

1. Issuance of License-To- Operate (LTO) VDAP Establishment Online Application

This describe process of preparing and issuing of Veterinary Drugs and Product Establishment LTO.

Office or Division:	Animal Feeds, Veterinary Drugs and Biologics Control Division (AFVDBCD)
Classification:	Highly Technical Transaction
Type of Transaction:	G2B – Government to Business,
Who may avail:	Business entity as VDAP Manufacturer, VDAP Trader, VDAP Importer, VDAP Exporter, VDAP Wholesaler, VDAP Outlet.
CHECKLIST OF REQUIREMENTS	
WHERE TO SECURE	
Activation of Account	
1. INS (InterCommerce Network Services) Enrollement Form	INS
2. Information Service Agreement	INS
3. BIR 2303	c/o Applicant, BIR
LTO Classification	
A. VDAP Manufacturer	
INITIAL (1 Electronic copy)	
1. Business Certificate of Registration: a.) Sole Proprietorship –Department of Trade and Industry (DTI) b.) Corporations - Security Exchange Commission (SEC) c.) Cooperative- Cooperative Development Authority (CDA)	DTI, SEC, or CDA whichever is applicable
2. Contract of Lease of the space (if rental) or Proof of Ownership of the building occupied	c/o Applicant

3. Environmental Compliance Certificate (ECC) / Certificate of Non-Coverage (CNC)/ Permit to Operate (PTO) from Department of Environment and Natural Resources (DENR) or Discharge Permit (DP) from Laguna Lake Development Authority (LLDA) if the establishment was discharging liquid waste and located within the vicinity of Laguna de Bay/ under the jurisdiction of LLDA	c/o Applicant,DENR-ECC/CNC/PTO, LLDA- DP, whichever is applicable
4. Business / Mayor's Permit for the current year	c/o Applicant, Local Government Unit (LGU)
5. Joint Affidavit of Undertaking (RF FVBD-16) of Veterinarian, and Chemist and valid Professional Regulation Commission (PRC) ID and Professional Tax Receipt (PTR).	c/o Applicant, Downloadable at www.bai.gov.ph -AFVDBCD Service form
6. Establishment with in-house veterinary laboratory requirements: a. Valid Certificate of Recognition, b. Valid PRC ID and PTR of Chemist	c/o Applicant
7. Establishment without their own veterinary laboratory requirements: a. Memorandum of Agreement (MOA) between the applicant and BAI Recognized Third-party Service Laboratory b. Valid Certificate of Recognition, and c. Valid PRC ID and PTR of Chemist	c/o Applicant,
8. List of products to be manufactured with Generic or Brand Names	c/o Applicant
9. Sketch location map	c/o Applicant
10. Current floor plan with complete dimension	c/o Applicant
11. Certificate of BAI Orientation Seminar	c/o Applicant,BAI

12. Site inspection of office, plant and warehouse and validation of submitted document	AFVDBCD- Inspection, Monitoring and Inspection Section (IMES) Inspector- Agriculturist II
RENEWAL (1 Electronic Copy)	
1. <i>Previously approved LTO Certificate</i>	c/o Applicant
2. Business/ Mayor's Permit for the current year	c/o Applicant, <i>LGU</i>
3. Joint Affidavit of Undertaking (RF FVBD-16) with valid PRC ID and PTR of Veterinarian	c/o Applicant, Downloadable at www.bai.gov.ph -AFVDBCD Service form
4. Establishment with in-house veterinary laboratory requirements: a. Valid Certificate of Recognition, b. Valid PRC ID and PTR of Chemist	c/o Applicant
5. Establishment without their own veterinary laboratory requirements: a. MOA between the applicant and BAI Recognized Third-party Service Laboratory b. Valid Certificate of Recognition, and c. valid PRC ID and PTR of Chemist	c/o Applicant
6. Annual production report and production report fees	c/o Applicant
7. Site inspection of office, plant and warehouse and validation of submitted document	AFVDBCD- IMES Inspector- Agriculturist II
8. <i>Certificate of BAI Orientation Seminar</i>	<i>c/o Applicant, BAI</i>
B. VDAP Trader	
INITIAL (1 Electronic copy)	
1. Business Certificate of Registration: a.) Sole Proprietorship –Department of Trade and Industry (DTI) b.) Corporations - Security Exchange Commission (SEC) c.) Cooperative- Cooperative Development Authority (CDA)	DTI, SEC, or CDA whichever is applicable

2. Contract of Lease of the space (if rental) or Proof of Ownership of the building occupied	c/o Applicant
3. Contract of Agreement between Licensed VDAF Manufacturers and Veterinary Drug Trader containing stipulations that both parties are jointly responsible for the quality of the veterinary drug and product.	c/o Applicant
4. Business / Mayor's Permit for the current year	c/o Applicant, LGU
5. Joint Affidavit of Undertaking (RF FVBD-16) with valid PRC ID and PTR of Veterinarian	c/o Applicant, Downloadable at www.bai.gov.ph -AFVDBCD Service form
6. Establishment without their own veterinary laboratory requirements: a. MOA between the applicant and BAI Recognized Third-party Service Laboratory b. Valid Certificate of Recognition, and c. valid PRC ID and PTR of Chemist	c/o Applicant
7. List of products to be manufactured with Generic or Brand Names	c/o Applicant
8. Sketch location map of office and warehouse	c/o Applicant
9. Certificate of BAI Orientation Seminar	c/o Applicant,BAI
10.Site inspection of office and warehouse and validation of submitted document	AFVDBCD-IMES Inspector- Agriculturist II
RENEWAL (1 Electronic copy)	
1. <i>Previously approved LTO Certificate</i>	c/o Applicant, electronic
2. Business/ Mayor's Permit for the current year	c/o Applicant, LGU
3. Joint Affidavit of Undertaking (RF FVBD-16) with valid PRC ID and PTR of Veterinarian	c/o Applicant, Downloadable at www.bai.gov.ph -AFVDBCD Service form
4. Establishment without their own veterinary laboratory requirements: a. MOA between the applicant and BAI Recognized Third-party Service Laboratory b. Valid Certificate of Recognition, and	c/o Applicant

c. valid PRC ID and PTR of Chemist	
5. List of products to be with Generic or Brand Names	c/o Applicant
6. <i>Site inspection of office, plant and warehouse and validation of submitted document</i>	c/o IMES Inspector- Agriculturist II
7. <i>Certificate of BAI Orientation Seminar</i>	c/o Applicant,BAI
C. VDAP IMPORTER	
INITIAL (1 Electronic copy)	
1. Business Certificate of Registration: a.) Sole Proprietorship –Department of Trade and Industry (DTI) b.) Corporations - Security Exchange Commission (SEC) c.) Cooperative- Cooperative Development Authority (CDA)	DTI, SEC, or CDA whichever is applicable
2. Contract of Lease of the space (if rental) or Proof of Ownership of the building occupied	c/o Applicant
3. Business / Mayor's Permit for the current year	c/o Applicant, <i>LGU</i>
4. Joint Affidavit of Undertaking (RF FVBD-16) With valid PRC ID and PTR of Veterinarian	c/o Applicant, Downloadable at www.bai.gov.ph -AFVDBCD Service form
5. List of products to be imported with Generic or Brand Names	c/o Applicant
6. Sketch location map	c/o Applicant
7. Certificate of BAI Orientation Seminar	c/o Applicant,BAI
8. Site inspection of office and warehouse and validation of submitted document	AFVDBCD- IMES Inspector- Agriculturist II
RENEWAL (1 Electronic copy)	
1. <i>Previously approved LTO Certificate</i>	c/o Applicant
2. Business / Mayor's Permit for the current year	c/o Applicant, Local Government Unit (LGU)
3. Joint Affidavit of Undertaking (RF FVBD-16) with valid PRC ID and PTR of Veterinarian and Chemist	c/o Applicant, Downloadable at www.bai.gov.ph -AFVDBCD Service form

4. List of products to be imported/ distributed with Generic or Brand Names	c/o Applicant
5. Sketch location map of office and warehouse	c/o Applicant
6. Site inspection of office and warehouse and validation of submitted document	AFVDBCD- IMES Inspector- Agriculturist II
7. <i>Certificate of BAI Orientation Seminar</i>	c/o Applicant,BAI
D. VDAP EXPORTER	
INITIAL (1 Electronic copy)	
1. Business Certificate of Registration: a.) Sole Proprietorship –Department of Trade and Industry (DTI) b.) Corporations - Security Exchange Commission (SEC) c.) Cooperative- Cooperative Development Authority (CDA)	DTI, SEC, or CDA whichever is applicable
2. Contract of Lease of the space (if rental) or Proof of Ownership of the building occupied	c/o Applicant
3. Business / Mayor's Permit for the current year	c/o Applicant, <i>LGU</i>
4. Joint Affidavit of Undertaking (RF FVBD-16) With valid PRC ID and PTR of Veterinarian.	c/o Applicant, Downloadable at www.bai.gov.ph -AFVDBCD Service form
5. List of products to be exported with Generic or Brand Names	c/o Applicant
6. Sketch location map of office and warehouse	c/o Applicant
7. Certificate of BAI Orientation Seminar	c/o Applicant,BAI
8. Site inspection of office and warehouse and validation of submitted document	AFVDBCD- IMES Inspector- Agriculturist II
RENEWAL (1 Electronic copy)	
1. <i>Previously approved LTO Certificate</i>	c/o Applicant
2. Business / Mayor's Permit for the current year	c/o Applicant, <i>LGU</i>
3. Joint Affidavit of Undertaking (RF FVBD-16) With valid PRC ID and PTR.	c/o Applicant, Downloadable at www.bai.gov.ph -AFVDBCD Service form

4. List of products to be exported with Generic or Brand Names	c/o Applicant
5. Sketch location map office and warehouse	
6. Site inspection of office and warehouse and validation of submitted document	AFVDBCD-IMES Inspector- Agriculturist II
7. <i>Certificate of BAI Orientation Seminar</i>	c/o Applicant,BAI
E. VDAP WHOLESALER	
INITIAL (1 Electronic copy)	
1. Business Certificate of Registration: a.) Sole Proprietorship –Department of Trade and Industry (DTI) b.) Corporations - Security Exchange Commission (SEC) c.) Cooperative- Cooperative Development Authority (CDA)	DTI, SEC, or CDA whichever is applicable
2. Contract of Lease of the space (if rental) or Proof of Ownership of the building occupied	c/o Applicant
3. Business / Mayor's Permit for the current year	c/o Applicant, <i>LGU</i>
4. Joint Affidavit of Undertaking (RF FVBD-16) With valid PRC ID and PTR of Veterinarian.	c/o Applicant, Downloadable at www.bai.gov.ph -AFVDBCD Service form
5. A valid contract of agreement with BAI Licensed VDAP Manufacturer, VDAP Importer, VDAP Trader.	c/o Applicant
6. List of products to be sold with Generic or Brand Names	c/o Applicant
7. Sketch location map of store	c/o Applicant
8. Certificate of BAI Orientation Seminar	c/o Applicant,BAI
9. Site inspection of office and warehouse/ store and validation of submitted document	AFVDBCD-IMES Inspector- Agriculturist II
RENEWAL (1 Electronic copy)	
1. <i>Previously approved LTO Certificate</i>	c/o Applicant
2. Business / Mayor's Permit for the current year	c/o Applicant, <i>LGU</i>

3. Joint Affidavit of Undertaking (RF FVBD-16) With valid PRC ID and PTR of Veterinarian.	c/o Applicant, Downloadable at www.bai.gov.ph -AFVDBCD Service form
4. A valid contract of agreement with BAI Licensed VDAP Manufacturer, VDAP Importer, VDAP Trader.	c/o Applicant
5. List of products to be sold with Generic or Brand Names	c/o Applicant
6. Sketch location map of store	c/o Applicant
7. Site inspection of office, store /warehouse and validation of submitted document	AFVDBCD-IMES Inspector- Agriculturist II
8. <i>Certificate of BAI Orientation Seminar</i>	c/o Applicant,BAI
F. VDAP OUTLET	
INITIAL (1 Electronic copy)	
1. Business Certificate of Registration: a.) Sole Proprietorship –Department of Trade and Industry (DTI) b.) Corporations - Security Exchange Commission (SEC) c.) Cooperative- Cooperative Development Authority (CDA)	DTI, SEC, or CDA whichever is applicable
2. Contract of Lease of the space (if rental) or Proof of Ownership of the building occupied	c/o Applicant
3. Business / Mayor's Permit for the current year	c/o Applicant, <i>LGU</i>
4. Joint Affidavit of Undertaking (RF FVBD-16) With valid PRC ID and PTR of Veterinarian.	c/o Applicant, Downloadable at www.bai.gov.ph -AFVDBCD Service form
5. List of products to be sold with Generic or Brand Names	c/o Applicant
6. Sketch location map of store	c/o Applicant
7. Site inspection of office and store , and validation of submitted document	AFVDBCD-IMES Inspector- Agriculturist II
RENEWAL (1 Electronic copy)	
1. <i>Previously approved LTO Certificate</i>	c/o Applicant

2. Business / Mayor's Permit for the current year	c/o Applicant, <i>LGU</i>
3. Joint Affidavit of Undertaking (RF FVBD-16) With valid PRC ID and PTR Veterinarian.	c/o Applicant, Downloadable at www.bai.gov.ph -AFVDBCD Service form
4. List of products to be sold with Generic or Brand Names	c/o Applicant
5. Sketch location map of store	c/o Applicant
6. Site inspection of store and validation of submitted document	AFVDBCD-IMES Inspector- Agriculturist II
CHANGE IN CIRCUMSTANCES (1 Electronic copy)	
1. Official Letter re change of address/ownership/ business name ect.	c/o Applicant
2. Previously approved LTO certificate	c/o Applicant
3. <i>Amended SEC (Corporation) / DTI (Sole Proprietorship)/ CDA (Cooperative)</i>	c/o Applicant, whichever is applicable,
4. <i>Amended ECC</i>	c/o Applicant, for Manufacturers
5. <i>Amended Business permit for the current year</i>	c/o Applicant
6. <i>Deed of Sale/ Transfer of Rights</i>	c/o Applicant, incase of change of ownership
7. <i>Proofed of payment for CIC</i>	c/o Applicant

CLIENT STEPS	AGENCY ACTIONS	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1.1. Inform their intention to apply thru phone call and/ or email	1. Provide helpdesk email of INS to client for registration and issue Order of Payment Remarks: Provide client instruction on the registration, payment, and application process thru email	None	5 minutes	Admin. Staff LRCS
1.2. Send an email request thru email helpdesk@intercommerce.com.ph and secure the following requirements: a) User Manual b) INS Enrollment Form c) Information Service Agreement	None	None	C/O INS	C/O INS
1.3. Register an account thru https://baireg.intercommerce.com.ph and accomplish the following: a) Account Info- Username and Password b) Company Info c) Attachments: i. INS Enrollment Form	None	None	C/O INS	C/O INS

ii. Information Service Agreement iii. BIR 2303				
1.4. Waits for the activation of account	None	None	C/O INS	C/O INS
2. Pay corresponding payment	2. Process payment and issue Official Receipt	1) VDAP Manufacturer PHP 6,000.00 2) VDAP Trader PHP 3,600.00 3) VDAP Importer PHP 2,400.00 4) VDAP Exporter PHP 2,400.00 5) VDAP Wholesaler PHP 2,400.00 6) VDAP Outlet PHP 240.00	10 minutes	BAI Cashier

<p>3. Login to <i>https://baireg.intercommerce.com.ph</i> to start application process as referred to INS User Manual, to wit:</p> <p>a. Filling-up necessary information</p> <p>b. Attach documentary requirements</p> <p>c. Payment of INS Service Fee</p> <p>d. Submit application</p>	None	Service Fee c/o INS	C/O INS	C/O INS
<p>4. Monitor status of application thru email and account:</p> <p>Remarks: If with compliance, the application is pending until requested requirements is satisfied maximum of 30 days from the day of request, otherwise, the system will automatically reject the application, then the applicant will return to Step 3.</p>	<p>4. Review and validate the application and documentary requirements:</p> <p>Remarks: If non-compliance, send compliance request.</p> <p>If complete, forward to Head of Inspection'</p>	None	1 hour	Technical Evaluator, LRCS
<p>5. Wait for the system generated email notification for schedule of Inspection</p>	<p>5. Assign field inspector and notify for the schedule of inspection</p> <p>Remarks: Schedule is set 14 working days upon receipt of head inspector</p>	None	14 working days	<p>Section Head, IMES</p> <p>For <i>Regional Field Office (RFO), Regional Animal Feeds Veterinary Drugs and</i></p>

				<i>Biologics Control Officer (RAFVDABCO)</i>
6. Participate in the inspection proper	6. Conduct inspection proper a. Entry meeting b. Verification of original documents c. Facility inspection d. Exit Meeting	None	3 hours	IMES Inspection Team For <i>RFO, RAFVDABCO</i> Team
7. Monitor status of application thru email and account: Remarks: If with compliance, the application is pending until requested requirements is satisfied maximum of 30 days from the day of request, otherwise, the system will automatically reject the application, then the applicant will return to Step 3.	7.1. Encode Inspection Findings in the INS System Remarks: If non-compliance, send compliance request. If complete, forward to endorser for Recommending approval to Assistant Director with the authority of the Director	None	30 minutes	IMES Inspection Team For <i>RFO, RAFVDABCO</i> Team
	7.2. Endorse the application to the Assistant Director for Regulations and Disease Control for approval with the authority of the Director	None	5 minutes	Supervising Agriculturist AFVDBCD
8. Print LTO Certificate	None	None	2 minutes	

TOTAL PROCESSING TIME		14 working days 4 hours 52 minutes	
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Prepared by:

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LRCS, AFVDBCD

Approved by:

MARIA FE B. CABULLO, DVM, MSA, MNSA
Chief, AFVDBCD

Annex I. Fees

SCHEDULE OF FEES				
A. LTO VDAP				
Nature of Business	Fees Initial	Fees Renewal	Validity	
			Initial	Renewal
b. 1 Manufacturer	PHP 6000.00	PHP 12,000.00	1 Year	2 Years
b. 2 Trader	PHP 3,600.00	PHP 7,200.00	1 Year	2 Years
b. 3 Importer	PHP 2,400.00	PHP 4,800.00	1 Year	2 Years
b. 4 Exporter	PHP 2,400.00	PHP 4,800.00	1 Year	2 Years
b. 5 Wholesaler	PHP 2,400.00	PHP 4,800.00	1 Year	2 Years
b. 6 Outlet	PHP 240.00	PHP 480.00	1 Year	2 Years