FOOD AND DRUGS AUTHORITY

APPLICATION FOR REGISTRATION OF PHARMACEUTICAL VETERINARY PRODUCT

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

CONFIDENTIAL

THE CHIEF EXECUTIVE OFFICER,
FOOD AND DRUGS AUTHORITY
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CANTONMENT-ACCRA
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Fax:
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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 (Parts 1-3)	
1.2 Application Information		
1.2.1	Trade Name/Proprietary of the product	
1.2.2	Approved/International Non-proprietary Name (INN)/Generic name of the Active Pharmaceutical Ingredient (API)	
1.2.3	Strength	
1.2.4	Dosage form	
1.2.5	Route of administration of the product	
1.2.6	Target Species	
1.2.7	Pharmacological Classification	
1.2.8	Indication	
1.2.9	Container- closure system	
1.2.10	Commercial presentation	
1.2.11	Category of Distribution	
1.2.12	Proposed shelf life	
1.2.13	Proposed storage conditions	
1.2.14	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 Certificate of Pharmaceutical Product		
1.7 Manufacturing and Marketing authorization (s)/international registration status		
1.7.1	List of the countries in which product has been registered	
1.7.2	List of countries in which product has been withdrawn	
1.7.3	List of the countries where an application for marketing in any country has been rejected, suspended, deferred or is pending.	
1.8 Copy of Certificate of Suitability of the European Pharmacopoeia (CEP) including any annexes. (if applicable)		
1.9 Labeling Information & Product Samples		
1.9.1	Summary of Product Characteristics	

1.9.2	Product information leaflet		
1.9.3	Product labels (Samples of Primary, Secondary and Tertiary labels)		
1.9.4	Samples of the product as per FDA sample schedule		
PART 2 QUALITY DOCUMENTATION			
2.0	Drug master file of active pharmaceutical ingredient (To be submitted as per CTD format)		
2.1	Qualitative and quantitative composition of product (including excipients and their role in the formulation)		
2.2	Active ingredients specification and certificate of analysis		
2.3	Description of the manufacturing process of product		
2.4	Analytical Control Procedures (Control tests carried out at intermediate stages of the production process for finished product)		
2.5	Batch manufacturing records for one executed batch of finished product		
2.6	Release specification for finished product		
2.7	Certificate of analysis of finished product		
2.8	Shelf life specification for finished product		
2.9	Protocol and report for accelerated stability study		
2.10	Protocol and report for long term stability study		
PART 3 SAFETY & RESIDUE INFORMATION			
3.0	Material safety data for active ingredient(s)		
3.1	User safety information		
3.2	Environmental risk assessment report		
3.3	Residue data on active ingredients		

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 agree that the applicant will implement a Pharmacovigilance plan for this product in accordance with FDA requirements
5. I/ we also oblige to follow the requirements of the FDA Act, which are related to pharmaceutical products.
6. I/ we also consent to the processing of information provided by the FDA.

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