Animal Diseases Act No. 59 of 1992 & Regulations

Schedule.....

APPLICATION FOR FREE SALES REGISTRATION OF VETERINARY TEST KITS AND DEVICES IN SRI LANKA

FORM.....

1. Brand Name of the Test kit/Device:

2. Generic/Approved Name of the Test kit/Device:

3. Category of the Device:

4. Name, Address, E mail and Telephone No. of the Manufacturer:

5. Name, Address, E mail and Telephone No. of the Importer:

6. Name, Address, E mail and Telephone No. of the Local Agent:

7. Capacity/ Pack size:

8. Manufacture license/Business Registration Certificate (Page/Annex No)

   A. Issued by:

   B. Validity:

   C. Endorsement by SL Embassy:

9. Free Sales Certificate (Page/Annex No)

   A. Issued by:

   B. Validity:

   C. Endorsement by SL Embassy:

10. Export Certificate (Page/Annex No)

   A. Issued by:

   B. Validity:

   C. Endorsement by SL Embassy:

11. GMP Certificate (Page/Annex No)

A. Issued by:

B. Validity:

C. Endorsement by SL Embassy:

12. Whether the product is having the Own Country Registration/If not reasons:

13. Whether the product is registered for free sale/use in other Countries:

14. Name of the Country/Countries where the product is registered for free sale (Page/Annex No):

15. Own standardization reports (Page/Annex No):

16. Independent standardization reports (Page/Annex No):

17. Approval obtained from Atomic energy Authority of Sri Lanka for radiation emitting devices (Page/Annex No):

18. Any requirement for special facilities, special training or particular qualifications for the use or maintenance of the veterinary device (If applicable):

19. Species Indicated:

20. Specimen of empty carton, label and pack insert (Page/Annex No):

21. Pack size and the number of samples submitted (It would be completed by annexing a copy of the VDCA's pre-clearance approval, after submission of the imported samples on Sample License issued by VDCA):

22. Method of disposal of unused/expired products (Page/Annex No):

23. Soft Copy (in 9 pen drives):

24. In case of a "New Test kit/Device" additional information is required on product information/pharmacology, methods of quantitative and qualitative analysis, adverse effects, human toxicity, safety to environment and relevant publications (New Test kit/Device is defined as one, which has not been used to a great extent or for a considerable period of time/New combinations or formulations).

25. Payment (Cheque or receipts No.):

26. Declaration by the applicant.

I make this application for registration of a veterinary product conscientiously believing the above to be true.

Suspension or withdrawal of an approval may be decided upon;

a. defective therapeutic/diagnostic effects or the product does not provide anticipated therapeutic/diagnostic results.

b. holder of the license is unable to supply the product for sale.

c. on request of the manufacturer or importer.

d. violation of any condition specified in the registration certificate/VDCA from time to time.

.....	.....
Signature of the applicant	Signature of the consultant
Name and the Official stamp	Name and the Official stamp
	with Reg: No.
Date:	Date:
.....	.....

Endorsed by, to produce for approval

.....

Dr (Mrs) A.P.Wickramasinghe

Registrar (C.U.D)/VDCA

REGISTRAR
Veterinary Drug Control Authority
Dept; of Animal Production & Health
Peradeniya

Animal Diseases Act No. 59 of 1992 & Regulations

Schedule.....

APPLICATION FOR RENEWAL OF FREE SALES REGISTRATION OF VETERINARY TEST KITS AND DEVICES IN SRI LANKA

FORM.....

1. Brand Name of the Test kit/Device:

2. Generic/Approved Name of the Test kit/Device:

3. Category of the Device:

4. Name, Address, E mail and Telephone No. of the Manufacturer:

5. Name, Address, E mail and Telephone No. of the Importer:

6. Name, Address, E mail and Telephone No. of the Local Agent:

7. Capacity/ Pack size:

8. First VDCA registration certificate (Page/Annex No):

9. Previous VDCA registration certificates (Page/Annex No):

10. Certified copies (Sri Lankan Embassy/High Commission) of free sales certificate, manufacturing certificate and GMP certificate. Certified original documents (excluding GMP Certificate) should be produced to the VDCA (Page/Annex No):

11. Other countries where the product is registered (Page/Annex No):

12. Own standardization reports (Page/Annex No):

13. Independent standardization reports (Page/Annex No):

14. Approval obtained from Atomic energy Authority of Sri Lanka for radiation emitting devices (Page/Annex No):

15. Species Indicated:

16. Method of disposal of unused/expired products (Page/Annex No):

17. Storage conditions and shelf life (Page/Annex No):

18. Quantities imported during last 3 years (pack size, quantity):

19. Information of sales during last 03 years (district, quantity):

20. Any changes of the product submitted for the previous registration:

21. Label/Carton/Pack insert:

22. Details of payment:

23. Declaration by the applicant:

I make this application for registration of a veterinary product conscientiously believing the above to be true.

Suspension or withdrawal of an approval may be decided upon;

a. defective therapeutic/diagnostic effects or the product does not provide anticipated therapeutic/diagnostic results.

b. holder of the License is unable to supply the product for sale.

c. on request of the manufacturer or importer.

d. violation of any condition specified in the registration certificate/VDCA from time to time.

.....	.....
Signature of the applicant	Signature of the consultant
Name and the Official stamp of the applicant	Name and the Official stamp with
	Reg: No:
Date:.....	Date.....

Endorsed by, to produce for approval.

.....

Dr (Mrs) A.P.Wickramasinghe

Registrar (C.U.D)/VDCA

REGISTRAR
y Drug Control Authority
imal Production & Health
Peradeniya