

## 2. ISSUANCE OF CERTIFICATE OF FEED PRODUCT REGISTRATION AND VETERINARY DRUG AND PRODUCT REGISTRATION

All feed and veterinary drug and product outlets are required to secure a Bureau of Animal Industry (BAI) Registration Certificate of License to Operate under RA 1556-The Livestock and Poultry Feeds Act; RA 3720- Foods, Drugs and Devices and Cosmetics Act; RA 9711- Food and Drug Administration Act of 2009 and RA 6675- Generics Act of 1988).

### Schedule of Availability of Service

Monday to Friday- 8:00 AM to 5: PM

### Schedule of Availability of Service

Services	Fees
<b>I. Feed Product Registration (per product)</b>	Php 100.00
<b>II. Veterinary Drug and Product Registration (per product)</b>	
<b>New</b>	
Unbranded Generic (for 2 years + cost of Laboratory Analysis)	Php 1,200.00
Branded Generic (for 2 years + cot of Laboratory Analysis)	Php 2,400.00
<b>Renewal</b> (for 5 years + cost of Laboratory Analysis)	Php 1,800.00
Inspection Fee ** (Php 0.25 per kilogram and Php 1.00 per liter for premix additives and supplements that are manufactured locally or imported shall be charged monthly on the basis of total volume of VDAP manufactured locally or imported)**	Php 0.25/ Php 1.00

<b>Office or Division</b>	<b>REGULATORY DIVISION</b>	
<b>Classification</b>	HIGHLY TECHNICAL	
<b>Type of transaction:</b>	G2C – Government to Client/ G2B – Government to Business	
<b>Who may avail:</b>	Citizens currently engaged in animal feeds and veterinary drugs and products trading and those who plan to engage in said business within Region XIII.	
<b>CHECKLIST OF REQUIREMENTS</b>		<b>WHERE TO SECURE</b>
<b>I. FEED ESTABLISHMENT (GENERAL REQUIREMENTS)</b>		
1. Notarized application form;	Requisitioner /DA RFO XIII Regulatory Division	
2. Latest 2pcs 1x1 ID Picture;	Requisitioner	
3. Documentary Stamp;	BIR or City Hall	

4. Photocopy of Community Tax Certificate;	Barangay Hall
5. Photocopy of PRC ID of attending Veterinarian / Nutritionist;	Veterinarian / Nutritionist
6. Community Tax Certificate, PTR, and Diploma; List of Product Sold.	Veterinarian or Nutritionist
<b>A. FEED PRODUCT REGISTRATION</b>	
<b>Imported Feed Products</b>	
1. Brand Name Clearance ( For branded Products);	DA RFO XIII Regulatory Division
2. Certificate of Free Sale from country of origin ( if CFS and GMP issued by the government agency from country of origin no need to comply #4);	Requisitioner
3. Certificate of Good Manufacturing Practice from country of origin(if applicable);	Requisitioner
4. Authentication issued by the Philippine Embassy or Consular Office at country of origin (Nos. 2 & 3);	Requisitioner
5. Government Veterinary Health/Phytosanitary Certificate from country of origin;	Requisitioner
6. Distribution Agreement between the importer and foreign manufacturer / supplier (for branded products);	Requisitioner
7. Technical description of the product;	Requisitioner
8. Process Flow / Manufacturing Procedure;	Requisitioner
9. Certificate of Analysis;	Requisitioner
10. Facsimile or draft of the proposed tag or label for each type of product;	Requisitioner
11. Sample of not less than 250 grams of each product.	Requisitioner
<b>Locally Manufactured Feed Products</b>	
1. Brand Name Clearance;	DA RFO XIII Regulatory Division
2. Technical description of the products;	Requisitioner
3. Process Flow / Manufacturing Procedure;	Requisitioner
4. Certificate of Analysis;	Requisitioner
5. Facsimile or draft of the proposal tag or label of each type of feed product;	Requisitioner
6. Sample of not less than 250 grams per product;	Requisitioner
7. Affidavit of Animal Nutritionist / Veterinary Consultant;	Requisitioner / Veterinarian or Nutritionist
8. Affidavit of Quality Control Chemist.	Requisitioner / Chemist

<b>II. VETERINARY DRUG AND PRODUCT REGISTRATION (GENERAL REQUIREMENTS)</b>	
1. Notarized and accomplished Joint Affidavit of Undertaking;	Requisitioner
2. Photocopy of Mayor's / Business Permit (nature of business specified) for the current year and Official Receipt;	Municipal Hall or City Mayor's Office
3. Photocopy of Business Name Registration with BDT / SEC (if corporation) and Articles of Incorporation;	Securities and Exchange Commission
4. ID (5cm x 5cm) picture of the Owner, Gen. Manager, Veterinarian;	Requisitioner
5. Photocopy of Pharmacist, Veterinarian, and Chemist Registration and Valid ID PTR, Community Tax Certificate (as applicable);	Requisitioner
6. Notarized valid Contract of Lease of the space / building occupied, if the applicant does not own it;	Requisitioner
7. List of Reference Books: <ul style="list-style-type: none"> <li>• USP /NF (Latest Edition)</li> <li>• RA 3720, RA 6675, RA 5921</li> <li>• Remington's Pharmaceutical Sciences (Latest Edition)</li> <li>• Goodman and Gilman Pharmacological Basis of Therapeutics</li> <li>• British Pharmacopeia</li> <li>• Philippine National Veterinary Formulary</li> </ul>	Requisitioner
8. Location Plan;	Requisitioner
9. List of products to be manufactured / distributed with Generic and Brand Names;	Requisitioner
10. Copy of Inspection and Evaluation Report;	Requisitioner /DA RFO XIII Regulatory Division
11. Original Copy of previous LTO.	Requisitioner
<b>A. VETERINARY DRUG AND PRODUCT REGISTRATION</b>	
1. Notarized letter of application from manufacturer / traders / distributor (Annex AFSD Form 3A) For Initial / Renewal of registration of Change of Circumstances (COC);	Requisitioner /DA RFO XIII Regulatory Division
2. Duly accomplished AFSD Form No. 3;	Requisitioner /DA RFO XIII Regulatory Division
3. Contract of Agreement / Authorization between manufacturer and distributor;	Requisitioner
4. List of all ingredients used as a component of the product indicating the quantity and technical specification;	Requisitioner
5. Full description of the methods used, the facilities	Requisitioner

and controls in the manufacture, processing and packaging of the product;	
6. Technical specification and physical description of the finished products;	Requisitioner
7. Complete assay procedure for active ingredients, finished product and degradation products, if any;	Requisitioner
8. Certificate of Analysis from BAI / LSD / Recognized Laboratory / Manufacturer's analysis (Imported) / Government Issued;	Requisitioner
9. Stability studies of the product to justify claimed expiration date of Accelerated Short Term Stability or actual Stability Study;	Requisitioner
10. Unattached generic labels or proposed labels to be used for the product with actual color and text (in accordance with A.O. 55, S1988);	Requisitioner
11. Duly accomplished and notarized Declaration Form;	Requisitioner
12. Approved Brand Name Clearance;	Requisitioner /DA RFO XIII Regulatory Division
13. Xeroxed copy of valid PRC license of Veterinary Medical Officer;	Requisitioner
14. MRL and ADI of the product (Where Applicable);	Requisitioner
15. Copy of latest Certificate of Product Registration (CPR) and License to Operate (LTO);	Requisitioner /DA RFO XIII Regulatory Division
16. Actual Commercial label and copy of previous BAI approved;	Requisitioner
17. Proof of payment of Registration upon approval of CPR.	Requisitioner /DA RFO XIII Regulatory Division
<b>CHANGE IN CIRCUMSTANCES:</b>	
1. Official letter re: change of address / owner / business name / Veterinarian / Pharmacist / Chemist / etc. as applicable;	Requisitioner
2. Surrender original CPR and approved label;	Requisitioner
3. Duly notarized Declaration Form, Form 3A and for any change(s) in the product;	Requisitioner
4. Pertinent documents required for the amendment of the product claims (based on Checklist);	Requisitioner

<b>ADDITIONAL REQUIREMENTS FOR IMPORTERS OF AUTHORIZED DISTRIBUTOR FROM FOREIGN SOURCES:</b>				
1. Government Certificate of Clearance and Free Sale / Registration approval of the product / Export Certificate from country origin;				Requisitioner
2. Government Certification attesting to the status of the manufacturer's competency and reliability of the personnel and facilities;				Requisitioner
3. Agreement must be authenticated by the territorial Philippine Consulate in case of Exclusive Distributorship. ***Note: Items 1,2 & 3 should be duly authenticated by territorial Philippine consulate or in the absence of the Consulate, any equivalent regulatory government Agency. ***To be submitted upon renewal of registration. ** Change of Circumstances (COC).				Requisitioner
<b>CLIENT STEPS</b>	<b>AGENCY ACTIONS</b>	<b>FEES TO BE PAID</b>	<b>PROCESSING TIME</b>	<b>PERSON RESPONSIBLE</b>
1. Secure application form and inquire for requirements and application procedures.	<b>Step 1.1:</b> Brief the customer on the application procedures and give list of requirements together with the application form.	None	(excluded)	Agriculturist II, <b>Regulatory Division</b>
2. Fill-up registration form (original) and submit for processing.	<b>Step 2.1:</b> Receive and review the application forms for the completeness of requirements (photocopy) submitted.	None	1 Day	Agriculturist II, <b>Regulatory Division</b>
	<b>Step 2.2:</b> Conduct ocular inspection, prepare report and endorse application for approval.	None	2 Days	Agriculturist II, <b>Regulatory Division</b>
3. Pay corresponding fees to Authorized Special Collecting Officers	<b>Step 3.1:</b> Special Collecting Officers receive payment and issue Order of Payment.	Refer to table of fees above	10 Minutes	Agriculturist II, <b>Regulatory Division</b>
	<b>Step 3.2:</b> Endorse application to Regional Executive Director for Approval	None	1 Day	Agriculturist II, <b>Regulatory Division</b>

	<b>Step 3.3:</b> Retrieve approved documents from the Regional Executive Director's Office.	None	1 Day	Agriculturist II, <b>Regulatory Division</b>
	<b>Step 3.4:</b> If new applications, submit documents to BAI-CO for approval of BAI Director for the issuance of the Certificate of the Registration.	None	1 Day	Agriculturist II, <b>Regulatory Division</b>
	<b>Step 3.5:</b> If renewal of Feed Product, submit a copy of applications to BAI-CO for their reference and file. Notify client for the release of their copy.  If renewal of VDAP, submit documents to BAI-CO for approval of BAI Director for the issuance of the License to Operate.	None		Agriculturist II, <b>Regulatory Division</b>
	<b>Step 3.6:</b> Receive approved Certificate of Registration and record the same.	None	1 Day	Agriculturist II, <b>Regulatory Division</b>
	<b>Step 3.7:</b> Notify the client to get approved Registration Certificate.	None	10 Minutes	Agriculturist II, <b>Regulatory Division</b>
4. Receive approved Registration Certificate	<b>Step 4.1:</b> Release approved Registration Certificate, record and file the documents.	None	10 Minutes	Agriculturist II, <b>Regulatory Division</b>
<b>TOTAL</b>			<b>7 hours and 30 Minutes</b>	**Note: Exclusive of number of Days of non-compliance during inspection and evaluation requirements.