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DEPARTMENT OF AGRICULTURE

Administrative Order No. 33

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DEPARTMENT OF HEALTH

Administrative Order No. 111-A

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SUBJECT **RULES AND REGULATIONS ON REGISTRATION OF VETERINARY DRUGS AND PRODUCTS**

Pursuant to R.A. No. 3720, as amended by Executive Order No. 175 otherwise known as the "Foods, Drugs and Devices, and Cosmetics, R.A. No. 6675, otherwise known as the "Generics Act of 1988" R.A. 1556, biologics and medicinal preparations and R.A. 3101, an Act authorizing the Director of the Bureau of Animal Industry, subject to the approval of the Secretary of Agriculture and Natural Resources to promulgate regulations for the preparation, sale, traffic in, shipment and importation of viruses, sera, toxins, or analogous products used for the treatment of domestic animals, the following requirements for the registration of veterinary drugs and products are hereby promulgated for the information, guidance and compliance of all concerned:

Section 1. **DEFINITION OF TERMS:**

For purposes of these Rules and Regulations, the following definitions are adopted:

1.1 "Registration" refers to the process of approval for the manufacture, importation, exportation, sale, offer for sale, distribution, labeling, advertising or transfer of veterinary drugs and products obtaining active ingredients(s) known chemical structures and properties determined to be safe, efficacious, and of good quality according to standards of Bureau of Food and Drugs (BFAD)/Bureau of Animal Industry (BAI).

1.2 "Veterinary Drugs and Products" refer to any substance, including biological products, applied or administered to food producing, companion, aquatic, laboratory and exotic animals, whether used for therapeutic, prophylactic or diagnostic purposes or for modification of physiological functions or behaviors.

1.3 "Veterinary Drug for General Use" refers to a veterinary drug approved for sale for animal use without restriction other than the usual.

1.4 "Veterinary Drug for Restricted Use" refers to a veterinary drug approved for sale for animal use under certain conditions.

Section 2. **GENERAL STANDARDS**

2.1 Establishments applying to register a veterinary drug and product are required to fully disclose all pertinent documentation and information regarding the veterinary drug and product. Failure to fully disclose material information about the veterinary drug and product is a ground for disapproval of registration application and one of the bases for withdrawal of the establishment's license to operate.

2.2 Action on registration application shall be based on the complete set of specification of the veterinary drug and product proposed to appear on the label, i.e. formulation, dosage form, strength, therapeutic indications and manufacturer. Any change in any of the above specification shall require a new registration.

2.3 Action on registration application shall include the classification of the veterinary drugs and products among each of the classification categories defined in Section 3 below. Any change in classification shall require a new registration. However, any change in the name of the same manufacturer shall require proper notification of BFAD/BAI.

2.4 The standards of veterinary drug and product registration as well as the methods of evaluation are subject to revisions. Any major change shall be made after proper consultation with the parties concerned. Revised standards and evaluation methods shall be made applicable to all covered veterinary drugs and products as appropriate.

2.5 Only establishments with valid license to operate required under joint Administrative Orders No. 100, Department of Agriculture and No. 138, Department of Health, series 1990 can apply to register veterinary drug and products.

Section 3. **CLASSIFICATION**

All veterinary drugs and products shall be evaluated and registered on the basis of specific requirements and standards pertinent to the classification of such veterinary drugs and products. All registered veterinary drugs and products shall be classified in terms of each of the following categories.

3.1 Number of Active Ingredients

3.1.1 Single Active Ingredients

3.1.2 Fixed-dose combination of two or more active ingredients

3.2 Available scientific and product's evidence and experience on the veterinary drug use.

3.2.1 “Investigational Veterinary Drugs and Products” refer to any new chemical or structural modification of Tried and Tested or Established Veterinary Drug and Product proposed to be used for a specific therapeutic indication. Investigational veterinary drug and product need further clinical pharmacology studies (Phase I, II, or III) to determine their safety and efficacy, and meet the requirements of new veterinary drugs and products.

3.2.2 “New Veterinary Drug and Product” refer to any new chemical or structural modification of Tried and Tested or Established Veterinary Drugs and Products proposed to be used for a specific therapeutic indication, which have undergone adequate clinical pharmacology Phase I, II, and III studies but which need further Phase IV Clinical Pharmacology studies before they can be given regular registration.

3.2.3 “Tried and Tested Veterinary Drugs and Products” refers to any veterinary drug and product which have been used for at least five (5) years.

3.2.4 “Established Veterinary Drug and Product” refers to veterinary drug and product the safety and efficacy of which have been demonstrated through long years of general use and can be found in current official USP-NF, and other internationally-recognized pharmacopeias.

3.2.5 “Pharmaceutical or Therapeutic Innovation of Tried and Tested or Established Veterinary Drug and Product” includes any or all the following:

3.2.5.1 An innovation involving use for new indication(s)

3.2.5.2 An innovation involving a new mode of administration

3.2.5.3 An innovation involving a new dosage form

3.2.5.4 An innovation involving a new fixed dose combination of two or more ingredients.

3.3 Pharmacologic/therapeutic category as specified in the Philippine National Veterinary Drug Formulary (See joint A.O. DOH-No. 100 and DA-No. 138 s. 1990)

3.4 Source or circumstance of veterinary drug and product production

3.4.1 Imported as finished

3.4.2 Locally-manufactured from imported materials

3.4.3 Locally-manufactured from local materials

3.5 Brand identification and patent protection of the veterinary drug and product

3.5.1 Brand and patented

3.5.2 Branded and off-patent

3.5.3 Unbranded and off-patent (generic veterinary drug and product)

3.6 Prescribing and dispensing regulations applicable

3.6.1 Over-the-counter (OTC) Veterinary Drugs and Products or Non-prescription Veterinary Drugs and Products or

Self Service (SS) Veterinary Drugs and Products.

3.6.2 Ethical or Prescription Veterinary Drugs and Products

3.6.3 Dangerous Drugs (Annex A – List A)

3.6.4 Veterinary Drugs requiring strict precaution in prescribing and dispensing (Annex B – List B)

Section 4. INITIAL PRODUCT REGISTRATION

4.1 Application

Any establishment applying for the initial registration of veterinary drug and product shall file an application under oath. The application shall be in a form promulgated by BFAD/BAI and supported by the documents and requirements listed in Annex C.

4.2 Evaluation by Review of Submitted Data

BFAD/BAI evaluates the submitted data. First, it determines if the data presented are complete. If not complete, applicant is requested to submit additional data or undertake needed animal or clinical studies. Second, it determines if on the

basis of data submitted, veterinary drug and product meet current BFAD/BAI standards for quality, purity, safety, efficacy, potency or therapeutic value.

4.3 Evaluation by Testing of Submitted Samples

BFAD/BAI evaluates submitted samples of veterinary drug and product. The evaluation shall cover physical, chemical and biological tests for quality, purity, safety, potency or efficacy.

4.4 Assessment of Findings

At any point during the evaluation, BFAD/BAI may conclude that the veterinary drug and product do not meet the standards of quality, safety, potency, purity, efficacy and therapeutic value. In such case, the application shall be denied. At the end of the evaluation, BFAD/BAI shall arrive at a recommendation regarding action on the registration application.

4.5 Action on Registration Application

BFAD/BAI action on the registration application consists of the following possible courses:

4.5.1 Disapproval of application for failure to meet standards of quality, safety, potency, efficacy, purity or therapeutic value.

4.5.2 Disapproval of application for lack of qualification required from veterinary drug and product establishment.

4.5.3 Approval for investigational use over a period of variable duration depending on the BFAD/BAI accepted protocol.

4.5.4 Approval for post-marketing surveillance for a period of 3 years subject to annual evaluation.

4.5.5 Approval for general use for a period of five (5) years subject to annual evaluation.

4.5.6 Approval for restricted use for a period of five (5) years subject to annual evaluation.

4.6 Grounds for Disapproval

The two (2) types of disapproval action (4.5.1 and 4.5.2) shall be taken on the following grounds.

4.6.1 Review of submitted data or testing of submitted samples indicate that the product does not meet current BFAD/BAI and or manufacturer's guaranteed standards of identity, purity, strength, quality, safety, potency, efficacy or therapeutic value.

4.6.2 The labelling material of the veterinary drug and product is false and misleading or does not conform with current labelling requirements.

4.6.3 Applicant materially misrepresented or withheld significant data or information regarding the veterinary drug and product.

4.6.4 Applicant failed to comply with the requirements for registration.

4.7 Grounds for Limited Approval

The two (2) types of limited approval actions (4.5.3 and 4.5.4) shall be taken on the following grounds:

4.7.1 An investigational Veterinary Drug and Product Application shall be approved when the following are met.

4.7.1.1 The results of prior laboratory animal studies are found adequate to warrant further clinical pharmacology studies (phase I, II and/or III)

4.7.1.2 The protocol submitted for the clinical pharmacology studies is found to be adequate and scientifically sound in experimental design.

4.7.1.3 The clinical investigator who shall undertake the study is competent and reliable and the facilities and control used for the study are adequate.

4.7.2 A New Veterinary Drug and Product Application shall be approved for post-marketing surveillance when the following are met.

4.7.2.1 The results of prior laboratory animal studies are found adequate and the clinical pharmacology Phase I, II and III show that the New Veterinary Drug and Product are safe and efficacious when used for their therapeutic indication.

4.8 Grounds for Approval

The two (2) types of approval actions (4.5.5 and 4.5.6) shall be taken on the following grounds.

4.8.1 Review of submitted data and testing of submitted samples indicate that the application is supported by substantial evidence showing the veterinary drug and product to be safe, efficacious and good quality.

4.8.2 Applicant demonstrated that the methods used in as well as the facilities and controls used for, manufacture of the veterinary drug and product are adequate to assure their identity, strength, quality, purity, safety, potency, efficacy and therapeutic value.

4.8.3 The label of the veterinary drug and product is a correct representation of such veterinary drug and product and conforms with current labeling requirements.

Section 5. **RENEWAL OF REGISTRATION**

5.1 Only veterinary drugs and products registered for general and restricted use are eligible for renewal of registration.

5.2 Application for renewal of registration shall be made on a form promulgated by BFAD/BAI.

5.3 Renewal application shall be reviewed and evaluated on the basis of the veterinary drug and product and the applicant meeting the current BFAD/BAI and manufacturers guaranteed standards of identity, purity, strength, quality, safety, potency, efficacy and therapeutic value.

Section 6. **SCHEDULE OF FEES**

Upon application for registration of a veterinary drug and product, the following non-refundable fees to be paid in full for the entire selected period of registration, shall be charged:

6.1 Initial Registration

6.1.1 Investigational – P 1,000 per year or any fraction thereof
veterinary drug and
product application

6.1.2 New veterinary – P 6,000 for 3 years + cost of laboratory analysis
drug and product
application for mar-
keting-surveilance

6.1.3 New veterinary – P 4,000 for 2 years or P10,000 for 5 years + cost of laboratory analysis
drug and product
application for gene-
ral or restricted use

6.1.4 New pharmaceu - P 4,000 for 2 years or P10,000 for 5 years + cost of laboratory analysis
tical or therapeutic

innovation of tried

and tested or estab-

lished veterinary

drug or product

6.1.5 Unbranded Generic – P 1,000 for 2 years or P 2,500 for 5 years + cost of laboratory analysis

Veterinary Drug or

Product

6.1.6 Branded Generic – P 2,000 for 2 years or P 5,000 for 5 years + cost of laboratory analysis

Product

6.2 Renewal of Registration – P 1,500 for 5 years + cost of laboratory analysis

Section 7. **APPEAL**

Disapproved application(s) may be appealed to the Secretary of Health / Secretary of Agriculture for reconsideration.

Section 8. **SEPARABILITY CLAUSE**

In case any provision of this administrative order is declared contrary to law or unconstitutional, other provisions which are not affected hereby shall continue to be in force in effect.

Section 9. **REPEALING CLAUSE**

All administrative orders, rules and regulations and other administrative issuance or parts thereof inconsistent with the provisions of this Administrative Order are hereby repealed or modified accordingly.

Section 10. **EFFECTIVITY**

This regulation shall take effect fifteen (15) days after its publication in a newspaper of general circulation.

(Sgd.) SENEN C. BACANI **(Sgd.) ALFRED R. A. BENGZON, M.D.**

Secretary of Health Secretary of Health

ANNEX A

(LIST A)

LIST OF PHARMACEUTICAL PRODUCTS CLASSIFIED AS PROHIBITED DRUGS OR REGULATED DRUGS BY THE DANGEROUS DRUGS BOARD

I. **Prohibited Drugs**

1.	ALFENTANIL	- Rapifen Injectable
2.	CODEINE (as sulfate)	- Codeine Sulfate H.T. - Codeine Sulfate T.T.
3.	CODEINE (as phosphate)	- Dolo-Adamon Suppository - Dolo-Adamon Tablet
4.	DIHYDROCODEINE	- NOT AVAILABLE IN THE MARKET
5.	FENTANYL (as citrate)	- Sublimaze Injectable
6.	FENTANYL (as citrate) / Droperidol	- Innovar
7.	HYDROCODONE (DIHYDROCODEINONE) (as bitartrate)	- Deka Syrup - Raminon Syrup
8.	HYDROCODONE (DIHYDROCODEINONE)	- Tussinex Suspension
9.	HYDROCODONE (DIHYDROCODEINONE)	-Codevite Syrup

	(as bitartrate) plus Pyrilamine (as maleate) / Sodium Citrate / Ammonium Chloride / Potassium Guaiacolsulfonate	
10.	HYDROCODONE (DIHYDROCODEINONE) / (as bitartrate) plus Pyrilamine (as maleate) / Homatropine (as methylbromide) / Phenylephrine (as hydrochloride) / Ammonium Chloride	- Endotussin Syrup
11.	MORPHINE (as sulfate)	- Morphine Sulfate H.T. - Morphine Sulfate Ampul - Morphine Sulfate Tablet
12.	MORPHINE (as sulfate) / Atropine	- Morphine with Atropine
13.	OPIUM	- Brown Mixture Tablet - Brown Mixture Liquid
14.	OPIUM / ALCOHOL	- Elixir Paregoric
15.	PETHIDINE (MEPERIDINE)	- Demerol Ampul - Demerol Tablet - Demerol Vial

II. **<u>Regulated Drugs</u>**

A. *Available in the Market*

1.	AMOBARBITAL (as sodium)	- Amytal Sodium Ampul - Amytal Sodium Capsule - Amytal Sodium

		Tablet
2.	AMPHETAMINE	- Benzedrine Tablet - Daprisal Tablet
3.	APROBARBITAL, BARBITAL, AND PHENOBARBITAL	- Plexonal
4.	CHLORAL HYDRATE	- Noctec
5.	DEXAMPHETAMINE	- Dexedrine Spansule
6.	EPHEDRINE (excluding exempt preparations)	
7.	ETHINAMATE	- Valamin Tablet
8.	FLUNITRAZEPAM	- Rohypnol
9.	NITRAZEPAM	- Mogadon
10.	PARALDEHYDE	- Paraldehyde Ampule
11.	PENTAZOCINE (as hydrochloride)	- Sosegon Tablet
12.	PENTAZOCINE (as base)	- Sosegon Ampule
13.	PENTHOTAL (as sodium)	- Penthotal Sodium Vial - Thiopental Sodium Vial
14.	PROPOXYPHENE (as hydrochloride)	- Doloxene Palin Tablet
15.	PROPOXYPHENE (as napsylate), Aspirin, and Caffeine	- Doloxene Compound-65
16.	PROPOXYPHENE (as napsylate) / Paracetamol	- Dologesic - 32
17.	PSEUDOEPHEDRINE (excluding exempt preparations)	

Local suppliers no longer carry these drugs but are still available in some drugstores and hospital pharmacies.

B. *Not Available in the Market*

1.	AMOBARBITAL / DEXAMPHETAMINE	- Dexamyl Spansule No.1
2.	BUTABARBITAL	- Butisol Sodium Tablet - Circuline Forte Tablet
3.	ETHCHLORVYNOL	- Placidyl Capsule
4.	HYDROCODONE (DIHYDROCODEINONE) / PENTOBARBITAL	- Calcidrine Syrup
5.	MECLOQUALONE	- Nubarene Tablet
6.	METHAMPHETAMINE	- Desoxyn Tablet
7.	METHAQUALONE / Diphenhydramine (as hydrochloride)	- Mandrax Tablet
8.	METHYLPRYLON	- Noludar Tablet
9.	PENTOBARBITAL (as sodium)	- Nembutal Sodium Vial
10.	PIPRADROL	- Gadexyl Tablet
11.	SECOBARBITAL	- Seconal Sodium Capsule

Local suppliers no longer carry these drugs but are still available in some drugstores and hospital pharmacies.

ANNEX B

(LIST B)

LIST OF VETERINARY DRUGS AND PRODUCTS REQUIRING STRICT PRECAUTION IN PRESCRIBING, DISPENSING AND USE

1.	ACEPROMAZINE	:	TABLET / INJECTABLE
2.	AMINOPHYLLINE	:	SUPPOSITORY / TABLET
3.	AMITRAZ	:	POUR ON
4.	AMPHOTERICIN B	:	INJECTABLE
5.	AZAPERONE	:	INJECTABLE
6.	BETAMETHASONE	:	TABLET
7.	BUNAMIDINE	:	TABLET
8.	CARBADOX	:	PREMIX
9.	CHLORAMBUCIL	:	TABLET
10.	CHLORAMPHENICOL	:	CAPSULE / INJECTABLE
11.	CHLORPROPAMIDE	:	TABLET

12.	COLISTIN	:	INJECTABLE
13.	CYCLOPHOSPHAMIDE	:	TABLET
14.	DEXAMETHASONE	:	TABLET
15.	DEXAMETHASONE ACETATE	:	INJECTABLE
16.	DIAZEPAM	:	TABLET
17.	DICHLORVOS	:	CAPSULE / GRANULES
18.	DIETHYLESTILBESTROL (DES)	:	INJECTABLE
19.	DIGITOXIN	: :	TABLET
20.	DIGOXIN	:	TABLET
21.	DIHYDROSTREPTOMYCIN	:	INJECTABLE
22.	DIMETRIDAZOLE	:	INJECTABLE
23.	DIMINAZINE	:	INJECTABLE
24.	EPINEPHRINE	:	INJECTABLE
25.	ERYTHROMYCIN	:	INJECTABLE
26.	ESTROGENS, CONJUGATED	:	INJECTABLE
27.	ETHINYLESTRADIOL	:	TABLET
28.	ETHOSUXIMIDE	:	CAPSULE
29.	FURAZOLIDONE	:	SUSPENSION / TABLET
30.	FUROSEMIDE	:	TABLET / INJECTABLE
31.	GENTAMACIN	:	INJECTABLE
32.	HALQUINOL	:	PREMIX
33.	HYDROCHLOROTHIAZIDE	:	TABLET

34.	HYDROCORTISONE	:	INJECTABLE
35.	IMIDOCARB	:	INJECTABLE
36.	INSULIN	:	INJECTABLE
37.	IVERMECTIN	:	TABLET / INJECTABLE
38.	KETAMINE	:	INJECTABLE
39.	LASALOCID	:	PREMIX
40.	LEVAMISOLE	:	INJECTABLE
41.	LINDANE	:	POUR ON
42.	LORAZEPAM	:	ORAL
43.	MELARSONYL	:	INJECTABLE
44.	MENADIONE	:	TABLET
45.	MENADIONE SODIUM BISULFATE	:	TABLET
46.	MEPHENYTOIN	:	TABLET
47.	METHDILAZINE HYDROCHLORIDE	:	TABLET
48.	METHOTREXATE	:	TABLET
49.	METHYLERGOMETRINE (METHYLERGONOVINE) MALEATE	:	TABLET
50.	METRONIDAZOLE	:	TABLET
51.	MONENSIN	:	PREMIX
52.	NEOMYCIN	:	INJECTABLE
53.	NICLOSAMIDE	:	TABLET

54.	NITROFURANTOIN	:	CAPSULE/SUSPENSION TABLET
55.	OLAQUINDOX	:	PREMIX
56.	OUABAIN	:	INJECTABLE
57.	OXYTETRACYCLINE (LONG-ACTING)	:	INJECTABLE
58.	OXYTOCIN	:	INJECTABLE
59.	PANCURONIUM	:	INJECTABLE
60.	PERPHENAZINE	:	SUPPOSITORY / SYRUP / TABLET / CR TABLET
61.	PHENYLBUTAZONE	:	CAPSULE / TABLET
62.	PHENYTOIN	:	SUSPENSION
63.	PHENYTOIN SODIUM, EXTENDED	:	CAPSULE
64.	PHENYTOIN SODIUM, PROMPT	:	CAPSULE
65.	PRAZIQUANTEL	:	TABLET
66.	PROBENECID	:	TABLET
67.	PROCAINAMIDE HYDROCHLORIDE	:	CAPSULE/TABLET/CR TABLET
68.	PROPIONYL PHENOTHIAZINE	:	INJECTABLE
69.	PROSTAGLANDIN F2 ALPHA	:	INJECTABLE POWDER
70.	PYRAZINAMIDE	:	TABLET
71.	QUINIDINE SULFATE	:	CAPSULE/TABLET/CR TABLET
72.	SALINOMYCIN	:	PREMIX

73.	SPIRONOLACTONE	:	TABLET
74.	STREPTOMYCIN	:	INJECTABLE
75.	SUCCINYLCHOLINE	:	INJECTABLE
76.	SULFADIAZINE; SULFAMERAZINE SULFAMETHAZINE	:	TABLET
77.	SULFAMETHIZOLE	:	SUSPENSION / TABLET
78.	SULFISOXAZOLE	:	SUSPENSION / TABLET
79.	SURAMIN	:	INJECTABLE

ANNEX C

REQUIREMENTS FOR REGISTRATION

A. General Requirements

1. License To Operate of the veterinary drug and product manufacturer, trader, distributor / importer, distributor / exporter.

2. Technical data which shall include:

2.1 Physical description of the veterinary drug and product.

2.2 Complete formulation and technical specifications for the raw materials and finished product.

2.3 Process of manufacturing including facilities and control used in the manufacturing and packaging of

the veterinary drug and product.

2.4 Description of all quality control tests performed stability including Dissolution Test, when applicable,

and results obtained.

2.4.1 For antibiotic products, results of batch analysis.

2.5 Certificate of analysis and assay procedures for active ingredient(s) and degradation product(s) if

any.

2.6 Complete stability studies under local conditions

3. Samples and corresponding reference standards.

4. Two copies of labels or specimens of the proposed label and other labeling materials such as inserts brochures, etc.

5. Relevant literature and/or scientific evidence based on local or foreign studies to show safety, efficacy, potency, and therapeutic value of the veterinary drug and product. Local studies must be based on protocols acceptable to BFAD / BAI.

B. Specific Requirements

1. Investigational Veterinary Drug and Product

1.1 Veterinary Medical Director / Officer registered with BFAD / BAI.

1.2 Laboratory Animal Studies

1.2.1 Acute toxicity

1.2.2 Sub-chronic toxicity

1.2.3 Teratogenicity

1.2.4 Other studies, e.g. carcinogenecity

1.3 Clinical Pharmacology Studies

1.3.1 Phases I and II tolerance and efficacy studies.

1.3.2 Phase III clinical trial for target animal species.

1.3.2.1 Local

1.3.2.2 Foreign when applicable

2. New Veterinary Drug and Product

2.1 Veterinary Medical Director / Officer registered with BFAD / BAI.

2.2 Results of laboratory animal and clinical studies as required in Section 1.2 and 1.3 of this Annex and

results of carcinogencity test if required by BFAD/BAI.

2.3 Results of Ecological or Environmental Impact Assessment (EIA) when applicable.

2.4 Phase IV Clinical Use

2.4.1 Post-marketing surveillance

3. Tried and Tested Veterinary Drug and Product

3.1 Dissolution test for solid oral dosage forms when applicable.

3.2 Bioavailability / bioequivalence study for certain veterinary drugs and products determined by BFAD /

BAI when applicable.

3.3 Local clinical trial to determine effective therapeutic dose range in target animals when applicable.

4. Established Veterinary Drug and Product

4.1 Dissolution test for solid dosage forms when applicable.

4.2 Bioavailability / bioequivalence study for certain veterinary drugs and products as determined by BFAD / BAI when applicable.

5. Pharmaceutical and Therapeutic innovation of Tried and Tested or Established Veterinary Drug and Product.

5.1 Veterinary Medical Director / Officer registered with BFAD / BAI.

5.2 Dissolution test for solid dosage forms when applicable.

5.3 Bioavailability / bioequivalence for certain drugs as determined by BFAD/BAI when applicable.

5.4 Local clinical and non-clinicals trial to test efficacy, potency, and safety of the

therapeutic innovation, when applicable.

C. Additional Requirements for Certain Categories.

1. Dangerous Drugs

1.1 Certificate of clearance from the Dangerous Drug Board.

2. Branded Drugs

2.1 Certificate of trademark from the Bureau of Patents

2.2 Certificate of brand name clearance issued by BFAD/BAI

3. Imported Finished Products

3.1 Certificate of Free Sale of Veterinary Drug and Product in country of origin authenticated by the territorial Philippine Consulate and/or

3.2 Certification from FAO/WHO International Certification Scheme for manufacturers or equivalent.

4. Locally-manufactured Products from Imported Materials.

4.1 Certificate of quality of imported raw materials from the Drug Regulatory Authority of the country of origin from the FAO/WHO.

4.2 License To Operate of the manufacturer, if different from applicant.

4.3 Copy of the contract between applicant and manufacturer, when applicable.

4.4 Certificate of Fee Sale for registration of any veterinary drug and product containing said ingredient or raw material in country of origin authenticated by the territorial Philippine Consulate.

5. Locally-manufactured Products from Local Materials.

5.1 License To Operate of the manufacturer of the local raw material(s).

5.2 License To Operate of the manufacturer of the finished product, if different from applicant.

5.3 Copy of contract between applicant and manufacturer of the finished products, when applicable.