CHAPTER 211

184/2001.

BELIZE AGRICULTURAL HEALTH AUTHORITY (VETERINARY DRUGS AND ANIMAL FEED) (REGISTRATION AND CONTROL)

ARRANGEMENT OF REGULATIONS

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BELIZE AGRICULTURAL HEALTH AUTHORITY (VETERINARY DRUGS AND ANIMAL FEED) (REGISTRATION AND CONTROL) REGULATIONS

[29th December, 2001.]

PART I

PRELIMINARY

Short title.

1. These Regulations may be cited as the

BELIZE AGRICULTURAL HEALTH AUTHORITY (VETERINARY DRUGS AND ANIMAL FEED) (REGISTRATION AND CONTROL) REGULATIONS.

Interpretation.

2. In these Regulations, unless the context otherwise requires –

CAP. 211

"Act" means the Belize Agricultural Health Authority Act;

"active ingredient" means the substance that is biologically active in a veterinary drug or veterinary pesticide;

"animal" includes cattle, buffalos, horses, mules, asses, sheep, swine, goats, dogs, cats, birds, poultry, insects, fish, reptile, amphibians, eggs of any kind and all animals of whatever kind, be they genetically engineered or altered or otherwise, whether similar to the foregoing or not;

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"animal feed" means a mixture of nutrients that are produced under hygenic conditions that comply with the requirements of each species, age, and type of production, either as the only source of feed or as a supplement;

"antidote" means a substance used to neutralize the toxic effects produced by a chemical agent;

"antimicrobials" means substances that inhibit or kill micro-organisms that affect animals;

"Authority" means the Belize Agricultural Health Authority established under section 3 of the Act;

"distribute" means to supply, deliver or give out veterinary drugs or veterinary pesticides, or to divide and dispense such drugs or pesticides in portions to retailers or others;

"extra label use", in respect of a veterinary drug or veterinary pesticide includes-

(a) actual use or intended use of the veterinary drug or pesticide in an animal in a manner that is not in accordance with the approved labelling of the drug;

(b) use of the veterinary drug or pesticide for diseases, conditions and other indications in an animal that is not listed on the labelling of the drug or pesticide;

(c) use in or on an animal of the drug or pesticide at dosage levels, frequencies or routes of administration other than those stated on the labelling of the drug or pesticide; or

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(d) deviation from the withdrawal time labelled on the drug or pesticide based on the uses of the drug as specified in paragraph *(a)* to *(c)* of this definition;

"import" means import into Belize by any means and "importation" has a corresponding meaning;

"importer" includes any person who, whether as owner, consignor, consignee, agent or broker, is in possession of or in any way entitled to the custody or control of any thing;

"maximum residue limit" in respect of a veterinary drug, means the maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg on a fresh weight basis) that is recommended, permitted or recognised as acceptable in or on a food as defined by the Authority;

"owner", in respect of a veterinary drug or a veterinary pesticide, means -

(a) a person having or claiming any right, title or interest in the drug or pesticide;

(b) an agent or a representative of a person referred to in paragraph (a) of this definition;

(c) a person in charge, or who appears to be in charge of a veterinary drug;

"quality control" means all activities included to ensure and to verify that the production, identification, efficacy, purity, safety, management and commercialization and rational use of a veterinary drug, pesticide or animal feed comply with established norms;

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"raw materials" in respect of a veterinary drug or animal feed, means an active or inactive substance, either altered or modified, that is utilised to manufacture the veterinary drug or animal feed;

"Registrar" means an officer of the Authority designated in writing by the Managing Director of the Authority to be the Registrar of Veterinary Drugs, Veterinary Pesticides and Animal Feed;

"residue" in respect of a veterinary drug or pesticide, means any specified substance found in any edible portion of animal product destined for human or animal consumption, resulting from the use of such veterinary drug or pesticide, and includes derivatives of a veterinary drug such as metabolites and impurities associated with a particular veterinary drug;

"sell" means to vend, offer for sale, exchange or give up for money or money's worth or as a gift;

"veterinary drug" means every substance or composition applied or administered to any animal, including poultry, fish or bees, whether used for therapeutic, prophylactic or diagnostic purposes or for the modification of an animal's physiological functions or behaviour, or any substance or composition presented as owning such properties;

"veterinary pesticide" means any substance or composition that prevents, kills or controls any pest which is utilized exclusively on animals;

"withdrawal period", in respect of a veterinary drug, means the period following the last treatment of an animal with the drug during which -

(a) the animal may not be offered for slaughter; and

(b) products from the animal may not be sold or

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offered for sale,

based on the time necessary for drug residues in the animal to deplete to the maximum residue limit.

Scope.

3. (1) These Regulations apply to -

(a) veterinary drugs, veterinary pesticides, animal feed, biologicals and biotechnological products of veterinary use, which are used, or prescribed for use, or intended to be used, in connection with the treatment, prophylaxis or diagnosis of disease in animals;

(b) the manufacture, importation, distribution and sale of the products specified in paragraph (a) of this regulation.

CAP. 216.

(2) Where there is any inconsistency between the provisions of these Regulations and the provisions of the Pesticide Control Act, the provisions of that Act shall prevail.

PART II

ADMINISTRATION

Establishment of Veterinary Drugs Control Unit within the Authority.

4. There shall be and is hereby established a Unit within the Authority called the Veterinary Drugs Control Unit (hereinafter called "the Unit"), which shall perform the functions and discharge the duties conferred and imposed upon it by these regulations.

Functions of the Unit.

5. The Unit shall perform the following functions and discharge the

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following duties -

(a) administering these Regulations;

(b) keeping records of the importation, distribution, manufacture, sale and use of veterinary drugs, veterinary pesticides, animal feed, biologicals and biotechnological products of veterinary use which are used, or prescribed for use, or intended to be used, in connection with the treatment of animals;

(c) developing strategies and actions of conciliation, arbitration, dissemination and evaluation of, and promoting, the rational and proper use of veterinary drugs, pesticides and animal feed;

(d) evaluating and determining applications for the registration of veterinary drugs, pesticides and animal feed;

(e) evaluating and determining applications for the registration of importers of veterinary drugs, pesticides and animal feed;

(f) advising the Minister in order to keep up-dated the Schedules to these Regulations;

(g) establishing maximum residue limits for veterinary drugs;

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(h) maintaining and updating a National Formulary of Veterinary Drugs and publishing it periodically in the *Gazette;*

(i) establishing standards for the dispensation and use of veterinary drugs, pesticides and animal feed;

(j) harmonising, in accordance with Belize's obligations under bi-lateral, regional or multilateral trade agreements, including the WTO Agreement, procedures and protocols relating to the registration, distribution, sale, importation, manufacture and control of veterinary drugs, veterinary pesticides and animal feed, including but not limited to harmonising-

(i) forms and certificates,

(ii) registration procedures,

(iii) quality control and standards,

(iv) analytical methods,

(v) implementation procedures,

applicable under these Regulations with those of Belize's trading partners in the Caribbean, North America, Central America, the European Union and other regions of the world.

Registrar.

6. (1) The Unit shall be headed by an officer of the Authority

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designated in writing for that purpose by the Managing Director of the Authority, and such officer shall be called the Registrar of Veterinary Drugs, Veterinary Pesticides and Animal Feed (hereinafter called "the Registrar").

(2) The Registrar shall perform his functions and discharge his duties pursuant to these Regulations under the direct control and supervision of the Managing Director of the Authority or an officer of the Authority designated for that purpose by the Managing Director.

Veterinary Drug Control Committee.

7. (1) There shall be and is hereby established, for the purpose of advising the Unit in performing its functions and discharging its duties under these Regulations, a Veterinary Drug Control Committee comprised of -

(a) the Registrar, who shall be Chairman of the Committee;

(b) the Director of Animal Health of the Authority;

(c) the Director of Food Safety of the Authority;

(d) the Laboratory Administrator of the Authority;

(e) a veterinary surgeon appointed by the Veterinary Surgeons Board appointed under section 3 of the Veterinary Surgeons Act; and CAP. 326.

(f) a member appointed by the Veterinary Association of Belize.

(2) The Veterinary Drugs Control Committee shall determine -

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(a) the times and places at which it shall meet to transact business;

(b) the procedure to be followed at a meeting; and

(c) the quorum at a meeting.

(3) The Veterinary Drugs Control Committee shall act notwithstanding any vacancy in its membership or the absence of any member.

Functions of the Veterinary Drug Control Committee.

8. The Veterinary Drugs Control Committee shall advise the Unit and, in this respect, shall -

(a) review periodically the list of veterinary drugs registered pursuant to these regulations, and advise the Unit of any desired changes to such list;

(b) make recommendations respecting the registration of veterinary drugs, animal feed and importers, manufacturers, distributors and sellers of the same;

(c) make recommendations respecting amendments to these Regulations.

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PART III

REGISTRATION OF VETERINARY DRUGS, VETERINARY PESTICIDES AND ANIMAL FEED, ETC.

Registration of veterinary drugs, veterinary pesticides and animal feed. First Schedule.

9. The Unit shall register all veterinary drugs, veterinary pesticides and animal feed imported, exported, distributed, used, manufactured, packaged or labelled in Belize in accordance with the procedures set out in the First Schedule.

Classification of veterinary drugs and veterinary pesticides.

10. (1) At the time of registration, the Unit shall classify a veterinary drug or a veterinary pesticide as -

(a) over-the-counter;

(b) prescription-only; or

(c) restricted.

(2) An over-the-counter veterinary drug or veterinary pesticide may be sold to any person over eighteen years without a prescription.

(3) A prescription-only veterinary drug or veterinary pesticide may only be sold to a person over eighteen years upon a prescription issued by a veterinary surgeon registered under the Veterinary Surgeons Act. CAP. 326.

(4) A restricted veterinary drug or veterinary pesticide may only be sold to a veterinary surgeon registered under the Veterinary Surgeons Act and shall be used only under his direct supervision. CAP. 326.

(5) No veterinary drugs shall be sold to a person below the age of

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eighteen years.

Unregistered drugs, etc., are prohibited.

11. (1) No person shall sell, manufacture, import, package, label or distribute a veterinary drug or veterinary pesticide or animal feed that is not registered by the Unit under Regulation 9.

Second Schedule.

(2) The veterinary drugs specified in the Second Schedule are banned for use in Belize.

Second Schedule.

(3) The Unit, on the advice of the Veterinary Drugs Control Committee, may amend the Second Schedule by adding or removing the name of a drug specified therein.

Registration of premises selling etc., veterinary drugs, etc.. Third Schedule.

12. Every premises, establishment or outlet that manufactures, re-packages, re-bottles, re-labels, sells, imports, exports, bottles, packages, labels or exports veterinary drugs, veterinary pesticides or animal feed shall be registered in accordance with the procedure set out in the Third Schedule.

PART IV

RETAIL SALE OF VETERINARY DRUGS AND VETERINARY PESTICIDES

Labelling of veterinary drugs.

13. (1) All veterinary drugs intended for retail sale in Belize shall be clearly labelled in English with at least the following information -

(a) the commercial names of the drug or its conventional name;

(b) the qualitative, quantitative and pharmacologic composition of the drug, including its active and inactive ingredients;

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(c) the presentation of the packaging of the drug;

(d) the uses and indications of the drug;

(e) the volume and weight of the drug;

(f) the expiry date of the drug;

(g) the dosage per species, including the method of administration and use, and the instructions of use;

(h) the registration number of the drug in Belize;

(i) any contraindications, warnings, and antidotes (if any);

(j) the words "for veterinary use" displayed conspicuously on the packaging of the drug;

(k) the batch or lot number of the drug;

(l) the total quantity of the drug in each package or unit;

(m) any other precautionary information and measures respecting the use of the drug;

(n) the name of the manufacturer of the drug and the drug's country of origin;

(o) any applicable conditions of storage and preservation;

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(p) applicable withdrawal periods for meat, milk, and other types of food.

(2) The information referred to in subregulation (1) may be attached on the label to the drug or on the information leaflet in respect of the drug included in the packaging of the drug.

Labelling of veterinary pesticides.

14. (1) All veterinary pesticides intended for retail sale in Belize shall be clearly labelled in English with at least the following information:-

(a) the classification or type of the pesticide;

(b) the uses and indications of the pesticides, including the common and scientific names of pests for which the pesticide is used;

(c) where the pesticide is to be used after preparing a solution, instructions for preparing the solution;

(d) the withdrawal period of the pesticide;

(e) instructions respecting the de-contamination and proper disposal of the pesticide container;

(f) instructions respecting any precautionary measures which a person using the pesticide must take;

(g) information on the toxicity of the pesticide to humans and animals, and symptoms and signs of intoxication and any antidote (if

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any);

(h) the words "in the case of accidental intoxication consult your medical doctor or veterinary surgeon immediately and submit this label" printed in bold letters and placed conspicuously on the label;

(i) the words "keep out of the reach of children" and "stop, read the instructions on this label and the information leaflet before use" printed in bold letters and placed conspicuously on the label; and

(j) information on protective clothing to be worn when applying the pesticide.

PART V

IMPORTATION OF VETERINARY DRUGS, ETC.

Importer's licence.

15. (1) No person shall import a veterinary drug, veterinary pesticide or animal feed unless he has an importer's licence issued by the Unit.

Fourth Schedule.

(2) An importer's licence shall be issued and may be suspended or revoked by the Unit in accordance with the procedures outlined in the Fourth Schedule.

(3) The Unit may impose conditions in connection with the grant of an importer's licence.

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PART VI

MANUFACTURE OF VETERINARY DRUGS, ETC.

Manufacturer's licence.

16. (1) No person shall manufacture a veterinary drug unless he has a manufacturer's licence granted by the Unit.

(2) A manufacturer's licence shall be granted, and may be suspended or revoked, by the Unit in accordance with the procedures outlined in the Fifth Schedule.

Fifth Schedule.

(3) The Unit may impose conditions in connection with the grant of a manufacturer's licence.

PART VII

PREMISES OUTLETS AND ESTABLISHMENTS THAT SELL, DISTRIBUTE, ETC., VETERINARY DRUGS, PESTICIDES AND ANIMAL FEED

Conditions of registration.

17. (1) Any premises, outlet or establishment that sells, bottles, packages, labels, distributes, handles, re-packages, re-labels, re-bottles or otherwise deals with veterinary drugs, veterinary pesticides or animal feed shall, when making application to be registered pursuant to these Regulations, submit to the Unit –

(a) a duly completed application form;

(b) public health and environmental approval of the premises, outlet or establishment certifying the premises, outlet or establishment as posing no risks to human

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health or to the environment, and as suitable for the business for which application is made;

(c) floor plans of the premises, outlet or establishment; and

(d) city, town, community or village council approval.

(2) Where any premises, outlet or establishment is to be used to sell biological products or other veterinary products which require refrigeration to be preserved, such premises, outlet or establishment shall have the proper refrigeration system with its respective thermometer.

(3) All premises, outlets and establishments used to sell veterinary drugs shall have adequate lighting, storage facilities and ventilation systems.

(4) Where veterinary drugs, veterinary pesticides and animal feed are sold in one premises, outlet or establishment, they shall be physically stored separately.

PART VIII

OFFENCES AND PENALTIES

Offences and penalties.

18. (1) A person commits an offence who -

(a) uses, distributes, packages, bottles, labels or sells veterinary drugs, veterinary pesticides or animal feed in contravention of these Regulations;

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(b) manufacturers veterinary drugs, veterinary pesticides or animal feed in contravention of these Regulations;

(c) imports veterinary drugs, veterinary pesticides or animal feed in contravention of these Regulations;

(d) imports, manufactures, sells, distributes or uses a veterinary drug, veterinary pesticide or animal feed-

(i) without the packaging required under these Regulations;

(ii) without the labelling required under these Regulations;

(iii) which has passed its sell-by-date (is expired).

(iv) which is banned;

(v) except in accordance (in the case of veterinary drugs or veterinary pesticides) in accordance with its appropriate classification pursuant to these Regulations;

(e) contravenes any term or condition of an importer's licence, a manufacturer's licence or any other licence granted by the Unit under these Regulations;

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(f) obstructs any officer of the Unit in the performance of his duties under these Regulations.

(2) A person who commits an offence under subregulation (1) is liable to be penalised by the Unit -

(a) for a first offence, to a written warning or an administrative fine of five hundred dollars;

(b) for a second offence, to a suspension for a period of one month of the relevant licence (if any) held by that person, and to an administrative fine of one thousand five hundred dollars;

(c) for a third or subsequent offence, to cancellation of the licence (if any) held by that person and to an administrative fine of five thousand dollars.

(3) A veterinary drug, veterinary pesticide or animal feed in respect of which an offence has been committed may be seized by the Unit and upon such seizure shall be forfeited to the Authority:

(4) All fines collected under these Regulations shall be credited to the account of the Authority.

Appeals.

19. Any person who is aggrieved by an adverse decision of the Unit under these Regulations may, within three months after the date on which such decision is communicated to him, appeal to the Managing Director of the Authority.

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Extra label use of drugs or pesticides permitted in certain cases.

20. Notwithstanding any thing to the contrary in these Regulations, the extra-label use of a veterinary drug or a veterinary pesticide shall be lawful for treating a particular disease, condition or other indication in an animal where -

(a) no veterinary drug or pesticide is known to treat such disease, condition or other indication; or

(b) no veterinary drug or pesticide which treats such disease, condition or other indication is available for use in Belize.

(c) it is used under veterinary surgeons administration or supervision.

Effect of Schedules.

21. The Schedules shall be read and construed as one with these Regulations, and form an integral part of these Regulations.

Commencement.

22. These Regulations shall come into force on the 12th day of December, 2001.

MADE by the Minister responsible for Agriculture, Fisheries and Cooperatives this 12th day of December, 2001.

(DANIEL SILVA)
Minister responsible for Agriculture,
Fisheries and Cooperatives

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FIRST SCHEDULE

(Section 9)

PROCEDURE FOR THE REGISTRATION OF ALL VETERINARY DRUGS, PESTICIDES AND ANIMAL FEED PERMITTED FOR USE IN BELIZE

PART 1

PROCEDURE FOR REGISTRATION

1. (1) In this Schedule, unless the context otherwise requires:- Interpretation.

"certificate of registration" means a certificate showing that a veterinary drug, veterinary pesticide or animal feed has been registered pursuant to this Schedule and Regulation 9 of the Regulations;

"label" means any brand or mark or any written, pictorial or other descriptive matter appearing on or attached to or packed with any veterinary drug, veterinary pesticide or animal feed or its package and, when used as a verb, means to brand or mark or to attach or to provide in any other manner, with any written, pictorial or other descriptive matter;

"logo" means a trade-mark used by a manufacturer of veterinary drugs, veterinary pesticides or animal feed to designate its product or range of products;

"product" means a registered veterinary drug, veterinary pesticide or animal feed in the form in which it is packaged and sold;

"registered veterinary drug", "registered veterinary pesticide" or "registered animal feed" means a drug, pesticide or animal feed registered under Regulation 9 and this Schedule, in respect of which there is a current certificate of

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registration;

"trade name" means the name under which a registered veterinary product, registered veterinary pesticide or animal feed is registered, packaged and sold by the manufacturer, which is used exclusively by the manufacturer as a trade-mark to distinguish the product from other registered veterinary products, registered veterinary pesticides or animal feed.

(2) A word or phrase used in this Schedule which is not defined herein but which is defined in the Regulations shall have the meaning assigned to it in the Regulations.

Application for registration.

2. (1) A registered veterinarian, or an owner of veterinary drugs, pesticides or animal feed desirous of selling or using a veterinary drug, pesticide or animal feed in Belize shall make written application to the Unit pursuant to this Schedule I to have the veterinary drug, pesticide or animal feed registered under Regulation 9 of the Regulations.

(2) The written application referred to in subparagraph (1) shall be in the form set out in Part 11 of this Schedule, and shall be accompanied by the appropriate fee set out in paragraph 6 of this Schedule.

(3) The written application referred to in subparagraph (1) shall additionally be accompanied by -

(a) the trade name of the veterinary drug, veterinary pesticide or animal feed, or the logo used for the purposes of marketing the product;

(b) the maximum residue limit of the veterinary drug or veterinary pesticide, for veterinary drugs or pesticide used to treat food

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animals;

(c) details of the labels of the veterinary drug, veterinary pesticide or animal feed, including three copies of the proposed label for approval by the Unit.

(4) Where a veterinary drug, veterinary pesticide or animal feed has been registered pursuant to this Schedule, it shall not be a requirement to register such veterinary drug, veterinary pesticide or animal feed before using or selling it.

Procedure upon receipt of application.

3. (1) Upon receiving an application made under paragraph 2, the Registrar shall satisfy himself that -

(a) the application complies with the form set out in Part II of this Schedule;

(b) the application is accompanied by the appropriate fee set out in paragraph 6 of this Schedule;

(c) all the documents and information referred to in subparagraph (3) of paragraph 2 of this Schedule have accompanied the application.

(2) The Registrar shall –

(a) if the application is accompanied by all the required documents, information and fee, place the application before the Unit for consideration;

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(b) if the application is not accompanied by all the required documents, information, fee, or is incomplete or deficient in some material respect, return the application to the applicant.

(3) Where the Registrar returns an application to an applicant under subparagraph (2) (b), the Registrar shall inform the applicant of the steps which the applicant should take in order to complete the application in accordance with the requirements of this Schedule.

(4) Every application placed before the Unit by the Registrar under subparagraph (2)(a) shall be considered and either approved or rejected by the Unit within fourteen days.

(5) Where the Unit rejects an application under subparagraph (4), it shall give written notice thereof to the applicant, including the grounds of the rejection.

(6) An applicant aggrieved by a decision of the Unit not to register its veterinary drug may appeal against such decision to the Managing Director within fourteen days of the receipt of such decision, and the Managing Director's decision on the appeal shall be final.

Provisional registration.

4. (1) Subject to subparagraph (2), where the Unit, after considering an application for the registration of a veterinary drug, pesticide or animal feed under Regulation 9 of the Act and this Schedule, and after considering all the surrounding circumstances of the application, is not satisfied that a veterinary drug, pesticide or animal feed should be registered, it may grant provisional registration for use subject to such conditions as it may lay down, for a period not exceeding one year, after which -

(a) the veterinary drug, pesticide or animal feed

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shall either be registered as a veterinary drug, pesticide or animal feed; or

(b) the provisional registration may be withdrawn by the Unit.

(2) No veterinary drug, pesticide or animal feed used to treat food animals shall be provisionally registered.

Types of certificates of registration.

5. (1) All veterinary drugs, and pesticides shall be registered or provisionally registered as –

(a) over-the-counter; or
(b) prescription-only; or
(c) restricted,

and the relevant certificate shall be issued to the applicant upon decision by the Unit under paragraph 3 (4) or 4 *(a)*, whichever applies.

Part III Schedule.

(2) Certificates of registration shall be in the form set out in Part III of this Schedule.

Fees.

6. (1) The following fees shall be payable on the provisional registration or registration of each -

(a) over-the-counter veterinary drug or veterinary pesticide $100;

(b) prescription-only veterinary drug or veterinary pesticide $200;

(c) restricted veterinary drug or veterinary pesticide $300;

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(d) animal feed ... ... $150.

(2) The same applicable fees set out in subparagraph (1) shall be payable on the renewal of each registration of a veterinary drug or veterinary pesticide.

(3) The same applicable fees set out in subparagraph (1) shall be payable for the registration of a veterinary drug or veterinary pesticide which was previously provisionally registered.

Duration of certificates of registration.

7. A certificate of registration for a veterinary drug granted by the Unit under this Schedule shall be valid for three years.

Cancellation of registration.

8. If, after a veterinary drug, veterinary pesticide or animal feed has been registered, it comes to the knowledge of the Unit that the registration was procured by false or misleading information or the concealment of material facts, the Unit may cancel the registration with immediate effect, after inviting the holder of the registration to show cause why it should not be cancelled, and the fee in respect of the registration shall be forfeited.

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PART II

APPLICATION FORM

1. The Registrar of Veterinary Drugs,
Veterinary Pesticides and Animal Feed
Belize Agricultural Health Authority
Belmopan
Belize

2. Date _____

3. Name of Applicant _____

4. Address of Applicant _____

_____

5. Telephone Number/Email Address of Applicant _____

_____

6. Is Applicant a Registered Veterinarian or Owner of the Veterinary Drug, Veterinary Pesticide or Animal Feed? (choose one)

_____

7. Common Name of Veterinary Drug/Veterinary Pesticide/Animal Feed

_____

8. Trade Name of Veterinary Drug/Veterinary Pesticide/Animal Feed

_____

9. Maximum Residue Limit of Veterinary Drug/Veterinary Pesticide

_____

10. Details of Labels of the Veterinary Drug, Veterinary Pesticide or Animal Feed (Also attach 3 copies)

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_____

11. Type of animals on which Veterinary Drug, Veterinary Pesticide or Animal Feed may be used _____

_____

12. Classification of Veterinary Drug or Veterinary Pesticide (Tick appropriate) If you do not know the appropriate box to tick, leave blank.

(a) Over-the-counter ☐

(b) Prescription-only ☐

(c) Restricted ☐

13. Is Veterinary Drug, Veterinary Pesticide or Animal Feed being manufactured in Belize at time of application? (Tick appropriate)

YES ☐ NO ☐

14. If the answer to 13 above is NO, provide details of registration in -

(a) Country of manufacture (attach copies, if possible) _____

_____

(b) Any other countries where drug/pesticide/animal feed is registered

_____

15. Has registration of the drug, pesticide/feed ever been refused in another jurisdiction? (Tick appropriate)

YES ☐ NO ☐

(If YES, provide details and reasons for such refusal)_____

_____

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16. Fees included _____

_____

17. Declaration by Applicant: I hereby declare that all the information provided in this application is true and correct to the best of my knowledge and belief, and I understand that if the Unit discovers that any information in this application was fraudulent or misleading, or that I have concealed material facts herein, the registration of the veterinary drug, veterinary pesticide or animal feed which I hereby apply for may be cancelled and the fee forfeited.

SIGNATURE OF APPLICANT

_____

FOR OFFICIAL USE ONLY

_____

1. Application received _____

2. Fees paid _____

3. Application complete/incomplete _____

4. If application is incomplete, details of required follow up communicated to applicant and date _____

_____

5. Registration status _____

6. Other remarks _____

Date _____

_____

SIGNED REGISTRAR

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PART III

VETERINARY DRUGS CONTROL UNIT
BELIZE AGRICULTURAL HEALTH AUTHORITY

CERTIFICATE OF REGISTRATION
OF A VETERINARY DRUG

THIS IS TO CERTIFY that _____(the applicant)_____ of _____(address)_____, has as of the _____ day of _____,20 ____, been granted this Certificate of Registration pursuant to Regulation 9 and Schedule 1 of the Belize Agricultural Health Authority (Veterinary Drugs and Animal Feed) (Registration and Control) Regulations, 2001, and that the drug/pesticide/ animal feed commonly known as _____ _____; whose trade name is _____; has been registered as of the same date as over-the-counter/prescription-only/ restricted* and may by virtue of such registration be sold and used in Belize for the treatment or feeding of _____ animals.
(specify)

THIS CERTIFICATE is valid for three years from the date of issuance hereof.

WITNESS my hand and the Public Seal of the Veterinary Drugs Control Unit this _____day of _____, 20 _____.

_____
REGISTRAR

*Delete inappropriate.

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SECOND SCHEDULE

(Regulation 11(2) and (3))

LIST OF BANNED VETERINARY DRUGS WHICH SHALL NOT BE USED, SOLD, MANUFACTURED, DISTRIBUTED OR IMPORTED INTO BELIZE FOR TREATING FOOD ANIMALS

1. Chloramphenicol.
2. Clenbuterol.
3. Diethystilbestrol (DES).
4. Dimetridazole.
5. Ipronidazole.
6. Other Nitroimidazoles.
7. Furazolidine (except for approved topical use).
8. Nitrofurazone (except for approved topical use).
9. Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomenthazine, and sulfaethoxypyridazine).
10. Fluoroquinolones.
11. Glycopeptides.

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THIRD SCHEDULE
(Regulation 15 (2))

PART I

PROCEDURE FOR THE ISSUANCE, SUSPENSION OR REVOCATION OF AN IMPORTER'S LICENCE

Interpretation.

1. In this Schedule, unless the context otherwise requires a word or phrase used and not defined in this Schedule but defined in the Regulations shall have the meaning assigned to it in the Regulations.

Licence to import a registered veterinary drug, etc..

2. (1) Any person desirous of importing a veterinary drug, veterinary pesticide or animal feed into Belize shall make application to the Unit in the form set out in Part II of this Schedule.

(2) No person shall import the veterinary drugs listed in the Second Schedule to the Regulations for the purpose of treating food animals.

(3) The application referred to in subparagraph (1) shall be in the form set out in Part II of this Schedule, and shall be accompanied by the appropriate fee set out in paragraph 3 of this Schedule.

Import licence fees.

3. The annual import licence fee for a licence shall be determined by the Unit after consultation with persons interested in the importation of veterinary drugs, pesticides and animal feed.

Procedure upon receipt of application.

4. (1) Upon receiving an application for an import licence, the Registrar shall ensure that the appropriate fee accompanies the application, and shall then place it before the Unit for consideration.

(2) Where an application is not accompanied by the appropriate fee, the Registrar shall return the application to the applicant, with instructions to resubmit the application.

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(3) Every application placed before the Unit by the Registrar shall be considered by the Unit within fourteen days, and the Unit may approve the application and issue the relevant import licence, or refuse the application and inform the applicant in writing of the grounds for such refusal.

(4) Any applicant aggrieved by the decision of the Unit not to issue an import licence may appeal against such decision to the Managing Director of the Authority within fourteen days of the receipt of such decision, and the Managing Director's decision on the appeal shall be final.

Duration of licences.

5. (1) An import licence issued by the Unit under this Schedule shall be valid for one year.

(2) An import licence may be issued subject to conditions imposed by the Unit in connection with that licence.

(3) An import licence shall be in the form set out in Part III of this Schedule.

Revocation of import licences.

6. (1) If, after an import licence has been issued by the Unit under this Schedule, it comes to the knowledge of the Unit that the licence was procured by false or misleading information or the concealment of material facts, the Unit may revoke the licence with immediate effect, after inviting the holder of the licence to show cause why it should not be revoked, and the fee in respect of the issuance of the licence shall be forfeited.

(2) An import licence may be suspended by the Unit for a specified duration if the holder thereof breaches any of the conditions imposed by the Unit in connection with the issuance of that licence.

(3) Any person who contravenes this paragraph shall be liable to a penalty which may take the form of a reprimand but which may extend to a monetary penalty determined by the Unit after taking into account all the circumstances of the contravention.

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PART II

APPLICATION FORM FOR AN IMPORT LICENCE

1. The Registrar of Veterinary Drugs, Veterinary Pesticides and Animal Feed
Belize Agricultural Health Authority
Belmopan
Belize

2.Date _____

3. Name of Applicant _____

4. Address of Applicant _____

5. Telephone Number/Email Address of Applicant _____

6. Is Applicant a Registered Veterinarian. (tick appropriate box)

YES ☐ NO ☐

7. Common Name of Veterinary Drug/Veterinary Pesticide/Animal Feed for which application for import licence is made

_____

8. Is Veterinary Drug/Veterinary Pesticide/Animal Feed being manufactured or distributed in Belize at date of application?

YES ☐ NO ☐

If YES, give reasons for the desired importation _____

_____

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9. Types of animals on which Veterinary Drug/Veterinary Pesticide/ Animal Feed sought to be imported may be used (specify)
(i) _____
(ii) _____
(iii) _____

10. Classification of Veterinary Drug or Veterinary Pesticide (see Regulation 9)
_____

11. Fee included YES ☐ NO ☐

12. Class of import licence applied for (specify) _____
_____

Declaration by Applicant: I hereby declare that all the information provided in this application is true and correct to the best of my knowledge and belief, and I understand that if an import licence is granted due to any fraudulent or misleading information in this application, or due to the concealment of material information, such licence may be revoked by the Unit and the fee forfeited.

SIGNATURE OF APPLICANT _____
_____

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_____

1. Application received _____

2. Fees paid _____

3. Application submitted to Unit on _____

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4. Status of Application: Approved/Refused and reasons (if refused) _____

5. Import Licence issued on _____

6. Other remarks _____

7. Date _____

SIGNED _____ REGISTRAR

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PART III

BELIZE AGRICULTURAL HEALTH AUTHORITY
VETERINARY DRUGS CONTROL UNIT

FORM OF IMPORT LICENCE

IMPORT LICENCE NUMBER

DATE ISSUED

THIS IS TO CERTIFY that **(name of applicant) of (address of applicant) , is as of the _____day of_____, 20____, licensed under a licence to import into Belize _____ under licence.**

THIS LICENCE is valid _____

THIS LICENCE is issued subject to the following conditions -

1. _____ (specify conditions, if any)
2. _____
3. _____

WITNESS my hand and the Public Seal of the Veterinary Drugs Control Unit this_____ day of _____, 20 ____.

_____

REGISTRAR

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FOURTH SCHEDULE

[Section 16 (2)]

PART I

PROCEDURE FOR THE ISSUANCE. SUSPENSION OR REVOCATION OF A MANUFACTURER'S LICENCE

Interpretation.

1. (1) In this Schedule, unless the context otherwise requires -

"manufacturer" means a person licensed as a manufacturer under Part VI of the Regulations;

"manufacturer's licence" means a licence to manufacture veterinary drugs, veterinary pesticides or animal feed in Belize issued by the Unit under Part VI of the Regulations and pursuant to this Schedule.

(2) A word or phrase used and not defined in this Schedule but defined in the Regulations shall have the meaning assigned to it in the Regulations.

Manufacturer's licence.

2. (1) Any person desirous of manufacturing a veterinary drug, veterinary pesticide or animal feed shall make application to the Unit.

(2) No person shall manufacture the veterinary drugs listed in the Second Schedule for the purpose of treating food animals.

(3) Subject to subparagraph (1), any person desirous of manufacturing a registered veterinary drug, veterinary pesticide or animal feed shall make written application to the Unit for a manufacturer's licence, in the form set out in Part II of this Schedule.

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(4) The application referred to in subparagraph (1) shall be in the form set out in Part Il of this Schedule, and shall be accompanied by the appropriate fee set out in paragraph 3 of this Schedule.

Manufacturer's licence fee.

3. The fee payable for a manufacturer's licence shall be $750 per annum, or such other amount determined by the Unit after consultation with manufacturers of veterinary drugs, veterinary pesticide or animal feed in Belize.

Procedure upon receipt of application.

4. (1) Upon receiving an application for a manufacturer's licence, the Registrar shall ensure that the appropriate fee accompanies the application, and shall then place it before the Unit for consideration.

(2) Where an application is not accompanied by the appropriate fee, the Registrar shall return the application to the applicant, with instructions to resubmit the application.

(3) Every application placed before the Unit by the Registrar shall be considered by the Unit within fourteen days, and the Unit may approve the application and issue the manufacturer's licence, or refuse the application and inform the applicant in writing of the grounds for such refusal.

(4) An applicant aggrieved by the decision of the Unit not to issue a manufacturer's licence may appeal against such decision to the Managing Director of the Authority within fourteen days of the receipt of such decision, and the Managing Director's decision on the appeal shall be final.

Duration and form of manufacturer's licences.

5. (1) A manufacturer's licence issued by the Unit under this Schedule shall be valid for one year.

(2) A manufacturer's licence may be issued subject to conditions imposed by the Unit in connection with that licence.

(3) A manufacturer's licence shall be in the form set out in Part III

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of this Schedule.

Revocation of manufacturer's licences.

6. (1) If, after a manufacturer's licence has been issued by the Unit under this Schedule, it comes to the knowledge of the Unit that the licence was procured by false or misleading information or the concealment of material facts, the Unit may revoke the licence with immediate effect, after inviting the holder of the licence to show cause why the licence should not be revoked, and the fee in respect of the issuance of the licence shall be forfeited.

(2) A manufacturer's licence may be suspended by the Unit if the holder thereof breaches any conditions imposed by the Unit in connection with the issuance of that licence.

(3) Any person who contravenes this paragraph shall be liable to a penalty which may take the form of a reprimand but which may extend to a monetary penalty determined by the Unit after taking into account all the circumstances of the contravention.

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PART II

APPLICATION FORM FOR A MANUFACTURER'S LICENCE

1. The Registrar of Veterinary Drugs,
Veterinary Pesticides and Animal Feed
Belize Agricultural Health Authority
Belmopan
Belize

2. Date _____

3. Name of Applicant _____

4. Business Address of Applicant _____

5. Telephone Number/Email Address of Applicant _____

_____

6. Is Applicant a Registered Veterinarian. (tick appropriate box)

YES ☐ NO ☐

7. Common Name of Veterinary Drug/Veterinary Pesticide/Animal Feed for which application for import licence is made

_____

8. Is Veterinary Drug/Veterinary Pesticide/Animal Feed being manufactured or distributed in Belize at date of application?

YES ☐ NO ☐

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9. Types of animals on which Veterinary Drug/Veterinary Pesticide/ Animal Feed sought to be imported may be used (specify)

(i) _____
(ii) _____
(iii) _____

10. Classification of Veterinary Drug or Veterinary Pesticide (see Regulation 9)

_____

11. Fee included YES ☐ NO ☐

12. Business plans for the applicant for the next year (specify and attach additional information if necessary

_____

Declaration by Applicant: I hereby declare that all the information provided in this application is true and correct to the best of my knowledge and belief, and I understand that if a manufacturer's licence is granted due to any fraudulent or misleading information in this application, or due to the concealment of material information, such licence may be revoked by the Unit and the fee forfeited.

SIGNATURE OF APPLICANT

_____

_____

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_____

1. Application received _____

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2. Fee paid _____

3. Application submitted to Unit on _____

4. Status of Application: Approved/Refused and reasons (if refused)
_____

5. Manufacturer's Licence issued on _____

6. Other remarks _____

7. Date _____

_____

SIGNED **REGISTRAR**

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