

APPLICATION FORM FOR REGISTRATION OF FOOD/DIETARY SUPPLEMENTS

1.0 Details of the applicant

1.1 Details of the authorised representative in Kenya

2.0 Particulars of the dietary/food supplement product

2.1 Proprietary name

2.2 Approved / INN / generic name

2.3 Strength

2.4 Dosage form

2.5 Visual description of the Product

2.6 Commercial Pack sizes of the product

2.7 Labelling

2.8 Information leaflet

2.9 Registration status in the country of origin and other countries

2.10 Proposed shelf life and storage conditions

2.11 Particulars of the manufacturer(s) and activity.

3.0 Technical information

3.1 Composition of the product

3.2 Suitability of the product as a dietary supplement

3.3 Raw material specifications

3.4 Details of the procedures involved in the various stages of manufacture

3.5 Summarised specifications of the final product

3.6 Specifications of the packaging material

3.7 Stability data of the product

3.8 safety requirements for borderline products

5.0 Post market surveillance plan of the food supplement in the Kenyan market

6.0 References

Declaration

- a) I, the undersigned certify that all the information in this application form and accompanying documentation is correct, complete and true to the best of my knowledge.
- b) I further confirm that the information referred to in my application dossier is available for verification during current GMP inspection.

- c) I agree that the undersigned has not marketed or advertised this product in Kenya and will follow the PPB requirements for advertisements of food/dietary supplements
- d) I agree that the undersigned will implement a Pharmacovigilance plan for this product in accordance with PPB requirements
- e) I agree that I am obliged to follow the requirements of the Pharmacy and Poisons Act, which are related to food/dietary supplements.
- f) I consent to the processing of information provided to the Pharmacy and Poisons Board.

Name:

Position in the company:.....

Signature:

Date:.....

Official stamp:.....