Regional Field Office (RFO)

Issuance of Certificate of Compliance (COC), Recommendation for Disapproval (RFD) and Recommendation Letter (RL)

Center/Office/Division	:	Field Regulatory Operations Office (FROO)
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government to Business
Who may Avail	:	Manufacturers, Traders, Distributors (Importers, Exporters, Wholesalers) of health products, drug outlets or retailers and retail outlet for non-prescription drugs, as determined by the FDA
Fees to be paid	:	AO No. 50, s. 2001* + 1% Legal Research Fee (LRF), AO No.18-A, s. 1993 and Republic Act 8172

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. The following requirements shall be presented to the FDA Inspector for examination and review, when required, based on Administrative Order No. 2020-0017:	
● Risk Management Plan (RMP) Required for medium and large food manufacturers, and all drug, cosmetics, household urban hazardous substances (HUHS), including household/urban pesticides (HUP) and toys and childcare articles (TCCA), medical device manufacturers, traders and distributors (importer, exporter and/or wholesaler), among others.	Applicant Establishment/ Qualified Person
● Site Master File (SMF) Required for drug, cosmetic, HUHS, including HUHP and TCCA, medical device and large and medium food manufacturers, among others	Applicant Establishment/ Qualified Person
2. Refer to the FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection.	Applicant Establishment/ Qualified Person

Through ePortal:

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	1. Receives electronic application via FDA e-Portal System or Manual application trough FDA- Document Tracking System (DTS)	None	1 working day	Data Controller/ Assigned Personnel Regional Field Office
	2. Generates Document Tracking Number (DTN) thru DTS and Encodes in the Internal Database (IDB)	None		Data Controller/ Assigned Personnel Regional Field Office
	3. Decks and forwards application to Licensing Officer/ Designated Officer	None		Licensing Team Leader Regional Field Office
	4. Receives application via FDA e-Portal System or thru DTS	None	2 working days	Licensing Officer/ Assigned Personnel Regional Field

				Office
	5. Evaluates application: 5.1 If compliant and inspection is not needed, proceed to Step 12 (for RL) 5.2 If with major deficiencies, proceed to Step 12 (for LOD) 5.3 If with minor deficiencies, notify applicant thru e-mail/ declared contact no. to comply within 5 days ***STOP CLOCK*** 5.3.1 Receives and evaluates compliance: (Follow step 5.1, 5.2 or 5. 4) Note: Non -compliance within the 5 days grace period shall be treated as major deficiency and shall be a ground for disapproval of application. 5.4 If compliant and inspection is needed, forwards application to Inspection Section	None		Licensing Officer/ Assigned Personnel Regional Field Office
	6. Receives Electronic and Manual application thru DTS and decks to Inspectors	None	2 working days	Inspection Section Team Leader Regional Field Office

	7. Pre -inspection activities: 7.1 Receives application thru DTS 7.2 Schedules Inspection 7.3 Reviews Company File 7.4 Prepares Itinerary of Inspection, Attendance Sheet, Inspection Agenda, Inspection Plan 7.5 Forwards prepared documents to the Team Leader (TL)/Supervisor for approval 7.6 Prepare Notice of Inspection (when necessary)	None		FDA Inspectors Regional Field Office
	8. Conducts inspection as per approved itinerary: If non -compliant, the establishment is given maximum of 15 calendar days to comply /submit Corrective Action and Preventive Action (CAPA)*****STOP CLOCK*** until RFO receives the CAPA plan**	None	5 working days	FDA Inspectors Regional Field Office

	9. Post -inspection activities: 9.1 Classifies Deficiencies 9.2 Prepares Risk Assessment 9.3 Submits Inspection Report 9.4 Updates DTS 9.5 Conducts deliberation for Panel Approval (when applicable) 9.6 Submits to Team Leader 9.7 Evaluates CAPA and/or objective evidence (when applicable) 9.7.1 Submits inspection report with recommendation to TL *Note: If the establishment has not performed any corrective measures within the specified grace period or if the corrective measures made are not acceptable, the inspector recommends disapproval of the application*	None	5 working days	FDA Inspectors Regional Field Office
	10. Reviews Inspection Report 10.1 Updates DTS and Inspection Database	None	2 working days	Team Leader Regional Field Office
	11. Forwards Inspection Report to Licensing Section	None		
	12. Prepares Certificate of Compliance (COC) / Letter of Disapproval (LOD) / Recommendation Letter (RL) whichever is applicable	None	2 working days	Licensing Officer/Assigned Personnel

	12.1 Updates DTS 12.2 Forwards to Licensing TL/Supervisor			Regional Field Office
	13. Checks and affixes initials to COC / LOD / RL	None		Team Leader/ Supervisor Regional Field Office
	14. Approves/signs COC/RL/LOD	None		Director/Supervisor Regional Field Office
	15. Updates Database	None		Data Controller/Assigned Personnel Regional Field Office
	16. Releases COC/LOD/RL 16.1 Updates DTS 16.2 Forwards COC / RL to Centers or LOD to Central Releasing cc: Centers	None	1 working day	Data Controller/ Assigned Personnel Regional Field Office
	TOTAL:	**None**	**20 working days**	

Through eServices:

CLIENT STEPS	AGENCY ACTION	Fees to be Paid	PROCESSING TIME	PERSON RESPONSIBLE
	1. Receives electronic LTO application via FDA e-Services Portal and Generates Document Tracking Number (DTN) thru Document Tracking System	None	1 working day	Data Controller Regional Field Office
	2. Encodes received application in the Internal Database (IDB)	None		Data Controller Regional Field Office
	3. Decks and forwards application to Licensing Section (for application not requiring inspection) or to the Inspection and Compliance Section (for application requiring inspection	None		Licensing Officer or assigned personnel Deputy LICD Manager or Technical Manager (*see attached org chart) Regional Field Office
	4. Licensing Section: Receives application via FDA e-Services System	None	2 working days	Licensing Officer or assigned personnel Regional Field Office
	5. Evaluates application: 5.1 If compliant and inspection is not needed, proceed to Step 12 (for issuance of Recommendation Letter) 5.2 If with major deficiencies, proceed to Step 12 (for issuance of Recommendation for	None		Licensing Officer or assigned personnel Regional Field Office

	Disapproval) 5.3 If compliant and inspection is needed, forwards application to Inspection and Compliance Section			
	6. Inspection and Compliance Section: Receives electronic application thru DTS and decks to Inspectors	None	2 working days	Deputy LICD Manager or Technical Manager (*see attached org chart) Regional Field Office
	7. Pre -inspection activities: 7.1 Receives application thru DTS and claims application through FDA e-Services Portal 7.2 Schedules Inspection 7.3 Reviews Company File 7.4 Prepares Itinerary of Inspection, Attendance Sheet, Inspection Plan and / or Aide Memoire 7.5 Forwards prepared documents to the Team	None		FDA Inspectors Regional Field Office
	8. Conducts inspection as per approved itinerary: If non -compliant, the establishment is given maximum of 15 days to comply /submit Corrective Action and Preventive Action (CAPA) Plan ***STOP CLOCK***	None	5 working days	FDA Inspectors Regional Field Office

	9. Post -inspection activities: 9.1 Classifies Deficiencies 9.2 Prepares Risk Assessment 9.3 Submits Inspection Report 9.4 Updates DTS 9.5 Conducts deliberation for Panel Approval (when applicable) 9.6 Submits to Team Leader 9.7 Evaluates CAPA and/or objective evidence (when applicable) 9.7.1 Submits inspection report with recommendation to TL *Note: If the establishment has not performed any corrective measures within the specified grace period or if the corrective measures made are not acceptable, the inspector recommends disapproval of the application*	None	5 working days	FDA Inspectors Regional Field Office
	10. Reviews Inspection Report 10.1 Updates DTS and Inspection Database	None	2 working days	Deputy LICD Manager or Technical Manager Regional Field Office
	11. Forwards Inspection Report to Licensing Section	None		
	12. Prepares Certificate of Compliance (COC) / Recommendation for Disapproval (RFD) / Recommendation Letter (RL) whichever is applicable 12.1 Updates DTS 12.2 Forwards to LICD Manager	None	1 working day	Licensing Officer or assigned personnel Regional Field Office

	13. For COC / RL: Approves/signs COC/RL for routing to centers For RFD: Reviews and recommend final decision for routing to Director	None		LICD Manager Regional Field Office
	14. Vets RFD for routing to centers	None	2 working days	Director Regional Field Office
	TOTAL:	**None**	**20 working days**	

References:

- **AO. No. 2014-0029-** *Rules and Regulation on the Licensing of Food Establishments and Registration of Processed Foods, and Other Food Products, and for Other Purposes.*
- **AO No. 2014-0034-** *Rules and Regulations on the Licensing of Establishments Engaged in the Manufacture, Conduct of Clinical Trial, Distribution, Importation, Exportation, and Retailing of Drug Products, and Issuance of Other Related Authorization*
- **AO No. 2014-0038-** *Rules and Regulation Governing Household / Urban Pesticides Licensing of Establishment and Operators, Registration of Their Products and for Other Purpose***.**
- **FDA Circular 2014-025-** *Guidelines on Implementation of New Rules and Regulation on Licensing of Drugstore / Pharmacy / Botica and Similar Outlets following Administrative Order No. 2014-0034, dated 13 October 2014*
- **FDA Circular 2014-026-** *Guidelines on the Implementation of New Rules and Regulations on the Licensing of Drug Distributors following Administrative Order No. 2014-0034, dated 13 October 2014*
- **FDA Circular 2014 -027** *Guidelines on the Implementation of New Rules and Regulations on the Licensing of Drug Manufacturer following Administrative Order No. 2014-0034, dated 13 October 2014*
- **FDA Circular2014 -028** *Guidelines on the Implementation of New rules and regulation I the licensing of Retail outlet for Non-Prescription Drugs (RONPDs) following Administrative Order No. 2014-0034, dated 13 October 2014*
- **Amendment to FDA Circular No. 2013-002** *Revised Guidelines in Licensing of Cosmetic Establishments*
- **Amendment to FDA Circular No. 2013-009** *Revised Guidelines in Licensing of Household Hazardous Substances (HHS) Establishments*
- **FDA Memorandum Circular No. 2020-001 Interim** *Guidelines for the Issuance of Provisional License to Operate (LTO) and Certificate of Product Notification (CPN) for Manufacturers of Rubbing Alcohol Products Under the Center for Cosmetics Regulation and Research*
- **FDA Circular No. 2020-025** *Implementing Guidelines for Administrative Order No. 2019-0019, "Reinstatement of Requirements of Licensing as Importers, Exporters, Manufacturers, Toll Manufacturers, Wholesalers, Distributors, Retailers, or Re-Packers of Those Engaged in Certain Household/Urban Hazardous Substances, and from the Requirement of Prior Registration and/or Notification of Said Products***"**
- **FDA Advisory No. 2020-1599 Implementation** *of FDA Circular No. 2020-0025, entitled "Implementing Guidelines for Administrative Order No. 2019-0019, "Reinstatement of Requirements of Licensing as Importers, Exporters, Manufacturers, Toll Manufacturers, Wholesalers, Distributors, Retailers, or*

Re-Packers of Those Engaged in Certain Household/Urban Hazardous Substances, and from the Requirement of Prior Registration and/or Notification of Said Products"

- **FDA Advisory No. 2020-2035** *"Update on the Implementation of FDA Circular No. 2020-0025, entitled "Implementing Guidelines for Administrative Order No. 2019-0019, "Reinstatement of Requirements of Licensing as Importers, Exporters, Manufacturers, Toll Manufacturers, Wholesalers, Distributors, Retailers, or Re-Packers of Those Engaged in Certain Household/Urban Hazardous Substances, and from the Requirement of Prior Registration and/or Notification of Said Products"*
- **Administrative Order No. 2019-0019** *"Reinstatement of Requirements of Licensing as Importers, Exporters, Manufacturers, Toll Manufacturers, Wholesalers, Distributors, Retailers or Re-Packers of Those Engaged in Certain Household/Urban Hazardous Substances, and from the Requirements of Prior Registration and/or Notification of Said Products"*
- **FDA Circular 2017-003** "Strict Implementation of the Mandatory Requirement to Secure a License to Operate (LTO), Certificate of Product Registration (CPR) or Any Authorization from FDA Prior to Engaging in the Manufacture, Importation, Exportation, Sale, Offering for Sale, Distribution, Transfer, Promotion, Advertisement and/or Sponsorship of Medical Devices