National Agency for Food & Drug Administration & Control (NAFDAC)

Veterinary Medicines & Allied Products Directorate (VMAP)

GUIDELINES FOR INSPECTION OF FACILITIES FOR MANUFACTURE OF VETERINARY MEDICINAL COSMETICS IN NIGERIA

1. General

1.1. These Guidelines are for the interest of the general public and in particular manufacturers of Veterinary Medicinal Cosmetics in Nigeria.

1.2. It is necessary to emphasize that, no Veterinary Medicinal Cosmetics shall be manufactured, imported, exported, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provisions of NAFDAC Act CAP N1 (LFN) 2004, other related Legislations and the accompanying Guidelines.

Step I

2. Application for Inspection

2.1. Upon request for facility inspection from Registration and Regulatory Affairs Directorate, the following are required.

2.2. An application for inspection should be made on company's letter headed paper addressed to the Director-General (NAFDAC), ATTENTION: The Director, Veterinary Medicines & Allied Products Directorate (VMAP), 3rd Floor, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Express Way, Isolo, Lagos State.

The applicant should provide the exact location address (NOT P.O. Box), functional e-mail address and telephone number(s).

Step II

3. Procedure for payment

3.1. The application is reviewed to determine payment to be made.

3.2. Payment Advice for inspection and laboratory analysis is issued by NAFDAC desk officer.

3.3. Visit:

3.3.1. www.remita.net to generate Remita invoice and print out a copy of the invoice.

3.3.2. Any nearest commercial bank for payment.

3.3.3. NAFDAC Accounts Office to collect receipt of payment.

3.4. Attach photocopy of the receipt of payment to the application to be submitted.

Step III

Submission of Application

4. The reviewed application letter and two (2) sets of the under listed documents are submitted at Liaison Office of the Director (LOD), VMAP Directorate, 3rd Floor, NAFDAC Office Complex, Oshodi-Apapa Express Way, Isolo, Lagos State or any NAFDAC Office (outside Lagos).

4.1. Duly completed Registration form (obtainable on-line at www.napams.org)

4.2. Evidence of payment to the Agency

4.3. Evidence of Business Incorporation. In-case of Micro, Small and Medium Enterprises (MSMEs); evidence of Business name.

4.4. Evidence of registration of brand name/Evidence of Trade mark approval from the Federal Ministry of Commerce in Nigeria, done in the name of the owner of the trade mark.

4.5. Copy of organogram of the company

4.6. List of production and quality control equipment.

4.7. Comprehensive Certificate of analysis of the raw materials

4.8. Comprehensive Certificate of Analysis of the batch of product to be registered.

4.9. Certificate of analysis of the raw and treated water for production

4.10. Sample of Product labels

4.11. Appointment and acceptance letters of the technical officer/ production manager and Quality Control Manager including all credentials (Degree, NYSC certificates, etc.). The technical officer should have scientific background in drug and cosmetic production with minimum of Ordinary National Diploma; OND or its equivalent.

4.12. Appointment and acceptance letters of Superintendent Pharmacist or Veterinary Doctor including all credentials (Degree, NYSC certificates, etc.)

4.13. Evidence of medical Fitness certificate for technical staff

4.14. Retainership agreement with a Hospital/Clinic for periodic medical checkup of staff

4.15. Evidence of fumigation /pest control of premises (biannually)

4.16. Current premises license by Veterinary Council of Nigeria and or Certificate of Registration/ Retention of Premises by Pharmacist Council of Nigeria.

4.17. Valid Annual License of the Veterinary Doctor or Pharmacist's Annual License to Practice.

4.18. Site Master File (SMF) of premises

4.19. Dossiers of product in accordance with the Agency's approved format

4.20. Standard Operating Procedure (SOPs)

4.20.1. SOP for Production

4.20.2. SOP for Quality control

4.20.3. SOP for Cleaning, Sanitation and Maintenance

4.20.4. SOP for product recall and distribution

4.20.5. SOP for line clearance

Step IV

5. Scheduling of Inspection

5.1. Upon satisfactory vetting of the application, the date of the inspection is communicated to the company.

Step V

6. Inspection

6.1. The Inspection is conducted as scheduled. Where the Inspection is unsatisfactory a Compliance Directive is issued and communicated to the company.

6.2. For satisfactory Inspection, registration samples are taken at the end of the inspection for laboratory analysis while the summary inspection report is forwarded to Registration and Regulatory Affairs Directorate for further processing.

7. Tariff

7.1. Please refer to tariff section.

8. Labelling

8.1. Labelling shall be informative and accurate and in accordance with the Agency's Labelling Regulations and any other relevant Regulations.

8.2.

8.3. Minimum requirements on the package label:-

8.3.1. Name of Veterinary Medicinal Cosmetics (Common and/or brand name).

8.3.2. Name and full location address of the manufacturer.

8.3.3. Provision for NAFDAC Registration Number on product label.

8.3.4. Batch Number, Manufacturing date and Expiry date.

8.3.5. Dosage form & strength on the package.

8.3.6. Indications, frequency, route and conditions of administration.

8.3.7. Dosage regimen on the package.

8.3.8. Quantitative listing of all the active ingredients per unit dose.

8.3.9. Adequate warnings where necessary.

8.3.10. Net content of products.

9. Note

9.1. Failure to declare the presence of, and the specific active pharmaceutical ingredients (API) of a medicated cosmetics product during registration processes is a serious offence which may result in severe regulatory action.

9.2.

9.3.

9.4. Please note that the clock stops once Compliance Directives are issued.

All correspondence should be addressed to:

Director-General (NAFDAC)

Attn: The Director

Veterinary Medicine and Allied Product Directorate (VMAP), NAFDAC,

3rd Floor, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Express Way Isolo,

Lagos State.

NAFDAC website: www.nafdac.gov.ng

E-mail address: vmap@nafdac.gov.ng

Telephone Number: 01-4609756

All submissions should be made at the , VMAP, 3rd Floor, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Express Way Isolo, Lagos or the nearest NAFDAC Office (outside Lagos).