



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

Veterinary Medicines & Allied Products Directorate (VMAP)

GUIDELINE FOR ISSUANCE OF PERMIT TO IMPORT FIELD TRIAL SAMPLES

1. General

- 1.1. This Guideline is for the interest of the general public and in particular companies that want to conduct field trial on products for registration purpose.
- 1.2. It should be emphasized that no Fertilizers, Bio-fertilizers, Pesticides, Bio-pesticides or Premixes shall be manufactured for commercial purpose, imported, exported, distributed, sold or used in Nigeria except it has been subjected to field trials at approved Institute and monitored by the Agency in accordance with the provisions of NAFDAC Act CAP N1 (LFN) 2004, other related Legislations and the accompanying Guidelines.

Step 1

2. Application

- 2.1. The application letter 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 application should state the product name, active ingredient(s), pack size, Name and Address of the manufacturer and the institution to conduct the trial

- 2.2. The following documents are to be attached to the application;
 - 2.2.1. Evidence of Business Incorporation. For Micro, Small and Medium Enterprises (MSMEs); evidence of Business name.
 - 2.2.2. Certificate of Analysis of the product stating the batch number, manufacturing Date and Expiry Date.
 - 2.2.3. Material Safety Data Sheet (MSDS)
 - 2.2.4. Certificate of Product Registration in the country of Origin
 - 2.2.5. Proposed Protocol for the Field Trial.

Step II

3. Review of submitted documents

- 3.1. A check on all documents submitted is carried out using the checklist.

Step III

4. Payment

- 4.1. When all necessary documents are submitted, a Payment Advice is issued to the company.

Step IV

5. Review of Documentation & Issuance of Permit to Import

- 5.1. Upon satisfactory review of documentation, the Permit to Import is issued to the company.

6. Labelling Information

- 6.1. Labeling should be informative and accurate and in accordance with the Agency's Labelling Regulations and any other relevant Regulations.
- 6.2. The labelling requirements include:
 - 6.2.1. That the product is for field trial purpose only and is not for sale or human use.
 - 6.2.2. Name of product (brand name where applicable) must appear in bold
 - 6.2.3. Batch number, date of manufacture and expiry date.
 - 6.2.4. Net content (per unit volume or weight)
 - 6.2.5. The ingredients listed by their common names and quantitatively in order of their predominance by weight
 - 6.2.6. The directions for use, safe disposal of the primary packaging material
 - 6.2.7. Storage conditions

7. Tariffs

- 7.1. Please refer to Tariff section

8. Note

- 8.1. Applicants are advised to inform NAFDAC of the commencement of the experimental/efficacy trials through a Letter of Invitation for officers to visit the trial site.
- 8.2. The trial should be carried out according to the approved protocol for experimental/efficacy trial.
- 8.3. At the conclusion of the experimental /efficacy trials, a detailed report shall be submitted to the Agency for consideration.
- 8.4. The company shall bear the expenses for the trials.
- 8.5. For imported products, a legal Local Representative resident in Nigeria shall make the application.
- 8.6. 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).