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

Veterinary Medicines & Allied Products Directorate (VMAP)

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

1. **General**

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

1.2. No Veterinary Cosmetics shall be manufactured, exported, imported, distributed, sold or used in Nigeria except 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 & Regulatory Affairs Directorate, the following are required.

2.2. An application for inspection should be made on the company's letter head paper to 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

4. **Submission of Application**

4.1. The reviewed application letter and two (2) sets of the under listed documents are submitted at the 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).

4.1.1. Duly completed Registration form filled on-line at www.napams.org and printed

4.1.2. Photocopy of receipt of payment

4.1.3. Certificate of business Incorporation of the applicant with Corporate Affairs Commission in Nigeria.

4.1.4. Certificate 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.

4.1.5. Copy of organogram of the company

4.1.6. List of Production and Quality Control equipment

4.1.7. Comprehensive Certificate of analysis of the raw materials

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

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

4.1.10. Product labels

4.1.11. Evidence of expired NAFDAC Registration Certificate (for product registration renewal)

4.1.12. Appointment and acceptance letters of the technical officer including all credentials (Degree, NYSC certificates, etc.). The technical officer should have scientific background with minimum of Ordinary National Diploma; OND or its equivalent.

4.1.13. Medical Certificate of Fitness for technical ad production staff

4.1.14. Retainership agreement with a Hospital/Clinic for periodic medical check-up of staff

4.1.15. Evidence of fumigation of premises/ factory

4.1.16. Standard Operating Procedure (SOPs)

4.1.16.1. SOP for Production

4.1.16.2. SOP for Quality Control

4.1.16.3. SOP for cleaning, sanitation and maintenance

4.1.16.4. SOP for product recall and distribution

4.1.16.5. SOP for receipt of raw materials

4.1.16.6. 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 Information**

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

8.2. The labelling requirements include:

8.2.1. Name of cosmetics (common and brand name) and descriptive name where applicable.

8.2.2. Name and full location address of the manufacturer.

8.2.3. Provision for NAFDAC Registration Number on product label.

8.2.4. Batch Number, Manufacturing date and Expiry date

8.2.5. Dosage form & strength on the package

8.2.6. Description of the method of usage (Mode of application)

8.2.7. Quantitative listing of all ingredients in descending order of in-going weight

8.2.8. Adequate warnings where necessary.

8.2.9. Net content of products

8.2.10. Storage conditions

8.3. 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 Office of the Director, VMAP, 3rd Floor, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Express Way Isolo, Lagos or the nearest NAFDAC Office (outside Lagos).