Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

ADMINISTRATIVE ORDER
No.

SUBJECT : Revised Guidelines on the Licensing of Veterinary Establishments, Registration and Post-Market Surveillance of Veterinary Drug Products

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I. RATIONALE

Republic Act No. 9711 otherwise known as the "Food and Drug Administration Act of 2009", as enacted by the congress on 18 August 2009, among others, has the objective of strengthening and enhancing the administrative and technical capacity of the Food and Drug Administration (FDA) through the regulation and monitoring of establishments and products under its mandate, which include veterinary drugs & products.

To maintain the effectiveness of the regulation of the veterinary drugs products, ensure efficient supply thereof, and strengthen public protection to emerging health concerns such as antimicrobial resistance, the following guidelines are set forth herein.

II. OBJECTIVES

A. General Objective

To provide guidelines for the licensing, registration, and post-market surveillance (PMS), and issuance of other certifications for the effective regulation of veterinary drug products and establishments.

B. Specific Objectives

1. To provide guidelines for the issuance of License to Operate (LTO) to veterinary drug establishments,
2. To provide guidelines for the issuance Certificate of Product Registration (CPR) of veterinary drug products,
3. To establish labeling guidelines for veterinary drug products,
4. To provide guidelines for the issuance of other related certification for veterinary drug products such as Sales Promo Permit and Batch Notification,
5. To conduct joint PMS activities on veterinary establishments, drugs and products as needed.
6. To enforce regulatory actions such as but not limited to revocations, cancellation/suspension of LTO's/CPR's, issuance of preventive measure orders, summons and notice/Report of Violation (ROV), seizure, forfeiture,

destruction, disposal of violative veterinary products and imposition of administrative fines, sanctions, and penalties.

7. To prescribe guidelines, policies and/or standards in the regulation of veterinary establishments, drugs and products.

III. SCOPE AND COVERAGE

This Order shall apply to the manufacturers, distributors (importers, Exporters, Wholesalers), traders, and retailers/ outlets, of veterinary drug products, including, but not limited to the following:

1. Veterinary drug products with therapeutic claim (including vitamins, minerals, probiotics, prebiotics, traditional medicine, herbal supplements etc.);
2. Finished pharmaceutical dosage forms including but not limited to oral dosage forms such as tablets, capsules, paste, bolus, powder for suspension, granules for suspension, suspension, powder, syrup, solutions and emulsions;
3. Injectables in the form of solution, suspension, powder for injection, granules for injection and parenteral,
4. External Preparations including topical suspension, ointments, creams, lotions, aerosols, spray, pastes, gels, powders, medicated soaps and shampoo, solutions, medicated collars and the like;
5. Ophthalmic or otic creams, ointments, solutions or suspensions;
6. Veterinary vaccines and biologics
7. Veterinary drug premixes;
8. Veterinary therapeutic diets.

IV. DEFINITION OF TERMS

See ANNEX A

V. LICENSING OF ESTABLISHMENTS

A. General Guidelines

1. No veterinary drug establishment shall manufacture, import, export, sell, offer for sale, distribute, transfer, promote, advertise, and/or sponsor any activity that involves veterinary product without first securing an LTO.
2. All issued LTO covered by this Order that was previously under the jurisdiction of Bureau of Animal Industry shall now be under the jurisdiction of FDA.
3. All licensed establishments must continuously comply with the existing requirements, regulations and standards, otherwise the establishment may be ordered closed or their licenses suspended or revoked *motu proprio* or upon petition by any person.
4. All licensed establishments engaged in the importation of veterinary drugs products which have been banned or withdrawn for health and safety reasons in the country of manufacture or country of origin shall not be imported or offered for import, sold or used in the Philippines and shall likewise be refused admission.

5. All licensed establishments engaged in the manufacture, distribution, exportation, importation, selling, transportation/shipment of vaccines, biologics and other temperature-sensitive veterinary drug products are hereby directed to comply with the cold chain management requirements as per Bureau Circular (BC) 2007-003 (Cold Chain Management Requirements).
6. A violation with any of the terms and conditions of the LTO issued by FDA, shall likewise result in the suspension, revocation or cancellation of the LTO or disapproval of the application for renewal, after due process.
7. All licensed establishment shall immediately recall, withdraw, seize, or ban from public sale or distribution or donation any veterinary drug and product that is declared to be imminently injurious, unsafe or dangerous.
8. The FDA shall have the authority to enter any veterinary establishments for, but not limited to:
    a. Verification of submitted documents in relation to any LTO application,
    b. Inspection of compliance to licensing requirements, GDPs, GSPs and
    c. PMS activities especially investigation within their respective regulatory jurisdictions.
9. The validity of the LTO shall be 2 years for initial application and 3 years for renewal application.
10. All establishments are required to implement a risk management plan which is a requirement for the issuance of an LTO or other authorization (possible consideration in post-market surveillance for risk management plan).
11. Veterinary Drug Product Retailers
    a. Only the veterinary drug retailers/outlets are allowed to sell and dispense prescription or ethical veterinary drug products to the general public the general public or consumer.
    b. The veterinary drug retailers/outlets are not allowed to sell and dispense veterinary drug products without a written order (VDO/prescription) of a duly-licensed veterinarian.
    c. Prescription veterinary drug products are not allowed to be sold within the same establishment as prescription human drug products.
    d. No veterinary retailer/outlet shall conduct online ordering and selling activities without a valid LTO and CPR.

B. Specific Guidelines

1. Requirements
   The requirements for Licensing shall follow the AO No. 2020-0017 (Revised Guidelines in the Unified Licensing Requirements and Procedures of FDA) **Annex B.**
2. Processing
    a. Filing
       An application for LTO, whether initial, renewal, or variation and other authorizations are deemed filed upon submission of completed requirements including payment of required fees and charges.

    b. Evaluation
       The evaluation of all applications for LTO shall be based on the veracity of the submitted documents and compliance with appropriate standards. In case the applicant falsified, misrepresented material facts or documents, or

withheld any material data or information, the application shall be disapproved. In such cases, the applicant may be investigated, appropriate charges may be filed, and penalties may be imposed. Should there be a need for clarification on the application, a notification, either written or through e-mail shall be sent to the applicant.

c. Inspection
Pre-opening inspection shall be mandatory for manufacturers. All covered establishments may be inspected at any time by FDA as part of its post-marketing surveillance activities.

d. Variation/ Amendments
Applicable changes as enumerated on **Annex B** shall be applied with the FDA.

3. Fees

The prescribed fees shall follow:

Classification	Fees (Php) + LRF	
	Initial (2 years)	**Renewal (3 years)**
Veterinary Drug Manufacturer		
20 Million and below	20,000.00	30,000.00
Over 20 Million and below 50 Million	30,000.00	45,000.00
50 Million and above	40,000.00	60,000.00
Veterinary Drug Trader	10,000.00	15,000.00
20 Million and below	6,0000.00	9,000.00
Over 20 Million and below 50 Million	10,000.00	15,000.00
50 Million and above	14,000.00	21,000.00
Veterinary Drug Distributor (Importer, Exporter, Wholesaler)	10,000.00	15,000.00
Veterinary Drug Outlets	2,000.00	3,000.00
Major Variation	Initial Fee	
Minor Variation	500.00	
Minor Variation – Additional Activity (per additional activity; fees shall be applicable during initial application to include additional activity)	500.00	

4. Cancellation of License to Operate
Upon cancellation of license, the FDA shall retain jurisdiction over violations committed by the establishments while it was in operation. All establishment shall settle all their monetary obligations to the appropriate Office.

a. Automatic Cancellation
Existing establishment that fails to file an application for renewal after one-hundred twenty (120) days from the date of expiration shall be automatically cancelled and deleted from the list of licensed establishments without prejudice to their re-application.

b. Voluntary Cancellation
The owner or authorized person of a licensed establishment may apply for voluntary cancellation of its existing license by filing a formal notification.

c. Cancellation as Penalty
The issuing Office, or upon the recommendation of the FDA may impose the penalty of cancellation of license.

VI. FOREIGN CURRENT GOOD MANUFACTURING PRACTICE

The application process, fees and requirements shall follow Administrative Order No. 2013-0022: Guidelines for Current Good Manufacturing Practice (cGMP) Clearance and Inspection of Foreign Drug Manufacturers, its implementing rules and regulations, and amendments.

VII. PRODUCT REGISTRATION

A. General Guidelines

1. No veterinary drug product shall be allowed for manufacture, import, export, sell, offer for sale, distribute, transfer, promote, advertise, and/or sponsor any activity without a valid CPR.
2. No veterinary drug products shall apply for Certificate of Product Registration (CPR) without a valid LTO.
3. Action on registration application shall be based on the complete set of specifications of the drug product proposed to appear in the label, i.e. formulation, dosage form, strength, therapeutic indications and manufacturer. Any change the mentioned specification shall require new registration.
4. Action on registration application shall include the classification of veterinary drugs and products among each of the classification's categories defined. Any change in classification shall require new registration. However, any change in the name of the same manufacturer shall require application of post approval notification to FDA.
5. All veterinary drugs and products shall be evaluated and registered based on specific requirements and standards pertinent to the classification of such veterinary drugs and products.
6. All veterinary drug products with one (1) target species but with different body weights should be registered separately.
7. A violation with any of the terms and conditions of the CPR shall likewise result in the suspension, revocation or cancellation of the CPR or disapproval of the application for renewal, after due process.
8. The FDA shall regulate the registration (including variations) and PMS of the manufacturers, traders and or distributors, importers, exporters, wholesalers, establishments and outlets of the following veterinary drugs and products.

B. Specific Guidelines

1. Requirements
The requirements for registration shall follow as per **Annex C.**

2. Processing

   a. Filing
   An application for CPR, whether initial, renewal, monitored release, monitored release extension or variation, and other authorizations are deemed filed upon submission of completed requirements including payment of required fees and charges.

   A CPR applied for renewal after the expiry date but within 120 calendar days shall be considered filed under Regular Renewal Registration and is subject to a surcharge or penalty equivalent to twice the renewal fee and an additional 10% per month or a fraction thereof of continuing non-submission of such application up to a maximum of one hundred twenty (12) days. Any application for renewal of CPR filed thereafter shall be considered expired and the application shall be subject to a gee equivalent to the total surcharge or penalty plus the initial filing fee and the application shall undergo the initial filing and evaluation procedure.

   b. Evaluation
   The evaluation of all applications for CPR shall be based on the veracity of the submitted documents and compliance with appropriate standards. In case the applicant falsified, misrepresented material facts or documents, or withheld any material data or information, the application shall be disapproved. In such cases, the applicant may be investigated, appropriate charges may be filed, and penalties may be imposed. Should there be a need for clarification on the application, a notification, either written or through e-mail shall be sent to the applicant.

3. Post-Approval Changes (PAC)/ Variation
   Changes to the product shall be applied following the requirements and fees as per FDA Circular No. 2014-008: Application Process and Requirements for Post-Approval Changes of Pharmaceutical Products.

4. Fees
   The prescribed fees shall follow:

Application Type	**Fees (Php + LRF)**
Monitored Release (3 years validity)	
Registration	Php 20,000.00
Clinical Review	Php 5,000.00
Brand Name (if any, per proposed brand name)	Php 500.00
Monitored Release Extension (MRE) (2 years validity)	
Registration	Php 12,000.00
Initial (5 years validity) *Including MR to Initial*	
Branded	Php 15,000.00
Unbranded	Php 10,000.00

Brand Name (if any, per proposed brand name)	Php 500.00
Renewal (5 years validity)	
Branded	Php 10,000.00
Unbranded	Php 7,500.00
Post-Approval Changes	
Type of PAC	Fee per product per PAC
Regular PACs, including change of capsule color	P500 + LRF
With FDA Clinical review for additional indication With Subsequent Labelling Amendment (per product/ strength)	P2,500 + LRF + P500 + LRF
Change or addition of brand name	P2,500 + LRF + P510 (for each brand name proposed)
Shelf life extension/ reduction	P1,000 + LRF
Equivalent to Initial Registration, including Additional Route of Administration	
Unbranded	P10,000 + LRF
Branded	P15,000 + LRF
Monitored Release Status	P20,000 + LRF (for three years) + P20,000 + RF (for additional two years as per FDA Circular 2013-004)
Reclassification	P3,000 + LRF

5. Cancellation of CPR

   a. Automatic
   Existing establishment that has failed to file an application for renewal after one-hundred twenty (120) days from the date of expiration shall be automatically cancelled and deleted from the list of licensed establishments without prejudice to their re-application.

   b. Voluntary
   The owner or authorized person of a licensed establishment may apply for voluntary cancellation of its existing license by filing a formal notification.

   c. Cancellation as Penalty
   The issuing Office, or upon the recommendation of the FDA may impose the penalty of cancellation of license.

VIII. LABELING

A. General Guidelines

1. The following are the minimum mandatory information that shall appear in the labeling materials accompanying a veterinary drug product:
   a. Product Name
   b. Dosage Form and Strength

c. Pharmacologic Category
d. Formulation/ Composition
e. Indication(s)
f. Dosage and Mode of Administration (Target Species)
g. Contraindication(s), Precaution(s), Warning(s) (if applicable)
h. Withdrawal Period (Antimicrobials)
i. Interactions (if applicable)
j. Adverse Drug Reactions (if applicable)
k. Overdose and Treatment (if applicable)
l. Storage condition(s)
m. Net Content or Pack Size
n. Name of Address of Manufacturer, MAH and entities indicated on the CPR
o. Rx Symbol and Caution Statement (for prescription veterinary drug products)
p. Registration Number
q. Batch Number and/or Lot Number (if any)
r. Expiration Date and Date of Manufacture

2. All information required to appear on the label shall only be written in English and/or Filipino.
3. All information shall be readable with normal vision without straining. The color contrast, position and spacing of the printed matter on the label must be taken into consideration in complying with labeling requirements.
4. For all NCEs, biological products, and prescription generic products and herbal medicines, a PI shall be submitted; for all household remedies, over-the-counter drug and herbal medicines, and traditionally-used herbal products, a PIL shall be submitted. The SPC shall be the basis of the submitted PI for NCEs and biological products.
5. In lieu of PI or PIL, the foregoing information shall be printed directly on the reverse side or inner panel of the outer packaging material or inner carton; provided, that the product is intended to be sold or dispensed together with such packaging material or inner carton.
6. For products intended to be sold without any product information sheet and unit carton, the minimum mandatory information shall be required to be reflected on the primary label.
7. The revised labeling materials compliant with this Administrative Order shall be submitted upon renewal of the MA of a registered drug product. The labeling materials of products due for renewal registration within the first year of implementation of this Administrative Order shall be granted reasonable exhaustion period.

B. Specific Guidelines

1. Requirements for each Mandatory Information (see **Annex D**)
   a. Product Name
      i. The product name shall indicate the generic name and the brand name (if any) of the drug product.
      ii. The generic name shall be as the active moiety based on the International Non-proprietary Name (INN), and consistent with the dosage strength indicated; for prodrugs, the generic name shall be the INN of the prodrug itself and not its active chemical (metabolite) form.

iii. The generic name shall appear prominently with an outline box, with the generic name's prominence over the other information being clearly and distinctly readable by normal vision as may be determined by common visual sense.

iv. For herbal medicines and traditionally-used herbal products, the generic name shall be the botanical origin or as recognized by FDA.

v. If a product is identified by a brand name together with its generic name, the generic name enclosed in an outline box shall in all cases appear immediately above the brand name; for narrative texts (whether in the unit carton, primary label or insert), the brand name shall in all cases be preceded by the generic name and enclosed in parentheses or brackets.

vi. For products with multiple APIs, the product name shall indicate all of the APIs, enumerated in the order of decreasing pharmacologic activity and placed inside the box in either of the given format:
Ex.:

Iron + Cyanocobalamin (Vit. B_{12})

Brand Name

100 mg/ 30 mcg/ mL Solution for Injection (IM/IV)

"For Veterinary Use Only"

Cotrimoxazole

Brand Name

40 mg/8 mg per mL Suspension

"For Veterinary Use Only"

If the APIs have more or less similar pharmacologic activity, they shall be enumerated in the order of decreasing potency and strength; provided, that if there exists a single approved name for fixed-dose combination (e.g. Cotrimoxazole for the standard formulation Sulfamethoxazole / Trimethoprim), the single approved name shall be used; provided further, that if there is no single approved name but there exist a generic class name (e.g. Multivitamins for multi-vitamin containing preparations, as approved by FDA), the generic class name shall be used. The individual components of the single approved name and generic class name shall be enumerated under Formulation.

b. Dosage Form and Strength

i. The label shall specify the (i) dosage form of the product such as tablet, capsule, suspension, ointment, etc., (ii) the specific delivery system, if any, such as modified release, and (iii) specific mode of administration, if any, and appropriate, such as vaginal/rectal suppository, etc., as approved by FDA. If there is no qualifier for tablets, it is understood as an oral, uncoated, immediate release tablet.

ii. The label shall specify the dosage strength of the product which shall be expressed in metric units reduced to lowest terms and in the number of the largest unit specified (e.g. 500 mcg, not 0.5 mg).

iii. FDA, as deemed necessary and appropriate, shall allow the strength of certain dosage forms (e.g. semisolid, ophthalmic, otic, nasal, and topical preparations) to be expressed as percentage.

iv. For products with multiple APIs, the dosage strength shall be stated in accordance with the generic name indicated: for multiple APIs, the individual strengths shall be indicated, separated by a slash sign O; it a single approved name is used, the dosage strength shall be indicated as the sum.
Ex.:

Iron + Cyanocobalamin (Vit. B_{12})

Brand Name

100 mg/ 30 mcg/ mL Solution for Injection (IM/IV)

"For Veterinary Use Only"

c. Pharmacologic Category

The pharmacologic category shall be as determined by FDA, taking into consideration current acceptable standards for therapeutic categories.

d. Formulation/Composition

i. The label shall state the name and strength of all APIs present per unit dose of the product, which shall be arranged in decreasing pharmacologic activity, or if having more or less similar pharmacologic activity, in decreasing potency and strength.

ii. The generic name of the API shall be stated in full (including salts and esters, if any) and correlated to the active moiety, when applicable. The name of the API shall be in accordance with its INN; for herbal medicines and traditionally-used herbal products, the official Philippine Pharmacopoeia name shall be used, or as determined by FDA.

iii. The reference monograph recognized by FDA (e.g. USP, BP, BP (Vet), EP, JP, PP, Ph. Int) used for the analysis of the finished drug product shall be indicated immediately after the API, unless a non-official method is used; for multiple APIs, it shall be indicated after the first API.

Ex.:

Each tablet contains:
Iron …….100 mg
(equivalent to 150 mg Iron Dextran Complex)
Cyanocobalamin (Vit. B_{12})…….30 mcg

Each mL contains:
Trimethoprim…….48 mg
Sulfamethoxazole…….8 mg

iv. The coloring, antimicrobial, and antioxidant agents, and preservatives used in the manufacture of the product that may cause hypersensitivity and/or other adverse drug reactions shall also be indicated, with the amount expressed in the same manner as the API.

e. Indication(s)

The indication(s) stated in the labeling materials shall include only the FDA-approved clinical use(s) of the drug product.

f. Dosage and Mode of Administration
   i. The label shall contain full information on the product's recommended dosage, including the (i) initial or loading dose, (ii) optimal use or usual dose, (iii) frequency interval, (iv) duration of treatment, (v) dosage adjustment, and other pertinent aspects of drug therapy, if applicable.
   ii. Relevant information regarding dilution (e.g. the specific volume of diluent to be added), reconstitution, preparation, and administration shall also be included (such as "Shake well before use" for suspensions, "Do not crush" for tablets with special delivery system, etc.) in all labeling materials. The label shall include a description of the reconstituted preparation.
   iii. Target Species
   State the target species and sub-group when appropriate. The dosage should be expressed in mg per kg body weight classified relative to body sizes e.g. (small, medium, large).

g. Contraindication(s), Precaution(s), Warning(s)
   i. The label shall contain full information regarding the contraindication(s) of the drug product, as well as the precaution(s) to be observed in its administration and use.
   ii. The label shall include warning statements, as required and/or specified by FDA (e.g. "Flammable," "For external use only," "Keep out of reach of children"). Other specific additional instructions shall be issued by FDA in appropriate regulations.
   iii. Where the contents of a container are to be used on one occasion only, the label shall include the statement, "Single use only", "Single dose", "Use only once", "Discard any remaining portion", or any statement to that effect.

h. Interactions
   The label shall include drug-drug, drug-food, drug-laboratory testing interactions, as well as other relevant interactions, if applicable.

i. Withdrawal Period (Antimicrobials)
   The label shall include the withdrawal period for antimicrobial on target species. If necessary different withdrawal periods should be stated for **meat and offal, milk, eggs and honey**. Withdrawal periods should be indicated in days, except for milk withdrawal periods, which may be more appropriately expressed in hours. A zero withdrawal period should be expressed as **'Zero hours/days'**.

   For **fish meat**, the withdrawal period should be stated in degree days. The number of degree days is divided by the average water temperature, in °C, to give the withdrawal period in days.

j. Adverse Drug Reaction(s)

The label shall include detailed information on adverse drug reaction(s) for a drug product arranged by system organ class.

k. Overdose and Treatment
The label shall include signs and symptoms of overdose, as well as possible treatment.

l. Storage Condition(s)
i. The label shall indicate appropriate storage condition(s) and special instructions for handling of the drug product.
ii. Special labeling instructions shall be added for drug products with the following properties:

Properties	Special labeling instructions
Cannot tolerate refrigeration	"Do not refrigerate or freeze"
Cannot tolerate freezing	"Do not freeze"
Light-sensitive	"Protect from light"
Cannot tolerate excessive heat, e.g. suppositories	"Store and transport not above 30 °C"
Hygroscopic	"Store in dry conditions"

m. Pack Size or Net Content
i. The unit carton shall indicate the pack size of the drug product expressed in terms of the number of units in the pack or the volume of each unit, e.g. 60 mL (for liquids), 10 blister packs x 10 tablets (for tablets), 100 tablets, 12 sachets x 5 g, etc.; Provided, that in case of drug products for reconstitution for oral administration, the pack size shall reflect the volume of the product as reconstituted.
ii. For the primary label excluding blisters and foil strips, the net content of the product, stating the total amount/quantity/number of the dosage form in a given container shall be expressed in metric units, e.g. 60 mL (for liquids), 5 g (for sachets).

n. Name and Address of Marketing Authorization Holder
The label shall state the name and full address of the MAH of the drug product.

o. Name and Address of Manufacturer
The label shall state the name of the manufacturer and full address of the specific manufacturing site of the drug product as determined by FDA.

p. Rx Symbol and Caution Statement
i. The labeling materials of prescription drug products shall always include the Rx symbol, which shall be prominently displayed. The Rx symbol may be allowed to be over-printed or superimposed, provided, that such will not result in the obliteration by or being rendered less legible than other required labeling information.
ii. The caution statement, **"Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription."** shall always be included in the package insert, unit carton, primary label except blister pack, foil

strip, and small containers of prescription drug products. In addition, for products classified as Dangerous Drug as per Republic Act No. 9165, the caution statement shall be followed by an additional statement as specified by the Philippine Drug Enforcement Agency (PDEA).

q. ADR Reporting Statement
For the **product information sheet and the unit carton or primary label except blister pack, foil strip, and small containers of products intended to be sold without a unit carton**, the statement "**For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph**" shall appear. In addition, a statement instructing the patient to seek medical attention immediately at the first sign of any adverse drug reaction shall appear.
The MAH may also include a reporting statement for their own pharmacovigilance system.

r. Registration Number
The label shall indicate the registration number assigned by FDA to the product, which is denoted by a combination of letters and/or numbers.

s. Batch Number and Lot Number
The label shall indicate the product's batch number; provided, that if the entire batch is marketed by one drug establishment, only the batch number shall be indicated. However, if a batch is divided into lots marketed by different drug establishments, the lot number and corresponding batch number shall be indicated.

t. Expiration Date and Date of Manufacture
i. The label shall bear the month and year of the product's manufacturing and expiration date either in letters or words and numbers, or in numbers alone; if expressed in numbers alone, the year shall be stated completely in order to distinguish it from the month; and if the day is specified, the month shall be spelled out, as shown below:
- June 2021 or Jun 2021
- 06/2021
- 03 June 2007 or 03 Jun 2021

ii. Unless a certain day of the month is specified, the last day of the stated month shall be deemed as the date of the product's expiration/manufacturing date.

iii. For products reconstituted prior to use and those which can be administered multiple times (e.g. suspensions), the label shall include the period of guaranteed safety, efficacy, and quality of the reconstituted preparation/after first opening at a given storage condition(s).

2. Special Labeling Instructions
In addition to the minimum mandatory requirements mentioned, the following shall be required to appear on the label of specific product types:
a. Parenterals
For parenteral products, the following additional information shall be required:

i. A statement of the recommended mode of administration such as "IV", “IM” or “SC”, etc., as the case may be.
ii. Where the product consists of a concentrated solution for injection, a direction not to administer the solution undiluted and a direction to dilute the solution with the specified diluent to the appropriate volume before use shall be stated.

b. Fluid Replacement Products
i. For fluid replacement products which follow the standard formulations contained in the current edition of the official compendium, the nomenclature to be adopted as the generic class name shall be determined by FDA.
ii. For fluid replacement products not included in any official compendium, FDA shall determine the generic class name.
iii. Directly below the generic class name but still inside the generic outline box are the individual components (including excipients) with the corresponding mEq/l or mmol/L enumerated in the order of decreasing pharmacologic activity.
iv. Where one or more substances are amino acids and/or proteins, the total amount of nitrogen in the volume of fluid in the container shall be reflected.
v. The osmolality, such as "hypotonic" or "hypertonic"; and the pH value or range (where applicable) of the solution shall be indicated.

c. Products for External Use
For products that are intended for external use, the statement "For external use only" shall appear on all labeling materials, rendered in capital letters against a red background or printed in red font.

d. Biological Products
For biological products, the following additional information shall be reflected on the Formulation:
i. The name of the species of animal or organism from which the product has been prepared.
ii. The name of any adjuvant in the product or any substance which, when administered with an antigen, modifies the immune response to that antigen.

e. Multivitamin/ Mineral/ Herbal Products with Non-vitamin/ Mineral/ Herbal Components Multivitamins, consisting of at least three vitamins, and minerals, consisting of at least three mineral ingredients, shall have the following additional requirements:
i. The generic name adopted for multivitamin-containing products shall be "Multivitamins"; for multi-mineral-containing products the official name shall be "Minerals".
ii. For multivitamin and/or multi-mineral preparations containing at least three herbal ingredients, the generic class name of the herbal ingredients shall be "Herbs".
iii. For multivitamin products with non-vitamin components (i.e. mineral or herbal ingredient), or multi-mineral products with nonmineral

components (i.e. vitamin or herbal ingredient), or multiherbal products with non-herbal components (i.e. vitamin or mineral ingredient) the term "Multivitamins" or "Minerals" or "Herbs", respectively, shall first be stated, followed by the generic name of the specific additional individual components, as shown below:
Ex.:

Multivitamins + Iron
Multivitamins + Iron + *Panax ginseng L.*(American ginseng) rhizome
Multivitamins +Ascorbic Acid + *Panax ginseng L.*(American ginseng) rhizome

iv. The unit content of each vitamin, mineral, and/or herbal ingredient present shall no longer be required to be indicated in the generic box, but rather shall be reflected under Formulation.

3. Exemptions
The requisites provided in this Order shall not apply to the following cases:
   a. Drug products manufactured for export,
   b. If the container or primary pack containing the product is enclosed in a transparent covering and the particulars which are required to be set on the label on the container or primary pack are clearly visible through transparent covering, the transparent covering is exempted,
   c. Investigational products,
   d. Foreign donations of drug products
   e. Products that require special handling or with special packaging (e.g. products that require cold-chain management, pre-filled syringes);
   f. Low volume of importation (<12,000 units per year, wherein units is defined as the number of individual finished dosage form [such as tablets, capsules] or finished packed products [such as vials, sachets, and bottles of liquid preparations], where appropriate).

A Generic Labeling Exemption (GLE) application shall be concurrently submitted by applicant companies with their application for drug product registration, except for low volume of importation which shall be requested yearly. A letter stating the grounds for which the GLE is requested, as well as sample labels shall be included in the application.

For low volume of importation, in addition to the letter the following shall be submitted:

   a. A notarized market forecast copy of the summary of importation for the current year (Number of boxes and contents per box or forecast of sales for the period applied must be specified).
   b. Shipping documents must be submitted and consistent with the forecast of the summary of importation:
      i. Packing list
      ii. Shipping invoice
      iii. Airway Bill

If granted, FDA shall issue a GLE certificate with a corresponding validity and number. The following shall reflect on the sticker labeling: (1) Rx/OTC symbol, (2) Name and Address of the MAH and Importer/Distributor, (3) Registration Number, (4) Expiration date of the drug product, (5) Batch/lot number, (6) "For Veterinary Use Only" and (7) "For suspected adverse Drug Reaction, report to the FDA: www.fda.gov.ph". FDA is hereby authorized to require the MAH to make the appropriate labeling changes.

Manufactured by:
Company Name
Address

Registration No.
Expiration Date
Batch/Lot#

For/Imported and distributed by:
Company Name
Address

"For Veterinary Use Only"
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

4. Fees
   The prescribed fees shall follow:

Application Type	Fees (Php + LRF)
Generic Labeling Exemption	Php 500.00

IX. BATCH NOTIFICATION

Batch Notification shall be required to all veterinary drug products containing antibacterial and antifungal APIs. The application procedure, fees and requirements following FDA Circular No. 2017-011: New Batch Notification Form and Procedure, its implementing rules and regulations, and amendments.

X. ADVERTISEMENT AND SALES PROMOTION OF VETERINARY DRUGS

A. General Guidelines

1. No person shall advertise or promote veterinary drug and product unless such products are duly registered with the FDA.

2. The conduct of advertisement and sales promotion of veterinary drugs and products under FDA requires prior approval. Its application follows the e-application process of the FDA.

3. All therapeutic claims for veterinary drugs and product made in advertising or promotional materials must be based on adequate scientific, pharmacological,

technical and clinical evidence demonstrating their safety, efficacy and therapeutic indications approved by the FDA.

4. Veterinary drugs classified by the FDA as Prescription Drugs are not allowed to be advertised or promoted in any form of mass media. All advertising and promotional materials, whether print, visual or auditory, shall feature prominently the generic name of the veterinary drugs and products designated by FDA. In the case of branded products, the prominence of the generic name shall be insured in all print, visual or auditory materials but can feature the brand name.

5. The Marketing Authorization Holder shall be responsible and accountable for the content and form of their advertisement and promotion materials it shall establish suitable mechanism for internally reviewing such materials.

6. Stickering or tampering in the previously approved packaging materials shall not be allowed.

7. Request for exhaustion or extension beyond six (6) months shall not be granted.

8. Superlative & misleading claims are not allowed. Claims shall be within the FDA's approved indication or quality, safety & efficacy profile.

9. Labels used in collateral materials shall be in compliance with the existing guideline of the FDA and the applicable provisions following RA Nos. 6675 and 9502, and their implementing rules and regulations.

B. Specific Guidelines

1. Filing

   An application for advertisement and sales promo are deemed filed upon submission of completed requirements (refer to **Annex F & G**) including payment of required fees and charges.

2. Evaluation

   The evaluator checks the completeness and correctness of the requirements. The desired advertisements and promo title, duration (maximum of one year), coverage, and mechanics shall be compliant with existing laws and regulations.

   If application for amendment, the following are allowed within the existing promo scheme:
   a. Extension of duration up to 6 months, except for Price reduction/Discount Scheme
   b. Previously approved mechanics
   c. Coverage area (if the area is beyond the initially approved coverage, additional fee must be paid over and above the amendment fee)
   d. Collateral materials
   e. Additional Participating Products

3. Fees

The prescribed fees shall follow:

Application Type	Fees (Php + LRF)
Advertisement Certification	Php 2,500.00
Sales Promo Permit (SPP)	Php 500.00
SPP Amendment (per proposed amendment)	Php 500.00
SPP Extension of Validity	Php 500.00

C. **Monitoring and Enforcement**

1. Prior clearance from FDA is required for initial printing and broadcast and/or dissemination of advertisement and other promotional materials for veterinary drug products shall be submitted by the advertisers to obtain approval of the Ads Standard Council (ASC)
2. FDA shall monitor advertisement and promotion of veterinary products as well as received complaints. FDA shall determine if any advertising or promotional materials violates these guidelines.
3. Any advertising or promotional material found to be violative of this guideline shall be identified and the veterinary drug product and establishment responsible shall be notified. The FDA shall issue a cease and desist order stopping the further release, printing broadcast or dissemination of the violative advertising or promotional material.

4. Repeated or serious violations of these guidelines means inability of veterinary drug products establishments to ensure the proper use of its veterinary drugs and products. Under such condition, FDA may impose the following sanctions:

    a. Withdrawal of accreditation of the establishment's Veterinarian/qualified personnel.
    b. Suspension and or revocation of the License to Operate (LTO) the veterinary drug and product establishment.
    c. Cancellation of CPR

XI. POST-MARKET SURVEILLANCE

A. General Guidelines

1. All licensed establishments and registered veterinary drug products must continuously comply with the existing requirements, regulations and standards, and subject to post-market evaluation and surveillance.
2. Samples of registered veterinary drug products may be taken and tested for compliance with official or pharmacopoeia standards or specifications agreed by the manufacturer.

3. If sample fails to meet adequate specifications, the MAH will be issued a written warning. Unless the failure is serious enough to justify product recall, the product registration holder has up to fifteen working (15) days to identify the source/cause of quality defect and actions to be taken to improve quality.
4. The MAH should notify the authority of any product quality related problems (with registered products) that the holder is aware of.
5. It is also the responsibility of the veterinarians and/or authorized animal health practitioner to notify the authority of any product quality related problems.
6. All suspected adverse drug reaction related to the veterinary drug and product should be reported to the competent authorities as per FDA Circular (FC) 2013-003, 2013-004 & 2018-012.
7. Should quality problem(s) be found on veterinary drugs and products, regulatory actions will be implemented.
8. All licensed establishment shall immediately recall, withdraw, seize, or ban from public sale or distribution or donation any veterinary drug and product that is declared to be imminently injurious, unsafe or dangerous.
9. The MAH shall be primarily responsible for conducting recalls of defective or unsafe products. No recall should take place without first consulting/informing the FDA
10. The FDA shall have the authority to enter any veterinary establishments for PMS activities, to investigate within their respective regulatory jurisdictions.

B. Specific Guidelines

1. The FDA together with Field Regulatory Operation Office (FROO) and Regulatory Enforcement Unit (REU) shall impose appropriate regulatory actions which include warning letter, report of violation, advisories, and product recall.

XII. PHARMACOVIGILANCE

Guidelines for MAH on their pharmacovigilance for all registered veterinary drug products shall follow Administrative Order Administrative Order (AO) 2011-009 & FDA Circular (FC) 2020-003.

XIV. TRANSITORY PROVISION

All veterinary establishments and drug products shall be given one (1) year transition period to comply with this Administrative Order starting from the effectivity date of this order.

XIII. SANCTIONS AND PENALTIES

The FDA shall conduct the investigation and hearing involving cases of violation in the manufacture, importation, exportation, distribution, and sale of products and / or establishments under this Order.

The penalties imposable involving veterinary drugs and products in this Order shall be provided in Republic Act No. 9711, and its implementing rules and regulations.

XIV. SUPPLETORY CLAUSE

The provisions of all existing and applicable laws shall be deemed suppletory to this Order.

XV. SEPARABILITY CLAUSE

Should any part of this Order be declared unconstitutional, all other remaining portions not so declared shall remain valid and in effect.

XVI. EFFECTIVITY

This Order shall take effect immediately after publication in a national newspaper of general circulation and filing with the Office of the National Administrative Register.

XVII. REPEALING CLAUSE

All issuances pertaining to veterinary establishments, drugs and products applications that are inconsistent with this issuance are hereby withdrawn, repealed and revoked accordingly.

FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

Food and Drug Administration	Health Policy Development and Planning Bureau	Office of the Secretary
ROLANDO ENRIQUE D. DOMINGO, MD Director General	**FRANCES ROSE E. MAMARIL, MPH** OIC-Director IV	**ATTY. FATIMA P. LAPERAL** Health Executive Assistant

JESUSA JOYCE N. CIRUNAY, RPh Director IV, CDRR	**MARK RYANN A. LIRASAN, RPh** OIC – Chief, PRSDD - CDRR	**LANETTE LEE A. QUERUBIN, RPh, MSc** Chief, LRD, CDRR

Keywords	
Related Issuances, laws, directives from other government agencies	

ANNEX A

DEFINITION OF TERMS

1) Active Moiety – the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.

2) Active Pharmaceutical Ingredient (API) – a substance or mixture of substances intended to be used in the manufacture of a pharmaceutical product, that when used in the production of drug becomes an active ingredient in the drug product.

3) Advertisements – means any representations by means whatsoever for the purpose of promoting directly or indirectly the sale or disposal of any product.

4) Adverse Event (AE) – any untoward medical occurrence to an animal, or people administering or within vicinity of the site of administration to the pharmaceutical product. An AE can be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of the medicinal (investigational) product, whether or not considered related to the medicinal (investigational) product. A pre-existing condition, which, worsened in severity after administration of the product would also be considered as an adverse event.

5) Air Waybill – a transport document for airfreight, used by airlines and international freight forwarders, which specify the holder or consignee of the bill who has the right to claim delivery of the goods when they arrive at the port of destination. It is a contract of carriage that includes carrier conditions, such as limits of liability and claims procedures. In addition, it contains transport instructions to airlines and carriers, a description of the goods, and applicable transportation charges.

6) Antimicrobials – are medicines used to prevent and treat infections in humans, animals and plants.

7) Dosage Form – the pharmaceutical form of the preparation based on an official pharmacopeia.

8) Good Manufacturing Practice (GMP) - a part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

9) Good Distribution Practice (GDP) – part of quality assurance w/c ensures that the quality of pharmaceutical product is maintained through adequate control throughout numerous activities w/c occur during distribution process.

10) Good Storage Practice (GSP) – part of quality assurance w/c ensures that the quality of a pharmaceutical product is maintained through adequate control throughout the storage.

11) Inspection – the examination of veterinary drugs, facilities or establishments, and the management and production systems of veterinary drugs and products, including the examination of documents, finished product testing and registration, and of the origin and destination of production inputs and outputs to verify compliance with legal requirements by an agency mandated to perform veterinary drug safety regulatory and/or enforcement functions.

12) Licensing – the process of approval of an application to operate or establish an establishment prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution and transfer of veterinary products.

13) Marketing Authorization Holder (MAH) – the company or corporate or legal entity in the field of pharmaceuticals in whose name the MA for a drug product has been granted. This party is responsible for all aspects of the product, including quality and compliance with the conditions of the MA. The authorized holder must be subjected to legislation in the country that issued the MA, which normally means being physically located in that country. In the Philippines, the MAH may either be a manufacturer, trader or the distributor (exporter, importer or wholesaler).

14) New Chemical Entity (NCE) – new chemical or biological API not previously authorized for marketing for any pharmaceutical use in the country in question.

15) Package Insert (PI) – the document defining information that is supplied with prescription drug products by the MAH. The PI is intended for use by healthcare professionals.

16) Packing List – refers to a shipping document that contains the quantity and kinds of packages, their contents, the net and gross weight in kilograms, the full dimension and size of each package. It supplements the commercial invoice when numerous items are being shipped or when the quantity, weight or content of articles in a shipment vary.

17) Patient Information Leaflet (PIL) – the document defining information that is supplied with prescription drug products by the MAH. The PI is intended for use by healthcare professionals.

    Pharmacovigilance – means the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems.

18) Post-Market Surveillance – activities involved in safety, efficacy and quality monitoring of veterinary products. This shall also include among others adverse events reporting, product safety update reporting, collection and testing of veterinary products in the market.

19) Probiotics – live strains of strictly selected microorganisms which, when administered in adequate amounts, confer a health benefit on the host

20) Product Recall - method of withdrawing or correcting unsafe or hazardous products from the distribution chain that may present a health hazard to the consumer or user. It is an action taken by establishments involved in the supply chain (manufacturers, distributors, retailers) as 1). part of their responsibility to protect public health and well being; 2).

compliance to appropriate practices and 3). compliance to existing standards and regulations.

21) Registration – the process of approval for the manufacture, importation, exportation, sale, offer for sale, distribution, labelling, advertising or transfer of veterinary drugs and products obtaining active ingredient(s) of known chemical structures and properties determined to be safe, efficacious, and of good quality according to standards of FDA.

22) Sales Promotion – means techniques intended for broad consumer participation which contain promises of gain such as prizes, in cash or in kind, as reward for the purchase of product, security, service or winning in contest, game, tournament and other similar competitions which involve determination of winner/s and which utilize mass media or other widespread media of information. It also means techniques purely intended to increase the sales, patronage and/or goodwill of a product.

23) Summary of Product Characteristics (SPC) – the product information as approved by the DRA. It also serves as the source of information for health personnel as well as for consumer information on labels and leaflets of drug products, and for control of advertising. A Company Core Data Sheet (CCDS) approved by the DRA may also be considered.

24) Vaccines – A product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease.

25) Veterinary Drugs – articles used for diagnosis, cure, mitigation, treatment, prevention of diseases to animals. This shall also include those for modification of physiological functions or behaviors which includes but not limited to:

    a) Veterinary Biologics and Vaccines/ Veterinary Biological Products/ Veterinary Biotherapeutic Product are Veterinary Drugs which are products of biological origin, prepared with biological processes, derived from blood and plasma, or manufactured by biotechnology, consisting of substances of higher molecular weight whose purity, potency, and composition cannot be readily and reliably be determined by chemical or physicochemical analysis. This definition does not include antibiotics and substances that, although of biological in origin, are of low molecular weight and can be isolated as pure substance, such as purified steroids and alkaloids.

        (1) Biological products – are viruses, sera, toxins and analogous products used for the prevention or cure of animal diseases.

26) Veterinary Drug Outlet – any establishment which sells or offers to sell any veterinary product directly to the general public which includes but not limited to:

    a) Drugstore, Pharmacy and *Botica* and drug outlets where registered veterinary drugs and products, chemical products, active pharmaceutical, proprietary medicines or pharmaceutical specification are compounded and/or dispensed and hold executive veterinary hospitals, clinic and farm storage store where drugs and products are stored for their exclusive use.

    b) Veterinary Agricultural and Aquaculture Supply Store, livestock and poultry supply stores and any other outlets selling prescription veterinary drugs and products.

c) Retail Outlet for Non-prescription Veterinary Drugs (RONPVD) including the traditional outlets such as supermarkets and stores, including veterinary agriculture and aquaculture, means a drug outlet where registered non-prescription or over-the-counter (OTC) or self-service (SS) veterinary drugs and products are sold in their original packages, bottle or containers or in small quantities nor in their original containers.

d) Other veterinary drug and products establishment such as pet shops, pet grooming/salon shops, and pet hotels.

27) Veterinary Drug Order (VDO)/Prescription – is a written instruction (prescription) to pharmacist or of veterinary drug establishment to fill a veterinary prescription of large quantities of a specific veterinary drug and product provided that there is an accompanying VCPR letter from the prescribing veterinarian. VCPR is required when prescribing for ten (10) or more animal units.

28) Veterinary Establishment – means a sole proprietorship, a partnership, a corporation, an institution, an association, or an organization engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, use, testing, promotion, advertising, or sponsorship of veterinary products.Prebiotic - a non-digestible compound that, through its metabolization by microorganisms in the gut, modulates the composition and/or activity of the gut microbiota, thus, conferring a beneficial physiological effect on the host.

29) Veterinary Drug Distributor/Exporter – refers to any veterinary drug and product establishment that exports raw materials, active ingredients that exports raw materials, active ingredients and/or finished products to another country.

30) Veterinary Drug Distributor/Importer – refers to any veterinary drug and product establishment that imports raw materials, active ingredients and/or finished products, for its own use or for wholesale or distribution to other drug establishments or outlets.

31) Veterinary Drug Distributor/Wholesaler – refers to any veterinary drug products establishment that procures raw materials, active ingredients and/or finished products from local establishments for local distribution on wholesale basis.

32) Veterinary Drug Manufacturer – refers to any establishment engaged in operations involved in the production of a drug including propagation, processing, compounding, finishing, filling, repacking, labelling, advertising, storage, distribution or sale of the veterinary drug products proving that for the purpose of this regulation the compounding and filling of prescription by drugstores shall not be considered as production operations.

33) Veterinary Drug Premixes – mixture of one or more active ingredients, usually suitable bases, that are prepared to facilitate feeding the active ingredients to animals.

34) Veterinary Drug Trader – refers to any establishment which is a registered owner of the drug product, procures the raw materials and packaging components, and provides the production monographs, quality control standards and procedures, but subcontracts the manufacture of such veterinary drug and product to a licensed manufacturer. In addition, a

trader may also engage in distribution, and/or marketing of its veterinary drugs and products.

35) Veterinary Therapeutic Diet – any feed or feeding stuff containing a substance which is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or any function of the animal body.

ANNEX B
CHECKLIST OF REQUIREMENTS FOR LICENSING APPLICATIONS

I. Application Description

A. Application Form

Among other information, the applicant shall provide the following information:

1. Location Plan
2. Global Positioning System (GPS) coordinates
3. Name of the Qualified Person

B. Proof of Business Name Registration and Address

Any one of the following shall be submitted as proof of business name registration. Note that the submitted proof must be consistent with those indicated on the Application Form to be considered as an acceptable proof.

1. Mayor's Permit;
2. For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI);
3. For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation;
4. For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation; or
5. 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.
6. 6. When business or establishments address is different from the business name registration address, the applicant shall submit a copy of the business Permit (e.g. Mayor's Permit)

C. Proof of Income

Proof of income shall as latest audited Financial Statement with Balance Sheet (in pdf) shall be submitted. This is to verify the capitalization of the establishment to their corresponding application fees.

D. Qualified Person and Qualification Requirements

Type of Veterinary Drug Establishment	Qualified Person	Qualification Requirements
Manufacturer	Licensed Pharmacist (RA 10918)	• Professional Regulatory Commission (PRC) ID • Certificate of Attendance to seminars, training, learning and development activities on drug safety, quality, end
Trader	Licensed Pharmacist (RA 10918)	
Distributor (wholesaler, importer, exporter)	Licensed Pharmacist (RA 10918)	
Retailer	Licensed Doctor of Veterinary Medicine (RA 9268), or Licensed Pharmacist (RA 10918)	

		efficacy and other applicable trainings

II. Initial Application for LTO

1. Application Form
2. Proof of Business Name and Registration
3. Proof of Income
4. Qualified Person and Qualification Requirements
5. Payment

III. Renewal Application for LTO

A. For renewal of LTO previously issued under CDRR

1. Application Form
2. Payment

B. For renewal of LTO previously issued by BAI

1. Application Form
2. Proof of Income
3. Qualified Person and Qualification Requirements
4. Payment
5. Copy of LTO issued by BAI

IV. Major Variation for Local Manufacturers

Type of Variation	Requirements*
Transfer of Location of Manufacturing Plant - Physical transfer of the establishment (and may entail changes in the previously approved address)	• Business permit reflecting the new address • Updated Site Master File to be presented upon inspection • Copy of LTO issued by BAI • Payment
Expansion of Manufacturer and/or Additional Product Line; or Change of Manufacturing Activity - Expansion shall refer to the expansion made which is adjacent ot the existing location of the establishment - Additional product line refers to additional type or class of products produced within the same manufacturing site (e.g. sterile line, beverage line, etc.) - Change in manufacturing activity shall refer to an additional activity that a manufacturer engages in (e.g. LTO as Manufacturer with additional activity as repacker).	• Updated Site Master File to be presented upon inspection • Payment

* For current valid LTO issued by BAI, the copy of the LTO issued by BAI must also be submitted.

V. Minor Variation

Type of Variation	Requirements*
Transfer of Location of Offices - Physical transfer of the office of the establishment (which may also entail changes in the previously approved address	• Business permit reflecting the new location office • Payment
Transfer of Location of Retailers - Physical transfer of the retailer (which may also entail changes in the previously approved address)	• Business permit reflecting new address • Payment
Change of Distributor Activity - Shall refer to an addition/deletion of activity the distributor engages -	• Business permit reflecting new address • Payment
Transfer/ Addition of Warehouse - Physical transfer and addition of the warehouse of the establishment (which may also entail changes in the previously approved address)	• Business permit reflecting new address • Payment
Expansion of Office Establishments and Retailers - Shall refer to expansion made which is adjacent to the existing location of the establishment	• Expansion Floor Plan • Payment
Change of Ownership - Change in ownership of the licensed established	• 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; or Notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the transfer • Payment
Change of Business Name - Change only in the business name of the establishment	• Business permit reflecting new name • Payment
Zonal Change in Address - Change of the name/number of the street/building without physical transfer of the establishment	• Certificate of Zonal Change • Payment
Change/Addition of Qualified Person	• Name of new qualified person

- Change in the identified qualified person initially registered with the FDA	• Applicable requirements as specified in Qualification Requirements • Updated contact details • Payment
Change/Addition of Authorized Person - Change in the authorized person initially registered with the FDA	• Name of new authorized person • Updated contact details • Payment

* For current valid LTO issued by BAI, the copy of the LTO issued by BAI must also be submitted.

VI. Additional Retailer Activities

Additional Activity	Requirements*
Dispense Vaccines and Biologicals	• Standard Operating Procedure • Payment
Online Ordering and Delivery	• Standard Operating Procedure • Payment
Sterile Compounding and Non-Sterile Complex Compounding - Applicable only to establishments with Licensed Pharmacist as the Qualified Person	• Certificate of Training of Licensed Pharmacist • Standard Operating Procedure • Payment

* For current valid LTO issued by BAI, the copy of the LTO issued by BAI must also be submitted.

VII. Notification

The following activities must be notified with the FDA. No payment shall be made. The FDA shall only issue a receiving copy of the Notification Letter.

Activity	Requirements*
Resignation from previous FDA-licensed establishment - Proof that the applicant is no longer connected to other establishments	• Notification Letter • Resignation letter from previous company • Details of previous company: - Company Name - LTO Number, or - Copy of LTO
Change, Deletion, or Addition of Supplier - Additional supplier of API, finished product, and packaging and labeling materials	• Notification Letter • Company Name and Address of the supplier to be changed, added or deleted
Deletion of Qualified Person - Deletion in the identified qualified person registered with the FDA - This shall only be applicable to licensed establishments with two or more Qualified Person	• Notification Letter • Name of the qualified person to be delisted from the company
Deletion of Authorized Person	• Notification Letter

- Change in the authorized person initially registered with the FDA - This shall only be applicable to licensed establishments with two or more Authorized Person	• Name of the authorized person to be delisted from the company

* For current valid LTO issued by BAI, the copy of the LTO issued by BAI must also be submitted.

ANNEX C
CHECKLIST OF REQUIREMENTS FOR REGISTRATION APPLICATIONS

I. INITIAL APPLICATION, INCLUDING MR AND MRE

Part I. Administrative Data and Product Information

Sec. A. Table of Contents

Sec. B. Guidance on the Administrative Data

1. Accomplished Application Form and Declaration and Undertaking
2. Letter of Authorization (where applicable)
3. Certifications
4. Copy of valid agreement between manufacturer and trader/distributor, importer/exporter
5. Valid License to Operate (LTO)
6. Foreign Good Manufacturing Practice (GMP) Certificate
7. For imported products
    a. License of pharmaceutical industries/importer/wholesaler (country specific)
    b. Certificate of Pharmaceutical Product issued by the competent authority in the country of origin according to the current WHO format
    c. Certificate of Free Sale

Sec. C. Product Particulars

1. Product Name
2. Name and Strength of Active Substance and Excipient
3. Dosage Form
4. Product Description
5. Pharmacodynamics
6. Pharmacokinetics
7. Environmental Properties
8. Withdrawal Period
9. Maximum Residual Limit (MRL)

Sec. D. Supplementary Documentation

1. Labeling Material
2. Patient Information Leaflet (for Over-the-Counter [OTC] Drugs) and Package Insert (Prescription [Rx] Drugs)
3. For products in plastic container: Certificate of Analysis for Test of Migratable Substances/ Leachability
4. **For Dangerous Drugs:** Certificate of Clearance from the Dangerous Drug Board (DDB)

Part II. Quality

A. Unit Dose and Batch Formulation
B. Technical Specifications of all Raw Materials
C. Certificate of Analysis of active Raw Material(s)
    1. From supplier of API
    2. From manufacturer of finished product
D. Technical Specifications of Finished Product

1. Method and Assay Validation for Non-Official Formulation and Tests

E. Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)
F. Manufacturing Procedure, Production Equipment, Sampling, In-process controls, and Master Packaging Procedure (including specification for container closure system)
G. Assay and Other Test Procedures including Identity, Purity Tests, with Data Analysis, where applicable
H. Stability Studies

Part III. Safety and Efficacy Documentation

Sec. A. Table of Contents
Sec. B. Summary of Safety Documentation
Sec. C. Safety Documentation

1. Pharmacodynamics
2. Pharmacokinetics
    a. Absorption
    b. Distribution
    c. Metabolism (inter-species comparison)
    d. Excretion
    e. Other Pharmacokinetics Studies
3. Toxicology
    a. Single Dose Toxicity
    b. Repeat Dose Toxicity
    c. Tolerance in the target species of animal –Target animal safety
    d. Reproductive Toxicity
    e. Studies of the effects on reproduction
    f. Embryotoxicity/fetotoxicity, including Teratogenicity, Mutagenicity, Carcinogenicity (if necessary)
4. Studies of other effects
    a. Special studies (e.g. neurotoxicity, sensitization etc.)
    b. Microbiological studies
    c. Studies on metabolites, impurities, other substances & formulation
5. User Safety
    a. Inherent toxicity or other harmful effects
    b. Route and degree of exposure
    c. Risk management proposal
6. Environmental Risk Assessment (Environmental Safety)
    a. Extent of exposure of the product to the environment
    b. Specific investigations of the following, as appropriate - fate and degradation in soil, fate and behavior in water and air, effects on aquatic organisms, effects on other non-target organisms
    c. Key Literature
7. Residue Documentation
    a. Formulation used in residue studies
    b. Residue Studies
        i. Pharmacokinetics
        ii. Depletion of residues
        iii. MRLs

iv. Withdrawal periods

c. Analytical Method(s)

i. Description of the method
ii. Validation of the method
iii. Specificity
iv. Accuracy, including sensitivity
v. Precision
vi. Limit of detection
vii. Limit of quantitation
viii. Practicability and applicability under normal laboratory conditions
ix. Susceptibility to interference
x. Storage stability

Sec. D. Efficacy Documentation

1. Target Species Tolerance
2. Resistance
3. Summary of the results and critical evaluations of dose determination and dose confirmation studies and clinical trials
4. Tabular presentation of all clinical trials and studies
5. Individual Summary of the most important and significant studies
6. Summary of Clinical Safety

NOTE:

A. Data to be submitted will be based on each application type as follows:
   1. For Prescription (Rx), OTC veterinary drugs and non-medicated vet products: Parts I and II only
   2. For MR (investigational, new and fixed dose combinations drugs): Parts I - III
   3. For MR or MRE to Initial application
      a. Parts I - III
      b. Risk Management Plan (RMP)
      c. Periodic Safety Update Report (PSUR)

B. Representative samples for all pack sizes and corresponding Certificate of Analysis (CoA) shall be submitted in addition to the documentary requirements outlined above.

C. Standards adapted from BC No. 5 S 1997 (Revised Checklist of Requirements and the 1997 Guidelines for the Registration of Pharmaceutical Products) and International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) and European Medicines Agency (EMA) Guidelines.

II. **RENEWAL APPLICATION**

A. Accomplished Application Form and Declaration and Undertaking
B. Payment
C. Valid LTO
D. Valid GMP (where applicable)
E. Copy of the previous CPR and Certificate of Post-Approval Change approved
F. Labeling Materials (Facsimile labels)
G. Representative samples of all approved pack sizes and corresponding CoA

III. INITIAL APPLICATION, INCLUDING MR AND MRE OF VETERINARY BIOLOGICAL PRODUCTS

Part I. Administrative Data and Product Information

Sec. A. Table of Contents

Sec. B. Guidance on the Administrative Data

1. Accomplished Application Form and Declaration and Undertaking
2. Letter of Authorization (where applicable)
3. Certifications
4. Copy of valid agreement between manufacturer and trader/distributor, importer/exporter
5. License to Operate (LTO)
6. Foreign Good Manufacturing Practice (GMP) Certificate
7. For imported products
    d. License of pharmaceutical industries/importer/wholesaler (country specific)
    e. Certificate of Pharmaceutical Product issued by the competent authority in the country of origin according to the current WHO format
    f. Certificate of Free Sale

Sec. C. Product Particulars

1. Generic or International Non-propriety Name (INN)
2. Brand name or trade name
3. Name and Strength of Active Substance and Excipient
4. Dosage Form
5. Product Description
6. Pharmacodynamics
7. Pharmacokinetics
8. Environmental Properties
9. Reconstruction
10. Dose and Dosage Regimen
11. Withdrawal Period
12. Maximum Residual Limit (MRL)

Sec. D. Supplementary Documentation

1. Labeling Material
2. Patient Information Leaflet (for Over-the-Counter [OTC] Drugs) and Package Insert (Prescription [Rx] Drugs)
3. For products in plastic container: Certificate of Analysis for Test of Migratable Substances/ Leachability

Part II. Quality

A. Table of Contents
B. Quality Overall Summary
C. Unit Dose and Batch Formulation
D. Technical Specifications of all Raw Materials
    1. Data on molecular and biological properties of raw materials
    2. Method of manufacture in flow chart along with

i. Description of source, specifications and test methods of all antigens and/or components
ii. Growth and harvesting
iii. Manufacture of synthetic raw materials
iv. Analytical procedures
v. Validation of analytical methods
vi. In process control specifications and tests at each stage of manufacturing of active raw materials
vii. Container closure system
viii. Stability

E. Certificate of Analysis of active Raw Material(s)
   1. From supplier of API
   2. From manufacturer of finished product
F. Technical Specifications of Finished Product
   1. Method and Assay Validation for Non-Official Formulation and Tests
G. Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)
H. Manufacturing Procedure, Production Equipment, Sampling, In-process controls, and Master Packaging Procedure (including specification for container closure system)
I. Assay and Other Test Procedures including Identity, Purity Tests, with Data Analysis, where applicable
J. Stability Studies

Part III. Safety and Efficacy Documentation

Sec. A. Table of Contents
Sec. B. Summary of Safety Documentation
Sec. C. Safety Documentation
   1. Pharmacodynamics
      a. Summary
      b. Primary Pharmacodynamics
      c. Secondary Pharmacodynamics
      d. Safety
   2. Pharmacokinetics
      a. Absorption
      b. Distribution
      c. Metabolism (inter-species comparison)
      d. Excretion
      e. Other Pharmacokinetics Studies
   3. Toxicology
      a. Single Dose Toxicity
      b. Repeat Dose Toxicity
      c. Tolerance in the target species of animal –Target animal safety
      d. Reproductive Toxicity
      e. Studies of the effects on reproduction
      f. Embryotoxicity/fetotoxicity, including Teratogenicity, Mutagenicity, Carcinogenicity (if necessary)
   4. Studies of other effects
      a. Special studies (e.g. neurotoxicity, sensitization etc.)
      b. Microbiological studies

c. Studies on metabolites, impurities, other substances & formulation

5. User Safety
   a. Inherent toxicity or other harmful effects
   b. Route and degree of exposure
   c. Risk management proposal
6. Environmental Risk Assessment (Environmental Safety)
   a. Extent of exposure of the product to the environment
   b. Specific investigations of the following, as appropriate - fate and degradation in soil, fate and behavior in water and air, effects on aquatic organisms, effects on other non-target organisms
   c. Trade
   d. Key Literature
7. Residue Documentation
   a. Formulation used in residue studies
   b. Residue Studies
      i. Pharmacokinetics
      ii. Depletion of residues
      iii. MRLs
      iv. Withdrawal periods
   c. Analytical Method(s)
      i. Description of the method
      ii. Validation of the method
      iii. Specificity
      iv. Accuracy, including sensitivity
      v. Precision
      vi. Limit of detection
      vii. Limit of quantitation
      viii. Practicability and applicability under normal laboratory conditions
      ix. Susceptibility to interference
      x. Storage stability

Sec. D. Efficacy Documentation

1. Table of Contents
2. Developmental Studies/Field trials/Other Studies
   a. Summary
   b. Product Development Rationale
   c. Laboratory Trials
      i. Experiment Protocol
      ii. Efficacy Trials
      iii. Target Species Tolerance
      iv. Safety Studies
   d. Clinical/Field Trials
      i. Experiment Protocol
      ii. Parameters
      iii. Control and Trial design
      iv. Efficacy Trials
      v. Safety Studies
   e. Immune Response and Post Vaccination Reactions
      i. Mode of action
      ii. Immunogenic interactions

iii. Toxicity, allergy, post vaccination reaction and adverse reaction.
iv. Immunization result and duration of immunity
v. Key Literature References

1. Target Species Tolerance
2. Resistance
3. Summary of the results and critical evaluations of dose determination and dose confirmation studies and clinical trials
4. Tabular presentation of all clinical trials and studies
5. Individual Summary of the most important and significant studies
6. Summary of Clinical Safety

Additional Requirements

A. List of Countries where the product is already licensed and the date of approval
B. Names of the medical director/veterinarian of the importer/distributor and local manufacturer who will monitor event/s reactions and prepare appropriate report to be submitted to FDA
C. Person/s responsible for production and control of the product (Name/s Position, Department, and sample of signature)
D. Information on the number system of the lots or batches
E. System for the re-processing of the product in event of rejection of the lot or batch by the manufacturer's QA/QC
F. Lot to Lot Consistency from three (3) consecutive batches
G. Description of the cold-chain procedures employed from the origin to the port of entry and in the Philippines (how and where)
H. MR/E to Initial
   1. Risk Management Plan (RMP)
   2. Periodic Safety Update Report (PSUR)

IV. RENEWAL APPLICATION

A. Accomplished Application Form and Declaration and Undertaking
B. Payment
C. Periodic Safety Update Report (PSUR) and Risk Management Plan (RMP)
D. Certification that there were no changes during the 5-year period. If there were any, the summary changes made by the manufacturer for the 5-year period shall be incorporated
E. Valid LTO
F. Valid GMP (where applicable)
G. Copy of the previous CPR and Certificate of Post-Approval Change approved
H. Labeling Materials (Facsimile labels)
I. Representative samples of all approved pack sizes and corresponding CoA

ANNEX D

MANDATORY INFORMATION FOR SPECIFIC LABELING MATERIALS

The provisions of Section VI equivalent to the mandatory information shall apply, unless otherwise specified.

A. *Unit Carton*

The unit carton shall contain the following minimum information:

1) Product Name
2) Dosage Form and Strength
3) Pharmacologic Category
4) Formulation/ Composition
5) Indication(s)
6) Dosage and Mode of Administration
7) Contraindication(s), Precaution(s), Warning(s) (if applicable)
8) Withdrawal Period (Antimicrobials)
9) Interactions (if applicable)
10) Adverse Drug Reactions (if applicable)
11) Overdose and Treatment (if applicable)
12) Storage condition(s)
13) Net Content or Pack Size
14) Name of Address of Manufacturer, MAH and entities indicated on the CPR
15) Rx Symbol and Caution Statement (for prescription veterinary drug products)
16) Registration Number
17) Batch Number and/or Lot Number (if any)
18) Expiration Date and Date of Manufacture
19) "For Veterinary Use only"

B. *Primary Label excluding blister pack, foil strip and small containers*

The primary label shall contain the following minimum information:

1) Product Name
2) Dosage Form and Strength
3) Pharmacologic Category
4) Formulation/Composition
5) Indication(s)
6) Warning(s) (if applicable)
7) Storage condition(s)
8) Net Content
9) Name and Address of Marketing Authorization Holder
10) Name and Address of Manufacturer
11) For prescription drug products, the Rx Symbol and Caution Statement
12) ADR Reporting Statement (if without accompanying unit carton)
13) Registration Number
14) Batch Number and Lot Number (if any)
15) Expiration Date and Date of Manufacture

C. *Blister Packs/Foil Strips*

The standard blister pack/foil strip packaging of a drug product shall contain the following minimum information:

1) Product name **on each unit for single API, or every two (2) units for multiple APIs**
2) Dosage form and strength of API **on each unit for single API, or every two (2) units for multiple APIs**
3) Name and/or logo of the Marketing Authorization Holder **on each unit for single API, or every two (2) units for multiple APIs** (for unbranded products only)
4) Rx symbol **on each unit for single API, or every two (2) units for multiple APIs**
5) Batch number and expiration date on every standard blister pack/foil strip, provided that, when the pharmaceutical product is not restricted to be dispensed in quantities less than the standard blister pack or foil strip, the batch or lot number and expiration date shall be indicated on each unit

D. *Primary label of small containers*

The primary label of small containers shall contain the following minimum information:

1) Product name
2) Dosage Form and Strength
3) Net Content
4) Name and/or Logo of Marketing Authorization Holder
5) Rx Symbol (if applicable)
6) Registration Number
7) Storage Condition(s)
8) Batch and/or Lot Number (if any)
9) Expiration Date and Date of Manufacture

Due consideration may be given in view of limited space on the label.

E. *Package Insert*

The package insert shall contain the following minimum information:

1) Product Name
2) Dosage Form and Strength
3) Pharmacologic Category
4) Product Description
5) Formulation/Composition
6) Pharmacodynamics/Pharmacokinetics/Environmental Properties
7) Indication(s)
8) Dosage and Mode/Route of Administration
9) Contraindication(s), Precaution(s), Warning(s) (if applicable)
10) Statement of usage during pregnancy and lactation (if applicable)
11) Interactions
12) Adverse Drug Reaction(s)
13) Overdose and Treatment
14) Storage Condition(s)
15) Dosage Forms and Packaging Available (pack size)
16) Instructions and Special Precautions for Handling and Disposal (if applicable)

17) Name and Address of Marketing Authorization Holder
18) Name and Address of Manufacturer
19) Caution Statement
20) ADR Reporting Statement
21) Registration Number
22) Date of First Authorization/Renewal of the Authorization
23) Date of Revision of Package Insert

Products with varying strengths may opt to use a common insert, provided that individual product description, packaging, formulation, or other differing information between the strengths are included.

F. *Patient Information Leaflet*

PIL shall be prepared and written in layman's terms, and shall contain the following minimum information:

1) Name of the Product
2) Description of the Product
3) What is in the Medicine?
4) Strength of the Medicine
5) What is this Medicine used for?
6) How much and how often should you give this Medicine to animal?
7) When should you not take this Medicine?
8) When should you not give this Medicine to animal?
9) Undesirable Effects/side effects of this Medicine
10) What other medicine or food should be avoided while giving this Medicine to animal?
11) What should you do if you miss a dose for the animal?
12) Signs and Symptoms of Overdose
13) How should you keep this Medicine?
14) When should you consult a Veterinarian?
15) Name and Address of Marketing Authorization Holder
16) Name and Address of Manufacturer
17) ADR Reporting Statement
18) Registration Number
19) Date of First Authorization/Renewal of the Authorization
20) Date of Revision of Patient Information Leaflet

ANNEX E

CHECKLIST OF REQUIREMENTS FOR ADVERTISEMENT CERTIFICATION

I. ADVERTISEMENT REVIEW

A. Application Form
B. Copy of the previous CPR and Certificate of Post-Approval Change approved
C. Labeling Materials (Facsimile labels)
D. For advertisements using reading materials (e.g. pamphlets, tarpaulins): clear copy of the Advertisement Material in pdf
E. For advertisements using auditory materials (e.g. TV, radio, movie commercials): script and clear audible advertisement material in common video audio file format i.e. MP4, AVI.

CHECKLIST OF REQUIREMENTS FOR SALE PROMO PERMIT APPLICATIONS

I. SALES PROMO PERMIT (SPP)

A. Application Form
B. Letter of Intent
C. Fully Accomplished Information Sheet and Mechanics of Sales Promotion Form
D. List of duly and validly registered participating products following the given format in Excel file (Sheet 3 of Information Sheet).
E. E-Copies of CPRs / CPNs / Certificate of Exemption (COE)
F. Layout/Design of Media/Collaterals/Promotional Materials to be utilized compliant to the labelling requirements.

II. SPP AMENDMENT

A. Accomplished Application Form and Declaration and Undertaking
B. Letter of Intent indicating the specific amendment (If applicable, attached the required documents for amendment such as collateral materials, copies of CPR and/or certificate of variation, mechanics, etc.)

III. SPP EXTENSION

A. Accomplished Application Form and Declaration and Undertaking
B. Letter of Intent indicating the currently approved and proposed validity

ANNEX F

CHECKLIST OF REQUIREMENTS FOR SALE PROMO PERMIT APPLICATIONS

IV. SALES PROMO PERMIT (SPP)

G. Application Form
H. Letter of Intent
I. Fully Accomplished Information Sheet and Mechanics of Sales Promotion Form
J. List of duly and validly registered participating products following the given format in Excel file (Sheet 3 of Information Sheet).
K. E-Copies of CPRs / CPNs / Certificate of Exemption (COE)
L. Layout/Design of Media/Collaterals/Promotional Materials to be utilized compliant to the labelling requirements.

V. SPP AMENDMENT

C. Accomplished Application Form and Declaration and Undertaking
D. Letter of Intent indicating the specific amendment (If applicable, attached the required documents for amendment such as collateral materials, copies of CPR and/or certificate of variation, mechanics, etc.)

VI. SPP EXTENSION

C. Accomplished Application Form and Declaration and Undertaking
D. Letter of Intent indicating the currently approved and proposed validity