FOOD AND DRUGS AUTHORITY

APPLICATION FOR REGISTRATION OF VETERINARY SUPPLEMENT

To be submitted as two electronic copies (in pdf on CD-Roms)

CONFIDENTIAL

THE CHIEF EXECUTIVE OFFICER,
FOOD AND DRUGS AUTHORITY
P.O. BOX CT 2783
CANTONMENT-ACCRA
GHANA.
Fax:
Telephone:
Mobile:
Website: www.fdaghana.gov.gh

For FDA use only
Application Number:
Date of submission of the dossier:

PART 1 ADMNISTRATIVE INFORMATION		
1.0	Attach a cover letter	
1.1	Table of content	
1.2 Application Information		
1.2.1	Trade Name/Proprietary of the product	
1.2.2	Active Ingredients/Strength	
1.2.3	Dosage form	
1.2.4	Mode of administration of the product	
1.2.5	Target Species	
1.2.6	Primary Container	
1.2.7	Commercial presentation	
1.2.8	Proposed shelf life	
1.2.9	Proposed storage conditions	
1.2.10	Proposed storage conditions (after re-constitution or dilution where applicable)	
1.3 Name and address of Applicant		
	(Company) Name: Address: Country: Telephone: Telefax: E-Mail:	
1.4 Name and address of Manufacturer(s)		
	(Company) Name:	

	Address: Country: Telephone: Telefax: E-Mail:	
1.5 Name and address of local Agent		
	(Company) Name: Address: Country: Telephone: Telefax: E-Mail:	
1.6 Manufacturing and marketing authorization(s)/international registration status		
1.6.1	Valid Manufacturing authorization from the country of origin/ free sale certificate issued to finished product manufacturer by competent regulatory body (Imported products)	
1.6.2	Product marketing authorization issued by other national regulatory authority(ies) if registered in other countries	
1.6.3	Valid manufacturing contract agreement between the applicant and manufacturer (If applicant is different from manufacturer)	
1.7 Labeling Information & Product Samples		
1.7.1	Product information leaflet	
1.7.2	Product labels (Samples of Primary, Secondary and Tertiary labels)	
1.7.3	Samples of the product as per FDA sample schedule	
PART 2 QUALITY DOCUMENTATION		
2.0	Qualitative and quantitative composition of product	
2.1	Active ingredients specification and certificate of analysis	
2.2	Description of the manufacturing process of product finished	
2.3	Release specification for finished product	
2.4	Certificate of analysis of finished product	
2.5	Shelf life specification for finished product	

2.6	Protocol and report for accelerated stability study	
2.7	Protocol and report for long term stability	

DECLARATION BY AN APPLICANT

1. I/ we, the undersigned certify that all the information in this application form and accompanying documentation is correct, complete and true to the best of my knowledge.
2. I/ we further confirm that the information referred to in my application dossier is available for verification during current GMP inspection.
3. I/ we understand that the product shall not be imported, distributed for sale or advertised in Ghana until the product has been duly registered by the FDA.
4. I/ we also consent to the processing of information provided by the FDA.

Name: ……..…….
Position in the company:…….
Signature: ……..……
Date:……
Official stamp:……