

**FOOD AND DRUGS AUTHORITY**

**ABRIDGED CTD APPLICATION FORM FOR REGISTRATION**

**OF PHARMACEUTICAL PRODUCT (SMALL SCALE)\***-

IMMUNOLOGICALTERINARY MEDICINAL PRODUCTS)

**TO BE SUBMITTED AS TWO ELECTRONIC COPIES (ON CD-ROMS)**

CONFIDENTIAL

THE CHIEF EXECUTIVE OFFICER,

FOOD AND DRUGS AUTHORITY

P.O. BOX CT 2783 CANTONMENT-ACCRA GHANA.

Fax: +233-302229794, 225502

Telephone: +233-3022333200, 235100

Website: www.fdaghana.gov.gh

|  |  |  |
| --- | --- | --- |
| Document Number:  |   | FDA/DRI/DER/AF-SSM/2019/12  |
| Date of First Adoption:  |   | October 10, 2019  |
| Date of Issue:  |   | October 15, 2019  |
| Version number:  |   | 01  |

 :

# MODULE 1- ADMINISTRATIVE INFORMATION

|  |  |
| --- | --- |
| 1.0  | Attach a cover letter  |
|   |   |
| 1.1  | Table of content of application(Attach table of content)  |
|   |   |
| 1.2  | **APPLICATION INFORMATION**  |
|   1.2.1  |  Approved/International Non-proprietary Name (INN)/Generic name of the Active Pharmaceutical Ingredient (API) & Source  |
|   |   |
|  1.2.2  |  Strength of API per unit dosage of the product  |
|   |   |
|  1.2.3  |  Dosage form  |
|   |   |
|  1.2.4  |  Route of administration of the product  |
|   |   |
|  1.2.5  |  Category of Distribution (OTC)  |
|   |   |
|  1.2.6  |  Indication  |
|   |   |
|  1.2.7  |  Container- closure system (Describe the packaging materials used for the finished product)  |
|   |   |
|  1.2.8  |  Commercial presentation  |
|   |   |
|  1.2.9  |  Shelf life\*\* (Limited to 12 months)  |
|   |   |
|   |   |
| 1.2.10  | Proposed storage conditions  |
|   |   |
| 1.2.11      | Name(s) and complete address of manufacturer (Company) Name: Address: Country: Telephone: E-Mail:  |
|   |   |
| 1.2.12      | Name and complete address of applicant (Company) Name: Address: Country: Telephone: E-Mail:  |
|   |   |
| 1.2.13       | Name and complete address of Distributor (Company) Name: Address: Country: Telephone: E-Mail:  |
|   |   |
|  1.2.14  |  Product labels (Samples of Primary, Secondary and Tertiary labels)  |
|   |   |
|  1.2.15  | Samples of the product as per FDA sample schedule  |

# 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 distributed for sale or advertised in Ghana until the product has been duly registered by the FDA.
4. I/ we also oblige to follow the requirements of the FDA Act, which are related to pharmaceutical products.
5. I/ we also consent to the processing of information provided by the FDA.

Name: …………………………………………………………………..……………………….

Position in the company:……………………………………………………………………….

Signature: …………………………………………………………………………….…………

Date:………………………………………………………………………………………………

Official stamp:……………………………………………………………………………………

**\*List of products for which this form is applicable is as follows:**

1. Mist Sennaco 7. Eusol Lotion
2. Mist Expect Sed 8. Hydrogen Peroxide
3. Mist Potassium citrate 9. Calamine Lotion
4. Ferric ammonium citrate 10. Gentian Violet
5. Methylated Spirit 11. Isopropyl Alcohol (70%)
6. Mist Magnesium Trisilicate 12. Mist Kaolin

**MODULE 2: CHEMICAL, PHARMACEUTICAL, NON-CLINICAL AND CLINICAL OVERVIEWS AND SUMMARIES**

***This section is not applicable for this application.***

# MODULE 3: CHEMICAL-PHARMACEUTICAL DOCUMENTATION

|  |  |
| --- | --- |
| 3.1  | **TABLE OF CONTENT**  |
|   |  |
| 3.2  | **BODY OF DATA**  |
|   |  |
| 3.2.S  | **PARTICULARS OF ACTIVE PHARMACEUTICAL INGREDIENT(S) DMF**  |
|  3.2.S.4.1  |  Active ingredients specification and certificate of analysis |
|   |  |
| 3.2.P  | **PARTICULARS OF FINISHED PHARMACEUTICAL PRODUCT(S)** **[FPP(S)]**    |
| 3.2.P.1  | **Description and Composition of the FPP(S)**   |
| 3.2.P.1.1  | Qualitative and quantitative composition of product (including excipients and their role in the formulation)  |
|   |   |
| 3.2.P.2  | **Pharmaceutical Development of the FPP(S)** **(This section is not applicable)**   |
|   |   |
| 3.2.P.3  | **Manufacture of the FPP(S)**   |
| 3.2.P.3.1  | Name and address of manufacturer   |
| 3.2.P.3.2  | Description of the manufacturing process  |
|   |   |
| 3.2.P.4  | **Control of Excipients for the FPP(S)**   |
|  3.2.2.4.1  |  Certificate of Analysis of Excipients  |
|   |   |
|  3.2.P.5  |  **Control of Finished Product**  |
|  3.2.P.5.1  |  Finished Product Specification  |
|  3.2.P.5.2  |  Method of Analysis of Finished Product  |
|  3.2.P.5.3  |  Certificate of analysis of the finished product  |
|    |    |
| 3.2.P.6  | **Reference Standards or Materials of the FPP(S)** **(This section is not applicable)**   |
|   |   |
| 3.2.P.7  | **Container Closure System of the FPP(S)**   |
|   | Description of Container– Closure- System  |
| 3.2.P.8  | **Stability of the FPP(S) (Applicable when shelf life is more than 12 months)**   |
|  3.2.P.8.1  |  Stability Summary Conclusion  |
|   |   |
|  3.2.P..8.2  |  Stability Protocol  |
|   |   |
|  3.2.P.8.3  |  Stability Data  |
|   |   |
|   |   |

# \*\*Shelf life can be extended beyond twelve (12) months upon submission of accelerated and long term stability data conducted under WHO Zone IVb conditions

|  |  |
| --- | --- |
|  3.2.R.1.1  |  Executed Batch Manufacturing Records  |

**MODULE 4: NON-CLINICAL STUDY REPORTS FOR NEW CHEMICAL ENTITIES ONLY**

***This section is not applicable for this application.***

# MODULE 5: CLINICAL STUDY REPORTS

***This section is not applicable for this application.***