

**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

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| **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 |  |

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| **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: …………………………………………………………………………………… |