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

Veterinary Medicine & Allied Product Directorate (VMAP)

GUIDELINES FOR INSPECTION OF FACILITIES

FOR THE MANUFACTURE MEDICATED IN

NIGERIA

1. **General**

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

1.2. It is necessary to emphasize that, no medicated feed 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.

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-head paper addressed to **The Director General,** National Agency for Food and Drug Administration and Control (NAFDAC) ATTN: The Director, Veterinary Medicines & Allied Products Directorate, Plot 1, 3rd Floor, 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 :**

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's 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 in Lagos or the nearest NAFDAC office in other States.

4.2. Duly completed Registration form to be filled on line at www.napams.org and printed.

4.3. Evidence of payment to the Agency

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

4.5. 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.

4.6. Copy of organogram of the company

4.7. List of production and quality control equipment

4.8. Comprehensive Certificate of analysis of the raw materials

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

4.10. Product labels

4.11. Expired License (for product registration renewal)

4.12. Letter of employment and credentials of technical/production manager and Quality control manager who shall be a scientist with knowledge of drug/feed production/compounding with a minimum qualification of OND or its equivalent.

4.13. Letter of employment and credentials of Superintendent Pharmacist or Veterinary Doctor

4.14. Passport photographs of all key Officers

4.15. Medical certificate of fitness (biannual)

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

4.17. Evidence of current fumigation/pest control of premises (quarterly)

4.18. Retainership agreement with a fumigation company for periodic fumigation

4.19. Current premises license by Veterinary Council of Nigeria and or Pharmacist Council of Nigeria.

4.20. Annual License of the Superintendent Pharmacist/Veterinary Doctor.

4.21. Site Master File (SMF) of Premises

4.22. Product Dossiers

4.22.1. In a Compact Disc (CD).

4.22.2. Searchable Portable Document Format (pdf).

4.22.3. Common Technical Document (CTD) format

4.23. Standard Operating Procedure (SOPs)

4.23.1. SOP for Production

4.23.2. SOP for Quality Control

4.23.3. SOP for Cleaning, Sanitation and Maintenance

4.23.4. SOP for Product Recall and Distribution

4.23.5. SOP for receipt of Raw materials

4.23.6. 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 to the company.

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

7. **Tariffs**

7.1. Please refer to ariff 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 Medicated Feed Stuff (MFS) (common/generic name and

8.3.2. Name and full location address of the Manufacturer.

8.3.3. Provision for NAFDAC Registration Number (or NAFDAC Reg. No. :)

8.3.4. Batch Number, Manufacturing date and Expiry date.

8.3.5. Storage condition

8.3.6. Dosage form

8.3.7. Quantitative listing of all ingredients.

8.3.8. The name and strength of the active ingredient(s) in mg/kg

8.3.9. Appropriate Warnings.

8.3.10. Net Content

8.3.11. The type of VMPs or SFAs used must be stated on the label

8.3.12. Directions for use, including reconstitution, where applicable

8.3.13. Methods of handling

8.3.14. Withdrawal Period

8.3.15. The Toll Manufacturer's name, address and Listing number should be indicated where applicable

8.3.16. Nutritional Information (for products with nutritional claims)

9. **Note**

9.1. Failure to declare the presence of, and the specific active Pharmaceutical Ingredient (API) in Feed, Feed Additives and Pre-mixture pharmaceutical ingredients (API) during registration processes is a serious offence which may result in severe regulatory action.

9.2. Any Medicated Feed product whose name, package or label bears close resemblance to an already registered product or is likely to be mistaken for such registered product, shall not be considered for registration.

9.3.

9.4.

9.5.

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.

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