:  • Aut Vaccination – Standard Operating Procedure  • Dispense Vaccines and Biologicals – Standard Operating Procedure  • Mobile Pharmacy – 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 foor plan  - Payment of fees		
- 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 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	Transfer of Location of Drug Retailers	
- 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	- Accomplished e-Application Form	
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	- Business permit reflecting new address	
- 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 oredentials 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	
- 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	Change of Distributor 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:	- Accomplished e-Application Form	
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	- Contract Agreements showing change in activity	
- 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:	- Payment of fees	
- 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:	Transfer/Addition of Warehouse	
- 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:	- Accomplished e-Application Form	
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	- Business Permit reflecting new warehouse location	
<ul> <li>Accomplished e-Application Form</li> <li>Additional credentials of pharmacist (as applicable)</li> <li>Other documents related or specific to the additional activity, such as but not limited to:         <ul> <li>Adult Vaccination – Standard Operating Procedure</li> <li>Dispense Vaccines and Biologicals – Standard Operating Procedure</li> <li>Mobile Pharmacy – Standard Operating Procedure</li> <li>Online Ordering and Delivery – Standard Operating Procedure and Website Screenshot</li> <li>Sterile Compounding and Non-Sterile Complex Compounding – Standard Operating Procedure</li> <li>Other additional activities that may require appropriate regulation</li> </ul> </li> <li>Payment of fees</li> <li>Expansion of Office Establishments and Drug Retailers         <ul> <li>Accomplished e-Application Form</li> <li>Expansion floor plan</li> </ul> </li> </ul>	- Payment of fees	
<ul> <li>Additional credentials of pharmacist (as applicable)</li> <li>Other documents related or specific to the additional activity, such as but not limited to: <ul> <li>Adult Vaccination – Standard Operating Procedure</li> <li>Dispense Vaccines and Biologicals – Standard Operating Procedure</li> <li>Mobile Pharmacy – Standard Operating Procedure</li> <li>Online Ordering and Delivery – Standard Operating Procedure and Website Screenshot</li> <li>Sterile Compounding and Non-Sterile Complex Compounding – Standard Operating Procedure</li> <li>Other additional activities that may require appropriate regulation</li> </ul> </li> <li>Payment of fees</li> </ul> <li>Expansion of Office Establishments and Drug Retailers <ul> <li>Accomplished e-Application Form</li> <li>Expansion floor plan</li> </ul> </li>	Additional Drugstore Activities	
<ul> <li>Other documents related or specific to the additional activity, such as but not limited to:         <ul> <li>Adult Vaccination – Standard Operating Procedure</li> <li>Dispense Vaccines and Biologicals – Standard Operating Procedure</li> <li>Mobile Pharmacy – Standard Operating Procedure</li> <li>Online Ordering and Delivery – Standard Operating Procedure and Website Screenshot</li> <li>Sterile Compounding and Non-Sterile Complex Compounding – Standard Operating Procedure</li> <li>Other additional activities that may require appropriate regulation</li> </ul> </li> <li>Payment of fees</li> <li>Expansion of Office Establishments and Drug Retailers         <ul> <li>Accomplished e-Application Form</li> <li>Expansion floor plan</li> </ul> </li> </ul>	- Accomplished e-Application Form	
<ul> <li>Adult Vaccination – Standard Operating Procedure</li> <li>Dispense Vaccines and Biologicals – Standard Operating Procedure</li> <li>Mobile Pharmacy – Standard Operating Procedure</li> <li>Online Ordering and Delivery – Standard Operating Procedure and Website Screenshot</li> <li>Sterile Compounding and Non-Sterile Complex Compounding – Standard Operating Procedure</li> <li>Other additional activities that may require appropriate regulation</li> <li>Payment of fees</li> </ul> Expansion of Office Establishments and Drug Retailers <ul> <li>Accomplished e-Application Form</li> <li>Expansion floor plan</li> </ul>	- Additional credentials of pharmacist (as applicable)	
<ul> <li>Dispense Vaccines and Biologicals – Standard Operating Procedure</li> <li>Mobile Pharmacy – Standard Operating Procedure</li> <li>Online Ordering and Delivery – Standard Operating Procedure and Website Screenshot</li> <li>Sterile Compounding and Non-Sterile Complex Compounding – Standard Operating Procedure</li> <li>Other additional activities that may require appropriate regulation</li> <li>Payment of fees</li> <li>Expansion of Office Establishments and Drug Retailers</li> <li>Accomplished e-Application Form</li> <li>Expansion floor plan</li> </ul>	- Other documents related or specific to the additional activity, such as but not limited to:	
<ul> <li>Mobile Pharmacy – Standard Operating Procedure</li> <li>Online Ordering and Delivery – Standard Operating Procedure and Website Screenshot</li> <li>Sterile Compounding and Non-Sterile Complex Compounding – Standard Operating Procedure</li> <li>Other additional activities that may require appropriate regulation</li> <li>Payment of fees</li> <li>Expansion of Office Establishments and Drug Retailers</li> <li>Accomplished e-Application Form</li> <li>Expansion floor plan</li> </ul>	Adult Vaccination – Standard Operating Procedure	
<ul> <li>Online Ordering and Delivery – Standard Operating Procedure and Website Screenshot</li> <li>Sterile Compounding and Non-Sterile Complex Compounding – Standard Operating Procedure</li> <li>Other additional activities that may require appropriate regulation</li> <li>Payment of fees</li> <li>Expansion of Office Establishments and Drug Retailers</li> <li>Accomplished e-Application Form</li> <li>Expansion floor plan</li> </ul>	Dispense Vaccines and Biologicals – Standard Operating Procedure	
<ul> <li>Sterile Compounding and Non-Sterile Complex Compounding – Standard Operating Procedure</li> <li>Other additional activities that may require appropriate regulation</li> <li>Payment of fees</li> <li>Expansion of Office Establishments and Drug Retailers</li> <li>Accomplished e-Application Form</li> <li>Expansion floor plan</li> </ul>	Mobile Pharmacy – Standard Operating Procedure	
<ul> <li>Other additional activities that may require appropriate regulation</li> <li>Payment of fees</li> <li>Expansion of Office Establishments and Drug Retailers</li> <li>Accomplished e-Application Form</li> <li>Expansion floor plan</li> </ul>	Online Ordering and Delivery – Standard Operating Procedure and Website Screenshot	
<ul> <li>Payment of fees</li> <li>Expansion of Office Establishments and Drug Retailers</li> <li>Accomplished e-Application Form</li> <li>Expansion floor plan</li> </ul>	Sterile Compounding and Non-Sterile Complex Compounding – Standard Operating Procedure	
Expansion of Office Establishments and Drug Retailers  - Accomplished e-Application Form  - Expansion floor plan	Other additional activities that may require appropriate regulation	
- Accomplished e-Application Form - Expansion floor plan	- Payment of fees	
- Expansion floor plan	Expansion of Office Establishments and Drug Retailers	
	- Accomplished e-Application Form	
- Payment of fees	- Expansion floor plan	
	- Payment of fees	



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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				
<ul> <li>Notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the</li> </ul>				
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	PROCESSING	PERSON
		BE PAID	TIME	RESPONSIBLE
Access the online application portal through <a href="http://eservices.fda.gov.ph">http://eservices.fda.gov.ph</a> and click "Applications "found on the upper right corner of the system.	Conducts pre-assessment on the submitted application and documentary requirements with regards to completeness and			CDRR Personnel
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	If the application passed the pre-assessment step, the applicant shall receive the			
"before proceeding with the application process.  Check the box "I agree to the Declaration and Undertaking" and click on "Start Application".	Order of Payment with Reference Number via email.	None		
Fills-out all necessary information. All fields mark with asterisk (*) are required to be filled-out.	If not, the FDA shall notify the client the reason/s for non-acceptance and prompt the			
Uploads the required documents as indicated on the Checklist of Requirements in pdf format.	applicant to apply again through the eServices Portal.			
Reviews the duly filled out form in the <b>Self-Assessment Review</b> . Once reviewed, click on " <b>Confirm</b> " to submit the application.				



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



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



#### 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
		lodized 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.	FDA e-Portal System
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	
2) Proof of Business Registration	
<ul> <li>Any one of the following shall be submitted as proof of business name registration (in pdf):</li> <li>For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF)</li> </ul>	
<ul> <li>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)</li> </ul>	
<ul> <li>For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF)</li> </ul>	
<ul> <li>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)</li> </ul>	
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	PROCESSING	PERSON
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.	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	TIME	FDA Cashier Administrative and Finance Service
Pays the assessed fee as per the system- generated Order of Payment through the existing payment channels				
	1.2 Conducts pre-licensing inspection			Regional Field Officer/ Inspector
	Refer to Regional Field Office (RFO) Citizen's Charter for the issuance of Certificate of Compliance /Recommendation for Disapproval/Recommendation Letter.	None		



	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			Center Director
	If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	3 working days	
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
		lodized 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



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	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 furti			
	Amended by PD 1856			
	CHECKLIST OF REQUIREMENTS	WHERE TO SECURE		
1) Basic Requirements base				
Accomplished e-Application Form as prescribed by FDA regulations.		FDA e-Portal (www.fda.gov.ph)		
<ul> <li>Declaration and Under</li> </ul>				
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 ins	pectors 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	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
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	LBP OnColl Payment: 5 wd Other Payment Channels: 2 wd			



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



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	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective RFO.			FDA Cashier Administrative and Finance Service
Downloads and prints the generated Order of Payment through the ePortal System and email notification.	LBP OnColl Payment : 5 wd Other Payment Channels : 2 wd	See above table		
Pays the assessed fee as per the system- generated Order of Payment through the existing payment channels				
	1.2 Conducts inspection			Regional Field Officer/ Inspector
	Refer to Regional Field Office (RFO) Citizen's Charter for the issuance of Certificate of Compliance /Recommendation for Disapproval/ Recommendation Letter.	None		
	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			Center Director
	If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	3 working days	
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
		lodized 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	FDA eServices
<ul> <li>Location plan and Global Positioning System (GPS) coordinates to be filled in the e-Application Form</li> <li>Name of the Qualified Person depending on the type of health product establishment Self-Declaration in the e-Application Form</li> </ul>	(www.fda.gov.ph)
2) Proof of Business Registration	
<ul> <li>Any one of the following shall be submitted as proof of business name registration (in pdf):</li> <li>For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF)</li> </ul>	
<ul> <li>For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and</li> </ul>	
<ul> <li>Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF)</li> <li>For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF)</li> </ul>	
<ul> <li>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)</li> </ul>	
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	



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



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## 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

7 Illiand by 1 B 1000	
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
Access the online application portal through <a href="https://eservices.fda.gov.ph">https://eservices.fda.gov.ph</a> and click "Applications" found on the upper right corner of the system.	Posts confirmed payments.     This will prompt automatic routing of application to Center	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	LBP OnColl Payment: 5 wd LBP Linkbiz: auto posting Other Payment Channels: 2 wd			



				PHILIPPINES
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	Mote: Acknowledgement Receipt will automatically be sent to the client once payment is posted and will signify the start of processing time of the application.			
Pays the application fee through existing payment channels				
2. Receives Acknowledgement Receipt through email				
3. Receives notification and link of LTO for		None		
Printing				
TOTAL:	The LTO shall be automatically	-	-	the payment has
	been po	sted by the FD	A 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	



	PHILIPPINES
- 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	
<ul> <li>Deed of Sale or assignment or transfer of rights/ownership</li> </ul>	
Memorandum of Agreement	
<ul> <li>Notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the</li> </ul>	
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	PROCESSING	PERSON
		TO BE	TIME	RESPONSIBLE
		PAID		
Access the online application portal through <a href="http://eservices.fda.gov.ph">http://eservices.fda.gov.ph</a> and click "Applications "found on the upper right corner of the system.	Conducts pre-assessment on the submitted application and documentary requirements with regards to completeness and			FDA Evaluator (Center/Licensing and Registration)
Selects the product category (Food) and the type of business establishment (Food Trader, Food Distributor) before clicking "Variations"	correctness.  If the application passed the pre-	None		
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".	assessment step, the applicant shall receive the Order of Payment with Reference Number via email.			
Fills-out all necessary information. All fields mark with asterisk (*) are required to be filled-out.	If not, the FDA shall notify the client the reason/s for non-acceptance and			



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



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



#### 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.	FDA e-Portal System
<ul> <li>Location plan and Global Positioning System (GPS) coordinates to be filled in the eApplication Form</li> </ul>	
<ul> <li>Name of the Qualified Person depending on the type of health product establishment</li> </ul>	
Self-Declaration in the e-Application Form	



2) Proof of Business Registration	
<ul> <li>Any one of the following shall be submitted as proof of business name registration (in pdf):</li> <li>For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF)</li> </ul>	
• 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)	
<ul> <li>For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF)</li> </ul>	
<ul> <li>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)</li> </ul>	
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
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	prompt automatic decking of			Administrative and Finance
(III DI Torriat) for C-LTO application	application to respective RFO.			Service
Downloads and prints the generated Order of Payment through the ePortal System and email notification.	LBP OnColl Payment: 5 wd Other Payment Channels: 2 wd			
Pays the assessed fee as per the system- generated Order of Payment through the existing payment channels				
	1.2 Conducts pre-licensing inspection			Regional Field Officer/ Inspector
	mapodion			Officer/ Inspector
	Refer to Regional Field Office	N.		
	(RFO) Citizen's Charter for the issuance of Certificate of	None		
	Compliance /Recommendation			
	for Disapproval/			
	Recommendation Letter.  1.3 Evaluates completeness and			FDA Evaluator
	veracity of the documents submitted.	None	13 working days	(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



	1.6Finalizes decision on the LTO application			Center Director
	If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	3 working days	
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 (CDR	RHR)	
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 Establishments and Registration of Health Products After Their Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Impulses and Regulations, and Other Purposes	Date of Expiration Pursuant to Section 3,	
		FDA Circular No. 2011-003  Collection of Legal Research Fee (LRF) Imposed by Republic Act No. Amended by PD 1856	o. 3870, as amended by PD 200 and further	
		CHECKLIST OF REQUIREMENTS	WHERE TO SECURE	
1) Basic Requirements bas	sed	on the Administrative Order No. 2020-0017:		
<ul><li>Accomplished e-Ap</li><li>Declaration and Un</li></ul>	-	ation Form as prescribed by FDA regulations. aking	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	PROCESSING	PERSON
1. Logs in to the e-Portal System	1.1 Posts payment in ePortal for	BE PAID See above	TIME	RESPONSIBLE FDA Cashier
1. Logs in to the e-Portal System (http://eportal.fda.gov.ph) using the issued	confirmed payments. This will	table		Administrative
username and password, and uploads the	prompt automatic decking of	10.0.0		and Finance
required documentary requirements (in PDF) for e-LTO application	application to respective Center/Office			Service
Downloads and prints the generated Order of Payment through the ePortal and Email notification	LBP OnColl Payment: 5 wd Other Payment Channels: 1. 2 wd			
Pays the assessed fee as per the system- generated				
Order of Payment through the existing payment channels				
CHAITIEIS	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/			



	December and otion for			
	Recommendation for			
	Disapproval/ Recommendation			
	Letter			
	1.3 Evaluates completeness and	None	3 working days	FDA Evaluator
	veracity of the documents			(Center/Licensing
	submitted			and Registration
	1.4 Checks evaluation and	None	1 working day	Technical Officer
		None	I Working day	
	veracity of documents			of Center
	submitted.			
	1.5 Quality assurance of the	None	1 working day	Technical Officer
	evaluation.			of Center
	1.6 Finalizes decision on the	None	2 working days	Center Director
	Approval of LTO			
	If application is disapproved,			
	the applicant will be notified			
	through email and will receive			
	the Letter of Denial			
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
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-	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
generated Order of Payment through the existing payment channels				D : 15:11
	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			FDA Evaluator
	veracity of the document	None	13 working days	(Center/Licensing
	submitted.			and Registration)
	Checks evaluation and veracity			Technical Officer
	of documents submitted.	None	3 working	of Center
		140110	days	
	1.4 Quality assurance of the	None	1 working day	Technical Officer of
	evaluation.	NOHE	i working day	Center
	1.5 Finalizes decision on the LTO			Center Director
	application			
			3 working days	
	1.6 If application is disapproved,	None		
	the applicant will be notified			
	through email and will receive			
	the Letter of Denial			
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  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).		PHILIPPINES
<ul> <li>Name of the Qualified Person depending on the type of health product establishment Self-Declaration in the e-Application Form</li> <li>2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration (in pdf): <ul> <li>For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF)</li> <li>For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and <ul> <li>Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF)</li> </ul> </li> <li>For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF)</li> <li>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)</li> </ul> </li> <li>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).</li> </ul>		FDA eServices
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).		(www.fda.gov.ph)
<ul> <li>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)</li> </ul>		
<ul> <li>Any one of the following shall be submitted as proof of business name registration (in pdf):</li> <li>For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF)</li> <li>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)</li> <li>For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF)</li> <li>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)</li> <li>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).</li> </ul>	the e-Application Form	
<ul> <li>Any one of the following shall be submitted as proof of business name registration (in pdf):</li> <li>For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF)</li> <li>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)</li> <li>For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF)</li> <li>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)</li> <li>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).</li> </ul>	2) Proof of Business Registration	
<ul> <li>For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF)</li> <li>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)</li> <li>For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF)</li> <li>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)</li> <li>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).</li> </ul>	,	
<ul> <li>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)</li> <li>For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF)</li> <li>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)</li> <li>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).</li> </ul>	• For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and	
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).		
<ul> <li>For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF)</li> <li>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)</li> <li>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).</li> </ul>		
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).	Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF)	
<ul> <li>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)</li> <li>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).</li> </ul>		
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).		
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).	· · · · · · · · · · · · · · · · · · ·	
applicant shall submit a copy of the Business Permit (e.g., Mayor's Permit).		
applicant shall submit a copy of the Business Permit (e.g., Mayor's Permit).		
	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	3) Proof of income (for Trader) - Latest Audited Financial Statement with Balance Sheet or Duly notarized	
Statement/Certification of Initial Capitalization.	Statement/Certification of Initial Capitalization.	
4) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	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	5) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the	
FDA inspectors during inspection	FDA inspectors during inspection	



CLIENT STEPS	AGENCY ACTION	FEES TO	PROCESSING	PERSON
	7.02	BE PAID	TIME	RESPONSIBLE
1. Access the online application portal through <a href="http://eservices.fda.gov.ph">http://eservices.fda.gov.ph</a> 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.	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		PROCESSING TIME	
Uploads the required documents as indicated on the Checklist of Requirements in pdf format.	applicant to apply again through the eServices Portal.			
Reviews the duly filled out form in the <b>Self-Assessment Review</b> . Once reviewed, click on " <b>Confirm</b> " to submit the application.				
Prints the Order of Payment form with Reference Number sent through the declared e-mail address				



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	See above table	0	Qualified Person  FDA Cashier Administrative and Finance Service (AFS)
	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.			
	2.2 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
Access the online application portal through <a href="https://eservices.fda.gov.ph">https://eservices.fda.gov.ph</a> and click "Applications" found on the upper right corner of the system.	System sends the Order of Payment after receipt of the application	None	0	Qualified Person
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.				



			FILIFFINES
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	Posts confirmed payments.     This will prompt automatic routing of application to	None	FDA Cashier Administrative and Finance
Receives Acknowledgement Receipt through email	Center		Service
	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.		



1.6.1.1	Receives notification and link of LTO		None		
for					
Prin	nting				
	TOTAL:	The LTO shall be automaticall	y generated by	the system once	the payment has
		been p	osted by the F	DA 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

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- 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	
<ul> <li>Notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the</li> </ul>	
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
Access the online application portal through <a href="http://eservices.fda.gov.ph">http://eservices.fda.gov.ph</a> and click "Applications" found on the upper right corner of the system.	Conducts pre-assessment on the submitted application and documentary requirements with regards to completeness	None		FDA Evaluator (Center/Licensing and Registration)
Selects the product category (Food) and the type of business establishment (Food Trader, Food Distributor) before clicking "Variations"	and correctness.  If the application passed the			
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".	pre-assessment step, the applicant shall receive the Order of Payment with Reference Number via email.			



				FILIFICA
Fills-out all necessary information. All fields mark with asterisk (*) are required to be filled-out.	If not, the FDA shall notify the client the reason/s for non-			
Uploads the required documents as indicated on the Checklist of Requirements in pdf format.	acceptance and prompt the applicant to apply again through the eServices Portal.			
Reviews the duly filled out form in the <b>Self-Assessment Review</b> . Once reviewed, click on " <b>Confirm</b> " to submit the application.				
Prints the Order of Payment form with Reference Number sent through the declared e-mail address				
2. Pays the application fee through existing payment	2.1 Posts payment in		0	FDA Cashier
channels	eServices Portal System for			Administrative and
Receives Acknowledgement Receipt through email	confirmed payments. This will prompt automatic decking of application to respective Center.			Finance Service (AFS)
	LBP OnColl Payment:	See above		
	5 wd	table		
	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.			
	2.2 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	Т.	Contar for Coomatic and Hayashald/Urban Hazardaya Cubatanasa Dagulatian and Dagaarah (CCHILLICPD)	
	•	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 at Amended by PD 1856	nd further

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.	FDA e-Portal System
<ul> <li>Location plan and Global Positioning System (GPS) coordinates to be filled in the eApplication Form</li> </ul>	(www.fda.gov.ph)
<ul> <li>Name of the Qualified Person depending on the type of health product establishment</li> </ul>	
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):	
<ul> <li>For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF)</li> </ul>	
• 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)	
<ul> <li>For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF)</li> </ul>	
• 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	PROCESSING	PERSON
		BE PAID	TIME	RESPONSIBLE
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	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective RFO.	See above		Qualified Person  FDA Cashier  Administrative  and Finance
Downloads and prints the generated Order of Payment through the ePortal and Email notification.	LBP OnColl Payment: 5 wd Other Payment Channels: 3 wd	table	0	Service
Pays the assessed fee as per the system- generated Order of Payment Form through the existing payment channels				
	1.2 Conducts pre-licensing inspection.			Regional Field Officer/Inspector
	Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/Recommendation for	None	0	



	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



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

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
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	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	None	3 working days	FDA Evaluator
	veracity of the documents			(Center/Licensing
	submitted			and Registration)
	1.4 Checks evaluation and veracity	None	2 working day	Technical Officer
	of documents submitted.			of Center
	1.5 Quality assurance of the	None	1 working day	Technical Officer
	evaluation.			of Center
	1.0 5: 1: 1: 1:		4 1: 1	0 1 5: 1
	1.6 Finalizes decision on the	None	1 working day	Center Director
	Approval of LTO			
	If application is disapproved, the			
	applicant will be notified through			
	email and will receive the Letter of			
	Denial			
2. Receives notification and link of LTO for printing		None		Qualified Person
TOTAL:			7 working	
TOTAL.				
			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	WHERE TO SECURE
(Based on Administrative Order No. 2020-0017)	
Major Variation	
A. Transfer of Location of Manufacturing Plant	Qualified Person
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	



<ul> <li>B. Expansion of Manufacturer and/or Additional Product Line; or Change of Manufacturing Activity</li> <li>1. Accomplished e-Application Form</li> <li>2. Updated Site Master File to be presented upon inspection</li> <li>3. Payment of fees</li> </ul>	
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
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	PROCESSING	PERSON
		BE PAID	TIME	RESPONSIBLE
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	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective RFO.      LBP OnColl Payment: 5wd	See above table	0	FDA Cashier Administrative and Finance Service
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	Other Payment Channels: 2 wd			



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	1.2 Conducts inspection	None	0	Regional Field
				Officer/
	Refer to Regional Field Office			Inspector
	Citizen's Charter for the issuance of			
	Certificate of			
	Compliance/Recommendation for			
	Disapproval/ Recommendation Letter			
	1.3Evaluates completeness and	None	12 working	FDA Evaluator
	veracity of the documents		days	(Center/Licensing
	submitted.			and Registration)
	1.4 Checks evaluation and veracity of	None	4 working days	Technical Officer
	documents submitted.		3 ,	of Center
	1.4Quality assurance of the	None	2 working day	Technical Officer
	evaluation.			of Center
	1.5 Finalizes decision on the LTO	Nana	O working days	Contor Director
		None	2 working days	Center Director
	application			
	If the application is disapproved, the			
	applicant will be notified through			
	email and will receive the letter of			
	Denial			
Receives notification and link of LTO for				Qualified Person
printing				
TOTAL:			20 working	
			days	
L	<u>.                                      </u>		i e	



## 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:	FDA e-Portal (www.fda.gov.ph)
<ul> <li>Accomplished e-Application Form as prescribed by FDA regulations.</li> </ul>	
<ul> <li>Location plan and Global Positioning System (GPS) to be filled in the eApplication Form</li> </ul>	
Name of the Qualified Person 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:	
<ul> <li>For single proprietorship, the Certificate of Business Registration issued by the Department of Trade</li> </ul>	
and Industry (DTI) (1 Scanned copy PDF)	
<ul> <li>For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by</li> </ul>	
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	PROCESSING	PERSON
		PAID	TIME	RESPONSIBLE
Logs in to the e-Portal	1.1 Posts payment in ePortal for	See above	0	FDA Cashier
(http://eportal.fda.gov.ph) using the	confirmed payments. This will	table		Administrative
issued username and password, and	prompt automatic decking of			and Finance
uploads the required documentary requirements for e-LTO application	application to respective Center.			Service (AFS)
requirements for e-E10 application	LBP OnColl Payment : 5wd			
Downloads and prints the generated Order	Other Payment Channels: 3 wd			
of Payment through the ePortal and	Canon raymond chamboo r c ma			
Email notification.				
Pays the assessed fee as per the system-				
generated Order of Payment Form				
through the existing payment channels				
	1.2 Evaluates completeness and	None	5 working days	FDA Evaluator
	correctness of the documents			(Center/Licensing
	submitted.			and Registration
				Division)
	1.3 Checks the veracity of documents	None	4 working days	Technical Officer
	provided			of Center
	1.4 Quality assurance of the documents	None	3 working days	Technical Officer
	provided and compliance			of Center
	1.6 Finalizes decision on the LTO	None	2 working days	Center Director
	application		,	



Receives notification and link of LTO for printing	If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None		Qualified Person
TOTAL:			14 working days	
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:			
		nporter, 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.	FDA e-Portal (www.fda.gov.ph)
Declaration and Undertaking	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	PROCESSING	PERSON
		BE PAID	TIME	RESPONSIBLE
1. Logs in to the e-portal (http://eportal.fda.gov.ph)	1.1 Posts payment in ePortal for	See above		FDA Cashier
using the issued username and password, and	confirmed payments. This will	table		Administrative
uploads the required documentary requirements	prompt automatic decking of			and Finance
for e-LTO application	application to respective			Service (AFS)
	Center/Office.			
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				
	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	None	2 working days	Center Director
	If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial			
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 a Household Urban Pesticides (HUPs)	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	R	EQUIREMENTS (based on Administrative Order No. 2020-0017)	WHERE TO SECURE		
Minor Variation			FDA website ( <u>www.fda.gov.ph</u> )		
A. Transfer of Location Off	ices	3	Qualified Person		
<ul> <li>Accomplished e-App</li> </ul>	nplished e-Application Form				
- Business permit refle	eflecting new location of office				
- Payment of fees	es				
B. Change of Distributor A	ctivi	ity			
- Accomplished e-Appl		•			
- Contract Agreements	sh	owing change in activity			



- 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	PROCESSING	PERSON
		BE PAID	TIME	RESPONSIBLE
Logs in to the e-portal	1.1 Posts payment in ePortal for	See above		FDA Cashier
(http://eportal.fda.gov.ph) using the issued	confirmed payments. This will automatic	table		Administrative
username and password, and uploads the	decking of application to respective			and Finance
required documentary requirements for e-LTO application	Center.			Service (AFS)
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				
the existing payment charmers	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
Receives notification and link of LTO for printing		None		Qualified Person
TOTAL:			14 working day	ys .



## 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	Applicant
No. 2020-025)	

CLIENT STEPS		AGENCY ACTION	FEES TO	EES TO PROCESSING	PERSON
			BE PAID	TIME	RESPONSIBLE
	Requests User Account credentials by accomplishing the Online User's Registration Form through the link: bit.ly/ePortal2 (refer to Annex B.1)	Checks for the completeness and appropriateness of the request	None	15 Minutes	CCHUHSRR Admin. Staff
2. Receives username and password		Issues user account (username and password) to the client	None	Next Working Day	CCHUHSRR Admin. Staff
		TOTAL:	None	1 Working Day ar	nd 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.	FDA e-Portalv2
<ul> <li>Location plan and Global Positioning System (GPS) coordinates to be filled in the e-Application Form</li> </ul>	(https://eportal2.fda.gov.ph)



<ul> <li>Personnel information of the Authorized Person and Qualified Person of the establishment</li> </ul>	
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):	
<ul> <li>For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF)</li> </ul>	
<ul> <li>For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities</li> </ul>	
and Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF)	
<ul> <li>For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF)</li> </ul>	
• 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	PROCESSING	PERSON
		BE PAID	TIME	RESPONSIBLE



	1		PHILIPPINES
Pre-assessment on the completeness of application and documentary requirements submitted			FDA Evaluator
	None		
2.1 Post payment in ePortalv2 for confirmed payments. This will prompt automatic decking of	See above table		Qualified Person  FDA Cashier
	completeness of application and documentary requirements submitted  2.1 Post payment in ePortalv2 for confirmed payments. This will	completeness of application and documentary requirements submitted  None  2.1 Post payment in ePortalv2 for confirmed payments. This will prompt automatic decking of table	completeness of application and documentary requirements submitted  None  2.1 Post payment in ePortalv2 for confirmed payments. This will prompt automatic decking of table



			Administrative
Posting of bank payment: LBP OnColl Payment – 5 wd Bancnet – 2 wd			and Finance Service
2.2 Pre-license Inspection by Regional Field Offices (RFO)			Regional Field Officer/ Inspector
Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/ Recommendation for Disapproval/ Recommendation Letter	None		*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	Applicant
No. 2020-025)	

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



Center/Office/Division : Ce		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:	



<ul> <li>Accomplished e-Application Form as prescribed by FDA regulations.</li> <li>Declaration and Undertaking</li> </ul>	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
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
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	Pre-assessment on the completeness of application and documentary requirements submitted	None		CCHUHSRR Personnel
form  Download and print 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 existing payment channels.	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  2.2 Evaluation on the completeness and	None	3 working days	FDA Evaluator
	veracity of the documents submitted.			(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
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	Applicant
No. 2020-025)	

CLIENT STEPS		AGENCY ACTION	FEES TO	PROCESSING	PERSON
			BE PAID	TIME	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)	Check for the completeness and appropriateness of the request	None	15 Minutes	CCHUHSRR Admin. Staff
1.2	Receive username and password	Issue user account (username and password) to the client	None	Next Working Day	CCHUHSRR Admin. Staff
		None	1 Working Day a	nd 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:	Qualified Person
A. Transfer of Location of Manufacturing Plant	
Documentary Requirement:	
Business permit reflecting the new address	
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	



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	Applicant/Qualified person		
presented to the FDA inspectors during inspection			

AGENCY ACTION	FEES TO	PROCESSING	PERSON
	BE PAID	TIME	RESPONSIBLE
1. Pre-assessment on the	None	0	Qualified Person
completeness of application and	d		
documentary requirement	3		
submitted			
	Pre-assessment on the completeness of application and documentary requirements	1. Pre-assessment on the completeness of application and documentary requirements	1. Pre-assessment on the completeness of application and documentary requirements



				PHILIPPINES
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	2.1 Post payment in ePortal V.2 for	See above	0	Qualified Person/
generated Order of Payment Form through	confirmed payments. This will	table		FDA Cashier
existing payment channels.	prompt automatic decking of			Administrative and
	application to respective Center			Finance Service
				(AFS)
	2.2 Pre-Inspection by Regional Field			Regional Field
	Office (RFO)			Officer/ Inspector
	Refer to Regional Field Office	Nana		
	Citizen's Charter for the issuance	None		
	of Certificate of Compliance/			
	Recommendation for Disapproval/			
	Recommendation Letter			
	2.3 Evaluation of the correctness of	None	15 working	FDA Evaluator
	submitted documentary		days	(Center/Licensing
	requirements.		<b>,</b> -	and Registration
				Division)
		1		D. 1101011)



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



# 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	Applicant
No. 2020-025)	

CLIENT STEPS	AGENCY ACTION	FEES TO	PROCESSING	PERSON
		BE PAID	TIME	RESPONSIBLE
Requests User Account credentials     by accomplishing the Online User's     Registration Form through the link: <u>bit.ly/ePortal2</u> (refer to Annex B.1)	Check for the completeness and appropriateness of the request	None	15 Minutes	CCHUHSRR Admin. Staff
2. Receives username and password	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-	FDA e-Portalv2
025:	(https://eportal2.fda.gov.ph)
<ul> <li>Location plan and Global Positioning System (GPS) coordinates to be filled in the e-Application</li> </ul>	Authorized Person
Form	Qualified Person



<ul> <li>Personnel information of the Authorized Person and Qualified Person of the establishment</li> </ul>	
Self-Declaration in the e-Application Form	
2) Proof of Business Registration	Applicant/Qualified Person
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)	
<ul> <li>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)</li> </ul>	
<ul> <li>For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF)</li> </ul>	
<ul> <li>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)</li> </ul>	
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	Applicant/Qualified person
Statement/Certification of Initial Capitalization.	
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	Applicant/Qualified person
to the FDA inspectors during inspection	

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



			PHILIPPINE2
1.Access the FDA e-Portal V2 at (https://eportal2.fda.gov.ph). Log in by entering the issued username and password	Pre-assessment on the completeness of application and documentary requirements submitted		FDA Evaluator
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.		None	
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.			
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:			Administrative
	LBP OnColl Payment – 5 wd			and Finance
	Bancnet – 2 wd			Service
	2.2Evaluation on the completeness and			FDA Evaluator
	veracity of the documents submitted.	None	8 working days	(Center/Licensing
	,			and Registration)
	2.3 Checking of the evaluation and			Technical Officer
	veracity of documents submitted.	None	3 working days	of specific Center
				of jurisdiction
	2.4 Final Decision on the Approval of			Center Director
	LTO			of jurisdiction
		Nissa	3 working	-
	If application is disapproved, the	None		
	applicant will be notified through email		days	
	and will receive the Letter of Denial.			
3. Receive notification and copy of e-LTO for				Qualified person
printing				•
TOTAL:			14 working	
TOTAL.			days	
			aays	



## 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	Applicant
No. 2020-025)	

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



Center/Division	r/Division : Center for Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)				
Classification	:	Highly Technical			
Type of Transaction	ype of Transaction : G2B – Government to Business				
Who May Avail : All Traders, Distributors (Importer, Exporter, Wholesaler) Household Urban Hazardous Substance					
_		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					
		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:	
<ul> <li>Accomplished e-Application Form as prescribed by FDA regulations.</li> </ul>	FDA e-Portal V.2 (www.fda.gov.ph)
Declaration and Undertaking	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	Applicant/Qualified person
presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO	PROCESSING	PERSON
		BE PAID	TIME	RESPONSIBLE
Access the FDA e-Portal V2 at     (https://eportal2.fda.gov.ph). Log in by     entering the issued username and     password.	Pre-assessment on the completeness of application and documentary requirements submitted	None	0	FDA Evaluator
Accomplish the LTO renewal application form				
Download and print 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 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)	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			
	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
<ol><li>Receive notification and copy of e-LTO for printing</li></ol>		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	Applicant
No. 2020-025)	

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



Center/Office/Division	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, V	Vholesaler) of Household Urban Hazardous			
		Substances (under Categories III and IV) based on AO 2019-0019	9 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 Correspondent	ing Services Rendered by the Bureau of Food			
		and Drugs				
		FDA Circular No. 2011-003				
		Collection of Legal Research Fee Imposed by Republic Act No	o. 3870, as amended by PD 200 and further			
		Amended by PD 1856				
		CHECKLIST OF REQUIREMENTS	WHERE TO SECURE			
1)List of Requirements for	Spe	cific Variation based on Administrative Order No. 2020-0017:	Qualified Person			
A. Transfer of Location Off	icas					
		office of the establishment				
- Triysical transici of	uic	office of the establishment				
Documentary Requireme	nt.		1			
· ·		g new location of office				
•	Business permit reflecting new location of office     Physical transfer of the office of the establishment					
1 Hydrodi danordi di dio dinod di dio detablicimient						
For Single Proprietorship: Business Permit/ Mayor's Permit or Barangay Business						
Permit/ Clearance reflecting the new office location;						
<ul> <li>For SEC-registe</li> </ul>						
,	a) Amended Articles of Incorporation (if transferred from one city/					
municipal	ity/p	province); or				



- 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:** 



Name of new qualified person, with credentials when applicable	
2. Valid Professional Regulation Commission (PRC) ID	
<ol> <li>Signed Letter of Resignation duly noted by the former employer, if previously connected with another pharmacy/establishment</li> </ol>	
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	PROCESSING	PERSON
		BE PAID	TIME	RESPONSIBLE
Access the FDA e-Portal V2 at	1. Pre-assessment on the	None		Qualified Person
(https://eportal2.fda.gov.ph). Log in by entering	completeness of application and			
the issued username and password.	documentary requirements			
	submitted			
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.				
<ul> <li>Upload Documents in PDF format.</li> <li>Proof of Business Name Registration, Proof of Income. Tick the box to certify all information is true and correct, then "Next".</li> <li>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</li> </ul>				
2. Pay the assessed fee as per the system	2.1 Post payment in ePortal V.2 for	See above		Qualified Person and FDA Cashier
generated Order of Payment Form through existing payment channels	confirmed payments. This will prompt automatic decking of	table		Administrative and
	application to respective Center			Finance Service (AFS)
	2.2 Evaluation of correctness of	None	3 working	FDA Evaluator
	submitted documentary		days	(Center/Licensing
	requirements.			and Registration Division)
	2.3 Checking of the evaluation and	None	2 working	Technical Officer of
	veracity of documents		days	specific Center of
	submitted.			jurisdiction
	2.4 Approval of LTO	None	2 working days	Center Director of
				jurisdiction



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

#### 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 whichever is higher, as imposed by RA 3870, as amended by PD 200	• • • • • • • • • • • • • • • • • • • •		
		surcharges and penalties for renewal applications filed beyond the validi	-		
		CHECKLIST OF REQUIREMENTS	WHERE TO SECURE		
1)Basic Requirements bas	ed (	on the Administrative Order No. 2019-0010 Annex B:			
Accomplished e-Application	on F	Form as prescribed by FDA regulations.	FDA eServices (www.fda.gov.ph)		
	Designation and analysis in the responsibilities of the approach as a container for the				
	processing and approval of the LTO;  Applicant/Qualified person				
<u> </u>	<ul> <li>The location plan and global position system (GPS) coordinates of the establishment;</li> <li>The name and credentials of the FDA-certified supervising pesticide handler</li> </ul> Applicant/Qualified person				
7. Applicant Qualified person					
2) Proof of Business Registration  Any one of the following shall be submitted as proof of business name registration (in pdf):  Applicant/Qualified person					
<ul> <li>For single proprietors</li> </ul>	ship	the Certificate of Business Registration issued by the Department of (1 Scanned copy PDF)			



	PHILIPPINE 2
<ul> <li>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)</li> <li>For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF)</li> </ul>	
In cases of inconsistencies with the business name and/or address, the following supporting documents must be submitted:	
<ul> <li>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)"</li> <li>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</li> </ul>	
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) <sup>1</sup>	Applicant/Qualified person

<sup>&</sup>lt;sup>1</sup> 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	PROCESSING	PERSON
		BE PAID	TIME	RESPONSIBLE
Access the online application portal through ( <a href="http://eservices.fda.gov.ph">http://eservices.fda.gov.ph</a> ) and click "Applications " found at the upper right corner of the system.  Proceeds to the Initial Application	Conducts pre-assessment on the submitted application based on the completeness of the documents submitted in accordance with the requirements			FDA Pre- Assessor (Center/ Licensing and Registration)
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".	If complete, an Order of Payment will be generated and will be given to the client thru the eServices and Email notification.	None		
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)	If incomplete, the application will not be received and will be returned to the client. A Preassessment Letter of Disapproval			



				PHILLIPPINE 2
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 and through the dealared a mail address.	will be given to the client thru eServices and Email notification.			
sent through the declared e-mail address  2. Pays the application fee through existing payment	2.1 Posts payment in eServices			FDA Cashier
channels.  Receives Acknowledgment Receipt through email	Portal System for confirmed payments. This will prompt automatic decking of application to respective Center.			Administrative and Finance Service (AFS)
	LBP OnColl Payment: 5 wd			
	Other Payment Channels: 2 wd	See above		
	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.	table		
	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
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
<ol> <li>Receives an email notification containing the system-generated LTO through the declared e- mail address for printing.</li> </ol>				Qualified Person
TOTAL:			20 working days	