

FOOD AND DRUG ACTION CENTER EXTERNAL SERVICES

1. PROCEDURE IN CALL HANDLING AT THE FOOD AND DRUG ACTION CENTER (FDAC)

This encompasses all telephone calls received by the FDAC seeking assistance for complaints, follow-ups, and requests for information relative to the mandate of the agency.

Center/Office/Division	:	Food and Drug Action Center/Telephone Operators Team
Classification	:	Simple
Type of Transaction	:	Government to Business - G2B ; Government to Government
Who May Avail	:	All Stakeholders (Internal and External)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Details of inquiries, complaints, follow-ups, and request	Must be provided by the client

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Calls the FDAC Hotline numbers: (02) 8857-1900 Local 1000 (02) 8842-5635	1.1 Answers phone calls. Identification and probing of concern	None	Minimum of 1 minute Maximum of 3 minutes	Information Officer II
	1.2 Checks resources & tools (e.g. CDS, EPortal EServices, DTS)	None	5 minutes	Information Officer II
	1.3 Provides appropriate response/resolution Escalates concern to proper Center/Office if technical concern	None	5 minutes	Information Officer II
	1.4 Provides closing spiels	None	1 minute	Information Officer II
	5. Documents call/s received at the database	None	1 minute	Information Officer II
TOTAL:		None	15 minutes	

2. RECEIVING OF LETTERS, MAILS, PARCELS, PRODUCT SAMPLES, AND OTHER DOCUMENTS SENT VIA COURIER/POSTAL SERVICE BY FDAC

This service is for the receiving of letters, mails, parcels, product samples, and other documents sent by internal (FDA Field Inspectors) and external stakeholders of the FDA through courier/postal service and other delivery services.

Center/Office/Division	:	Food and Drug Action Center/Courier Team
Classification	:	Simple
Type of Transaction	:	Government to Business - G2B, Government to Government – G2G
Who May Avail	:	All Stakeholders (External and Internal)

CHECKLIST OF REQUIREMENTS		WHERE TO SECURE
1. Signed Letters, Mails and Other Documents		FDA website (www.fda.gov.ph) – Citizen’s Charter portion
2. Properly labeled parcels and health product samples		

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends letters, mails, parcels, health product samples (for verification or laboratory analysis), and other documents through courier/ postal service and other delivery services available	1.1 Checks received letters, parcels, health product samples, and other documents for details needed in recording including attachments and enclosures	None	5 minutes	Food and Drug Action Center Information Officer II
	1.2 Records the details of sender to FDAC Courier Database and FIS-Document Tracking System (DTS)	None	3 minutes	Food and Drug Action Center Information Officer II

	1.3 Issues Acknowledgment Receipt (A.R) and sends it to the sender via email. Updates FIS-DTS if documents are from FDA \ Regional Offices.		2 minutes	Food and Drug Action Center Information Officer II
	1.4 Prepares daily summary of documents received and prints Transmittal Slip	None	5 minutes	Food and Drug Action Center Information Officer II
	1.5 Endorses received documents/parcels/samples to the proper Center/ Office	None	5 minutes	Food and Drug Action Center Information Officer II
TOTAL:		None	20 minutes	

**FDAC Courier Team transmits the following documents with urgency: all documents from Malacañang (Office of the President), DOH, DOJ, Supreme Court, Regional/Municipal Trial Court, House of Representatives, Senate, ARTA, and Presidential Complaint Center*

3. RECEIVING OF COMPLAINTS

3.1 RECEIVING OF COMPLAINTS VIA EMAIL

This service is for the receiving and handling of complaints involving health products and establishments, services and FDA personnel submitted via ereport@fda.gov.ph.

Center/Office/Division	:	FDAC/eReport Team
Classification	:	Simple
Type of Transaction	:	Government to Business - G2B, Government to Citizen- G2C, or Government to Government - G2G
Who May Avail	:	All Stakeholders

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Details of complaints	Website Food and Drug Action Center
Evidence of such complaint and other supporting documents if applicable.	

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends complaint with detailed information to ereport@fda.gov.ph	1.1 Checks the adequacy & quality of information. If complete: acknowledges the concern/complaint; encodes the details in the FIS- Document Tracking System (DTS) and generates a 14-digit Document Tracking System (DTS) ; and records the information in the e-Report Database for tracking and monitoring.	None	5 minutes	Food and Drug Action Center Information Officer I

	If Incomplete, sends an email to the client requesting additional information.			
	1.2 Sends email to the client with attached copy of the generated Document Tracking Log.	None	3 minutes	Food and Drug Action Center Information Officer I
	1.3 Forwards the client's email to the concerned FDA Center/Office for information and appropriate action.	None	3 minutes	Food and Drug Action Center Information Officer I
TOTAL:		None	16 minutes	

3.2 RECEIVING OF COMPLAINTS FROM WALK-IN CLIENTS

This service is for the receiving and handling of complaints involving health products and establishments, services and FDA personnel submitted onsite.

Center/Office/Division	:	FDAC/eReport Team
Classification	:	Simple
Type of Transaction	:	Government to Business - G2B, Citizen G2C, or Government G2G
Who May Avail	:	All Stakeholders

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Duly Signed letter of Intent	Food and Drug Action Center
Evidence of such complaint and other supporting documents if applicable.	

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Submits a duly signed letter addressed to the FDA Director General	<p>1.1 Checks the completeness of information provided by the client including supporting documents.</p> <p>If the information/documents provided by the client is sufficient:</p> <p>a. receives the concern and encodes the details in the FIS-Document Tracking System</p> <p>b. generates 14-digit Document Tracking Number (DTN); and records the details in the e-Report Database for tracking and monitoring.</p>	None	10 minutes	Food and Drug Action Center Information Officer I

	If the information/document provided by the client is insufficient, request additional documents.			
	1.2 Issues Acknowledgment Receipt with Document Tracking Number (DTN) to the client.	None	3 minutes	Food and Drug Action Center Information Officer I
	1.3 Prepares Transmittal Slip	None	3 minutes	Food and Drug Action Center Information Officer I
	1.4 Endorses the documents including product sample (if applicable) to the concerned Center/Office for information and appropriate action.	None	5 minutes	Food and Drug Action Center Information Officer I
TOTAL:		None	21 minutes	

4. ISSUANCE OF APPOINTMENT SCHEDULE AND DOCUMENT TRACKING NUMBER

This procedure covers the provision of 14-digit Document Tracking Number (DTN) and schedule of submission for pharmaceutical and household urban pesticide registration applications (initial, renewal, variations, and re-applications) via email to the Food and Drug Action Center (FDAC). This also applies to the submission of applications for other authorizations such as Sales and Promo Permit, Generic Labeling Exemption (GLE), Certificate of Pharmaceutical Product (CoPP), Certificate of Free Sale (CFS), Export Certificate, and re-issuance of authorizations processed using the Integrated Application Form (IAF).

Center/Office/Division	:	Food and Drug Action Center/Accounts and Schedulers Team
Classification	:	Simple
Type of Transaction	:	Government to Business - G2B
Who May Avail	:	Marketing Authorization Holders (MAH) of pharmaceutical products and household urban pesticides and company applicants of Sales and Promo Permits

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Accomplished Integrated Application Form (IAF) 2. Email request with the generated syntax (contained in the email worksheet of the accomplished IAF)	FDA Circular No. 2014-003 - Filing and Receiving of Registration, Licensing and Other Application Using the Integrated Form

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends an email request to fdac@fda.gov.ph following FDA Circular No. 2014-003	1.1 Checks the received email based on the requirements stipulated in FDA Circular No. 2014-003 If compliant, proceed with the procedure in the issuance of schedule and Document Tracking Number (DTN)	None	3 minutes	Food and Drug Action Center Information Officer II

	If not compliant, FDAC Officer sends an email to the requesting party for clarification or correction of the request			
	1.2 Issues Document Tracking Log (DTL) bearing the schedule of submission and DTN	None	5 minutes	Food and Drug Action Center Information Officer II
Receives Document Tracking Log (DTL)	2. Sends email to requesting party with DTL as an attachment and other reminders for guidance of the client	None	2 minutes	Food and Drug Action Center Information Officer II
TOTAL:		None	10 minutes	

5. ISSUANCE OF USER ACCOUNT (USER NAME AND PASSWORD) FOR THE ELECTRONIC PORTAL SYSTEM (E-PORTAL)

This service covers the issuance of a User Account (User Name and Password) for clients engaged in the manufacture of pharmaceuticals, processed food products, cosmetics, and medical devices applying for License To Operate (LTO) at the EPortal System.

Center/Office/Division	:	Food and Drug Action Center/Account and Schedulers Team
Classification	:	Simple
Type of Transaction	:	Government to Business - G2B
Who May Avail	:	Manufacturers of Pharmaceuticals, Processed Food Products, Cosmetics and Medical Devices

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Email request with signed and notarized Authorization Letter as an attachment (Annex B of FDA Circular No. 2016-004)	FDA Circular No. 2016-004 - Procedure on the Use of The New Application Form for the License To Operate (LTO) through the Food and Drug Administration (FDA) Electronic Portal (E-portal)

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends an email request to fdac@fda.gov.ph following the format specified in FDA Circular No. 2016-004 with a signed and notarized Authorization Letter	<p>1. Checks the received email based on the requirements stipulated in FDA Circular No.2016-004</p> <p>If compliant: Proceed with the procedure in the issuance of the User Account</p> <p>If not compliant: FDAC Information Officer sends an email to the</p>	None	7 minutes	Food and Drug Action Center Information Officer II

	requesting party for clarification or correction of the request.			
2. Receives User Account via email	2. Issues User Account to the requesting party	None	3 minutes	Food and Drug Action Center Information Officer II
TOTAL:		None	10 minutes	

6. RECEIVING OF DRUG CPR MINOR VARIATION NOTIFICATION AND FOREIGN GMP WITH REQUIRED PRE-ASSESSMENT BY CD RR AT THE FOOD AND DRUG ACTION CENTER (FDAC) LETTERS SECTION

This service covers acknowledgement of Minor Variation Notification and Foreign GMP applications, endorsement to CD RR's Pre assessment Team and issuance of pre-assessment result to client and receiving of proof of payment.

Center/Office/Division	:	Food and Drug Action Center (Letters Section)
Classification	:	Simple
Type of Transaction	:	Government to Business - G2B
Who May Avail	:	Marketing Authorization Holder (MAH) applying for Drug CPR Minor Variation Notification and Foreign GMP

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Signed Letter of Intent 2. Required documents specified in the application guidelines. 2.1 https://www.fda.gov.ph/wp-content/uploads/2021/05/Minor-Variation-Notification.pdf 2.2 https://www.fda.gov.ph/wp-content/uploads/2020/07/Philippine-Variation-Guidelines-V.1.0-with-fees-and-charges.pdf 2.3 https://www.fda.gov.ph/wp-content/uploads/2021/03/List-of-Requirements-for-Foreign-GMP-Clearance.pdf	FDA Circular No. 2020-026- Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration (FDA) and Its Related Issuances

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Submits application/request through fdac.letters.cdrr@fda.gov.ph	1.1 Checks the completeness of the submission For application with complete submission: Receives the application	None	10 Minutes	Food and Drug Action Center Information Officer I and Information Officer II

	For application/request with incomplete submission: Notifies the client that submission was rejected (state reason of rejection) and advises client to re-submit			
	1.2 Issues Acknowledgement Receipt containing Document Tracking Number (DTN)	None	5 Minutes	Food and Drug Action Center Information Officer I and Information Officer II
	1.3 Prepares and prints summary of documents received and endorses Transmittal Slip to CDRR for pre-assessment	None	5 Minutes	Food and Drug Action Center Information Officer I and Information Officer II
	1.4 Uploads the e-copy of documents to the shared network folder and updates FIS-Document Tracking System (DTS)	None	60 Minutes	Food and Drug Action Center Information Officer I and Information Officer II
	1.5 Receives transmittal slip with pre-assessment result (Accepted/Not Accepted) from CDRR and releases result to the client via email For Acceptable Result: informs client of the result of pre-assessment and advises to pay the required fees For Not Acceptable Result: informs client of the result of pre-assessment and advises client to resubmit the documents for issuance of a new DTN	None	5 minutes	Food and Drug Action Center Information Officer I and Information Officer II

2. Submits proof of payment	2.1 Receives proof of payment and updates status in the DTS and FDAC Letters Database	Based on AO 50 s. 2001	5 Minutes	Food and Drug Action Center Information Officer I and Information Officer II
	2.2 Prepares transmittal and uploads the softcopies via shared OneDrive	None	25 Minutes	Food and Drug Action Center Information Officer I and Information Officer II
	2.3 Endorses the Transmittal Slip to CDRR		5 Minutes	Food and Drug Action Center Information Officer I and Information Officer II
TOTAL:		None	2 Hours	

**Application/request emailed after 5:00pm will be treated as a submission for the next working day.*

**Received applications are transmitted on the next working day.*

7. RECEIVING OF APPLICATION AND OTHER DOCUMENTS BY THE FDAC LETTERS TEAM

This service includes acknowledging email requests, letter notifications and applications, as well as receiving proof of payment where applicable.

Center/Office/Division	:	Food and Drug Action Center (Letters Section)
Classification	:	Simple
Type of Transaction	:	Government to Business - G2B
Who May Avail	:	Stakeholders applying for Import Permit Clearance, Special Permit, Medical Device CPR Renewal and Amendment, CMDL, Donations, HACCP, Sangkap Pinoy Seal, Local GMP, IAC application, and other letter request

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
<p>1. Signed Letter of Intent 2. Other required documents specified in the application guidelines https://www.fda.gov.ph/downloadables/</p> <p>CFS MEDICAL DEVICE https://www.fda.gov.ph/wp-content/uploads/2022/05/Checklist-Requirements-CFS.pdf</p> <p>CDRRHR CPR VARIATION https://www.fda.gov.ph/wp-content/uploads/2022/05/Checklist-Requirements-Variation.pdf</p> <p>CPR RENEWAL FORMS https://www.fda.gov.ph/wp-content/uploads/2022/05/Application-Form-Renewal-IVD.pdf https://www.fda.gov.ph/wp-content/uploads/2021/05/Administrative-Order-No.-2018-002.pdf</p> <p>CMDL https://www.fda.gov.ph/wp-content/uploads/2022/05/LRD-13-Annex-02-Application-FormCMDL.pdf</p>	<p>FDA Circular No. 2020-026- Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration (FDA) and its related issuances</p>

SPECIAL PERMIT COVID TEST KIT

<https://www.fda.gov.ph/wp-content/uploads/2021/04/FDA-Advisory-No.2021-0684.pdf>

<https://www.fda.gov.ph/wp-content/uploads/2021/03/FDA-Memorandum-No.-2021-009.pdf>

SANGKAP PINOY SEAL

<https://www.fda.gov.ph/wp-content/uploads/2021/05/Administrative-Order-No.-2018-002.pdf>

<https://www.fda.gov.ph/wp-content/uploads/2021/05/Administrative-Order-No.-4-A-s.-1995.pdf>

Diamond Sangkap Pinoy Form

<https://www.fda.gov.ph/wp-content/uploads/2021/03/Application-Form-Diamond-Sangkap-Pinoy-Seal.pdf>

Sangkap Pinoy Form

<https://www.fda.gov.ph/wp-content/uploads/2021/03/Application-Form-Diamond-Sangkap-Pinoy-Seal.pdf>

<https://www.fda.gov.ph/wp-content/uploads/2021/05/Administrative-Order-No.-4-A-s.-1995.pdf>

IAC Application <https://www.fda.gov.ph/fda-advisory-no-2023-1544-schedule-of-receiving-of-inter-agency-committee-on-executive-order-no-51-milk-code-applications/>

Import permit

<p>https://www.fda.gov.ph/wp-content/uploads/2021/03/Requirements-for-Release-of-Food-Samples.pdf</p> <p>Donations</p> <p>https://www.fda.gov.ph/wp-content/uploads/2021/03/Requirements-for-Release-of-Food-Donations.pdf</p>	
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CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
<p>1. Submits application/request through fdac.letters@fda.gov.ph or fdac.letters.cdrr@fda.gov.ph (if document is for the CDRR)</p>	<p>1.1 Checks the application or request as indicated in the body of the email and its attachment.</p> <p>For application/request with complete submission: Receives the application</p> <p>For application/request with incomplete submission: Notifies the client that submission was rejected (state reason of rejection) and advises to submit a new application.</p>	None	10 Minutes	Food and Drug Action Center Information Officer I and Information Officer II
	<p>1.2 Issues Acknowledgement Receipt containing Document Tracking Number (DTN)</p> <p>For letter notification, application and request that do not require payment: issues Document Tracking Number</p>	None	10 minutes	Food and Drug Action Center Information Officer I and Information Officer II

	For application/request that requires payment: issues Document Tracking Number with required application fee and payment instruction			
2. Submits proof of payment	2.1 Receives proof of payment and requirements and updates status in the Document Tracking System (DTS) and FDAC Letters Database	Based on AO 50 s. 2001	10 minutes	Food and Drug Action Center Information Officer I and Information Officer II
	2.2 Prepares summary of documents received and prints Transmittal Slip.		20 minutes	Food and Drug Action Center Information Officer I and Information Officer II
	2.3 Uploads the e-copy of documents to the shared network folder and updates FIS DTS		60 minutes	Food and Drug Action Center Information Officer I and Information Officer II
	2.4 Endorses the Transmittal Slip to concerned Center/Offices		10 minutes	Food and Drug Action Center Information Officer I and Information Officer II
TOTAL:		None	2 Hours	

**Application/request emailed after 5:00pm will be treated as a submission for the next working day.*

8. RECEIVING OF PRE-ASSESSED APPLICATIONS BY PACD TEAM

8.1 RECEIVING OF APPLICATIONS FOR CERTIFICATE OF PRODUCT REGISTRATION AND OTHER AUTHORIZATIONS FOR CENTER FOR DRUG REGULATION AND RESEARCH (CDRR)

This service covers the acknowledgement of application, issuance of pre-assessment result, and endorsement to the Center for Drug Regulation and Research for further processing.

Center/Office/Division	:	FDAC/Public Assistance and Complaints' Desk (PACD)
Classification	:	Simple
Type of Transaction	:	Government to Business - G2B
Who May Avail	:	Marketing Authorization Holders (MAH) of pharmaceutical products and company applicants of Sales and Promo Permits for Pharmaceutical Products.

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Integrated Application Form (IAF)	FDA Website
2. Other required documents specified in the application guidelines https://www.fda.gov.ph/downloadables/	FDA Circular No. 2020-026- Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration (FDA) and its related issuances

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends an email to fdac.pacd.cdr@fda.gov.ph on the assigned date with all the necessary requirements	1.1 Checks the received email. compliant, receives application pre- assessment. non-compliant, sends an email to client advising them to request another schedule of submission.	None	20 minutes	Food and Drug Action Center Information Officer II

	1.2 Forwards the application via email to the Center Pre-Assessment Unit and updates the status on FIS/Document Tracking System and FDAC PACD Database.	None	5 minutes	Food and Drug Action Center Information Officer II
	1.3 Prepares transmittal for the acknowledged applications for pre-assessment and updates the status on FIS/Document Tracking System.	None	20 minutes	Food and Drug Action Center Information Officer II
	1.4 Endorses the Transmittal Slip to Center Pre-assessment Unit.	None	5 minutes	Food and Drug Action Center Information Officer II
	1.5 Issues pre-assessment result to client If acceptable , notifies the client via email to proceed with payment and updates the status on FIS-Document Tracking System and FDAC-PACD Database If not acceptable , notifies the client via email with advice to request for new DTN and updates the status on FIS-Document Tracking System and FDAC PACD Database	None	20 minutes	Food and Drug Action Center Information Officer II

2. Submits the proof of payment to FDAC in the same email thread	Upon receiving proof of payment, downloads the pre-assessed documents along with a copy of the pre-assessment result, and updates the status on FIS-Document Tracking System and FDAC PACD Database.	Based on AO 50 s. 2001	60 minutes	Food and Drug Action Center Information Officer II
	Prepares transmittal and uploads the electronically received documents to the FDAC OneDrive link shared with the Center Receiving–Releasing Personnel.		60 minutes	Food and Drug Action Center Information Officer II
	2.3 Endorses the Transmittal Slip to Center Receiving–Releasing Personnel.		5 minutes	Food and Drug Action Center Information Officer II
TOTAL:		None	3 hours and 15 minutes	

**Application emailed after 5:00pm will be treated as a submission for the next working day.*

8.2 RECEIVING OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) APPLICATIONS FOR HOUSEHOLD URBAN PESTICIDE

This service covers the acknowledgement of application, issuance of result, and endorsement to the Center for Cosmetics and Household Urban Hazardous Substances Regulation and Research for further processing.

Center/Office/Division	:	FDAC - Public Assistance and Complaints' Desk (PACD)
Classification	:	Simple
Type of Transaction	:	Government to Business - G2B
Who May Avail	:	Marketing Authorization Holders (MAH) of Household Urban Pesticide

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Integrated Application Form	FDA Website
2. Other required documents specified in the application guidelines https://www.fda.gov.ph/wp-content/uploads/2021/05/Administrative-Order-No.-2019-0008.pdf	FDA Circular No. 2020-026- Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration (FDA) and its related issuances

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends an email to fdac.pacd@fda.gov.ph on the assigned date from 8:00AM to 12:00NN with all the necessary requirements	1.1 Checks the received email submission. If compliant, receipt of the application shall be acknowledged and notifies the client via email. If not compliant, sends email to the client w advice to request another schedule.	None	5 minutes	Food and Drug Action Center Information Officer II

	1.2 Forwards the application to the center pre-assessment unit from 1:00PM to 2:00PM and updates the status on FIS/Document Tracking System and FDAC PACD Database.	None	5 minutes	Food and Drug Action Center Information Officer II
	1.3 Issues pre-assessment result to client. If acceptable , notifies the client via email to proceed with payment and updates the status on FIS/Document Tracking System and FDAC-PACD Database If not acceptable , notifies the client via email with advice to request for rescheduling and updates the status on FIS/Document Tracking System and FDAC PACD Database	None	5 minutes	Food and Drug Action Center Information Officer II
2. Submits the proof of payment to FDAC in the same email thread.	2.1 Upon receiving proof of payment, downloads the pre-assessed documents along with a copy of the pre-assessment result, and updates the status on FIS/Document Tracking System and FDAC PACD Database.	AO 50 s. 2001	10 minutes	Food and Drug Action Center Information Officer II

	2.3 Prepares transmittal and uploads the electronically received documents to the FDAC OneDrive link shared with the Center Receiving–Releasing Personnel.	None	45 minutes	Food and Drug Action Center Information Officer II
	2.4 Endorses the Transmittal Slip to Center Receiving–Releasing Personnel.		5 minutes	Food and Drug Action Center Information Officer II
	TOTAL:	None	1 hour and 10 minutes	

**Application emailed after 12:00pm will be acknowledged and will be endorsed on the next HUP day.*

8.3 RECEIVING OF CFRR PRE-ASSESSED PROMO APPLICATIONS VIA EMAIL BY THE FDAC - PUBLIC ASSISTANCE AND COMPLAINTS' DESK (PACD)

This service covers the receiving of acceptable promo applications pre-assessed by the Center for Food Regulation and Research submitted to Food and Drug Action Center via email.

Center/Office/Division	:	FDAC - Public Assistance and Complaints' Desk (PACD)
Classification	:	Simple
Type of Transaction	:	Government to Business - G2B
Who May Avail	:	Food Manufacturers, Importers, Exporters, Wholesalers/Distributors and Third-Party Marketing Agencies

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Proof of Payment	FDA Website
2. Pre-assessment Result Form	FDA Circular No.2021-013 Interim Guidelines of the Center for Food Regulation and Research (CFRR) for the Application and Receiving of Sales Promo Permit Applications in Compliance to the Republic Act No. 11032 otherwise known as The Ease of Doing Business and Efficient Government Service Delivery Act Of 2018

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends an email to fdac.pacd@fda.gov.ph with proof of payment and copy of pre-assessment result.	1.1 Checks status of application. If payment is already posted, receipt of the application shall be acknowledged and notifies the client via email. If payment is not posted yet, notifies the client that submission is pending for posting of payment and updates FIS/Document Tracking System	AO 50 s. 2001	5 minutes	Food and Drug Action Center Information Officer II

	1.2 Downloads proof of payment along with a copy of the pre-assessment result, and updates the status on FIS/Document Tracking System and FDAC PACD Database.	none	5 minutes	Food and Drug Action Center Information Officer II
	1.3 Prepares transmittal and uploads the electronically received documents to the FDAC OneDrive link shared with the Center Receiving–Releasing Personnel.		45 minutes	Food and Drug Action Center Information Officer II
	1.4 Endorses the Transmittal Slip to Center Receiving–Releasing Personnel.		5 minutes	Food and Drug Action Center Information Officer II
TOTAL:		None	60 minutes	

9. RECEIVING OF PAID APPLICATIONS FOR OTHER AUTHORIZATIONS (CERTIFICATE OF FREE SALE, SALES PROMO PERMIT, LICENSE TO OPERATE – ONE STOP SHOP) AND REAPPLICATION FOR MEDICAL DEVICES AND PHARMACEUTICAL PRODUCTS

This service covers the submission of applications with proof of payment for reapplication and other authorizations submitted to FDAC via email and endorsement of the complete documents to the concerned Center for further processing.

Center/Office/Division	:	FDAC/Public Assistance and Complaints' Desk (PACD)
Classification	:	Simple
Type of Transaction	:	Government to Business - G2B
Who May Avail	:	Marketing Authorization Holders (MAH) of pharmaceutical products, cosmetics and medical devices

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Integrated Application Form	FDA Website
2. Other required documents specified in the application guidelines https://www.fda.gov.ph/downloadables/	FDA Circular No. 2020-026- Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration (FDA) and its related issuances

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends an email to fdac.pacd@fda.gov.ph or fdac.pacd.cdrr@fda.gov.ph on the assigned date with all the necessary requirements	1.1 Checks the received email If compliant, receipt of the application shall be acknowledged and notifies the client via email. If non-compliant, sends an email to the client with advice to provide the lacking documents within the given timeframe.	Based on AO 50 s.2001	5 minutes	Food and Drug Action Center Information Officer II

	1.2 Downloads the documents and updates the status on FIS-Document Tracking System and FDAC PACD Database	None	5 minutes	Food and Drug Action Center Information Officer II
	1.3 Prepares transmittal and uploads the electronically received documents to the FDAC OneDrive link shared with the Center Receiving–Releasing Personnel.	None	20 minutes	Food and Drug Action Center Information Officer II
	1.4 Endorses applications to the concerned Center for evaluation.	None	5 minutes	Food and Drug Action Center Information Officer II
TOTAL:		None	35 minutes	

10. RECEIVING OF COMPLIANCES FOR REGIONAL FIELD OFFICES AND CENTER FOR DEVICE, RADIATION REGULATION AND HEALTH RESEARCH AND ADDITIONAL DOCUMENTS FOR CENTER FOR DRUGS REGULATION RESEARCH

This service covers the submission of compliances and additional documents submitted to FDAC via email and endorsement to the concerned Center for further processing.

Center/Office/Division	:	FDAC/Public Assistance and Complaints' Desk (PACD)
Classification	:	Simple
Type of Transaction	:	Government to Business - G2B
Who May Avail	:	Marketing Authorization Holders (MAH) of pharmaceutical products, cosmetics, processed and prepacked food and medical devices

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Letter of Intent	FDA Website
2. Other required documents specified in the application guidelines https://www.fda.gov.ph/downloadables/	FDA Circular No. 2020-026- Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration (FDA) and its related issuances

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends an email to fdac.pacd@fda.gov.ph or fdac.pacd.cdr@fda.gov.ph on the assigned date with all the necessary requirements	1.1 Checks the received email If compliant, receipt of the application shall be acknowledged and notifies the client via email. If non-compliant, sends an email to the client with advice to provide the lacking documents within the given timeframe.	None	5 minutes	Food and Drug Action Center Information Officer II

	1.2 Downloads the documents and updates the status on FIS-Document Tracking System and FDAC PACD Database	None	10 minutes	Food and Drug Action Center Information Officer II
	1.3 Prepares transmittal and uploads the electronically received documents to the FDAC OneDrive link shared with the Center Receiving–Releasing Personnel.	None	20 minutes	Food and Drug Action Center Information Officer II
	1.4 Endorses applications to the concerned Center for evaluation.	None	5 minutes	Food and Drug Action Center Information Officer II
TOTAL:		None	40 minutes	

11. RECEIVING AND PROCESSING OF REQUEST FOR PERMIT TO MAIL/HAND CARRY HEALTH PRODUCTS FOR NON-COMMERCIAL USE

This service covers the receipt and processing of request for Permit to Mail/Hand Carry Health Products for Non-Commercial Use/Personal Use.

Center/Office/Division	:	FDAC/Public Assistance and Complaints' Desk (PACD)
Classification	:	Simple
Type of Transaction	:	Government to Citizen G2C
Who May Avail	:	All Stakeholders (Internal and External)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Email request	Food and Drug Action Center
2. Duly accomplished online application form	

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends email request to fdac.permittomail@fda.gov.ph	<p>1. Checks the nature of request.</p> <p>If health products subject of the request for Permit to Mail/Hand Carry is for non-commercial use (for personal consumption), sends online application form to the client.</p> <p>If not, notifies the client that request shall not be granted.</p>	None	5 minutes	Food and Drug Action Center Information Officer II

2. Fills-out the online application form	<p>2.1 Checks the sender's address.</p> <p>If from NCR, conducts verification of valid product registration in coordination with concerned FDA Center.</p> <p>If outside the NCR, endorses application via email to the respective FDA Regional Field Offices for further processing and notifies the client.</p>	None	30 minutes	Information Officer II
	2.2 Encodes the details of request in the FIS-Document Tracking System and generates Document Tracking Number	None	5 minutes	Information Officer II
	2.3 Issues Order of Payment to the client via email with advice to proceed with payment	None	3 minutes	Information Officer II
3. Submits proof of payment to fdac.permittomail@fda.gov.ph .	3.1 Receives proof of payment and prepares the draft for FDAC OIC's final approval and signature	Php 50 + LRF (AO 50s 2001)	15 minutes	Information Officer II
	3.2 Sends soft copy of the electronically signed permit to the client.	None	2 minutes	Information Officer II
TOTAL:		None	60 minutes	