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

Veterinary Medicines & Allied Products Directorate (VMAP)

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

1. General

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

1.2. No Veterinary drugs shall be manufactured, exported, 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 1

2. Application for Inspection

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

2.1.1. An application letter on the company's letter head paper for Facility Inspection addressed to the DIRECTOR-GENERAL (NAFDAC), ATTENTION: The Director, Veterinary Medicines & Allied Products Directorate, 3rd Floor, NAFDAC Office Complex, Oshodi-Apapa Express Way Isolo, Lagos State.

2.1.2. The application letter should include 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 to submitted at the Liaison office of the Director (LOD), VMAP Directorate, 3rd Floor, NAFDAC Office Complex, Oshodi-Apapa Expressway, Isolo, in Lagos or the NAFDAC office in other States.

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

4.1.2. Evidence of payment

4.1.3. Evidence Letter of Recognition issued after Pre-Production Inspection

4.1.4. Evidence of Business Incorporation of the importing company with the Corporate Affairs Commission in Nigeria.

4.1.5.

4.1.6. 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.

4.1.7. Copy of organogram of the company

4.1.8. List of Production and Quality Control equipment

4.1.9. Comprehensive Certificate of analysis of the raw materials

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

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

4.1.12. Product labels

4.1.13. Evidence of expired NAFDAC Registration License (for product registration renewal)

4.1.14. Letters of employment, acceptance and credentials of the Key Technical Officers (Production manager and Quality control Manager who shall be a scientist with knowledge of drug production.

4.1.15. Letters of employment, acceptance and credentials of Superintendent Pharmacist or Veterinary Doctor

4.1.16. Evidence of current Medical Certificate of Fitness for technical and production staff (biannual)

4.1.17. Retainer-ship agreement with a Hospital/Clinic for periodic medical checkup of staff

4.1.18. Evidence of fumigation/ pest control of premises/ factory (quarterly)

4.1.19. Evidence of valid Premises Retention License for the facility by Pharmacist Council of Nigeria and license by Veterinary Council of Nigeria.

4.1.20. Copy of valid Annual License to practice for the Superintendent Pharmacist issued by Pharmacists Council of Nigeria /Veterinary Doctor.

4.1.21. Site Master File (SMF) of premises

4.1.22. Dossiers of product in accordance with the Agency approved format

4.1.23. Standard Operating Procedure (SOPs)

4.1.23.1. SOP for Production

4.1.23.2. SOP for quality control

4.1.23.3. SOP for cleaning, sanitation and maintenance

4.1.23.4. SOP for product recall and distribution

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 to the company. 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 medicine (brand name) where applicable and generic name.

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

8.2.6. Indications, frequency, route and conditions of administration

8.2.7. Dosage regimen (for OTC/GSL)

8.2.8. Leaflet insert

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

8.2.10. Appropriate Warnings

8.2.11. Net content of products.

8.2.12. Indicate if POM-Veterinarian, POM-Veterinarian, Pharmacist and Suitably Qualified Person, Non Food Animal-Veterinarian, Pharmacist and Suitably Qualified Persons (NFA-VPS) or Authorized Veterinary Medicine-General Sales List (AVM-GSL).

9. Note

9.1. Any special claims made must be substantiated.

9.2. An application for registration does not confer registration status on the product.

9.3. Failure to respond to concerns (CD) raised by NAFDAC on the application, will automatically lead to delay in further processing of the application.

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

All correspondence should be addressed to:

Director-General (NAFDAC)

ATTENTION: The DirectorVeterinary 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).