

DRUG

NATIONAL  **AUTHORITY**

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**GUIDELINES for REGULATION of FOOD/DIETARY
SUPPLEMENTS in UGANDA**

Version 5, March 2009

LIST OF ACRONYMS

DS	Dietary Supplement (Can be used interchangeably with NS – referring to Nutritional Supplement)
FAO	Food and Agriculture Organization
INN	International Non-proprietary Name. (Internationally recognised non-proprietary name of such a product or Name of the active substance or such other name as the NDA may determine).
NDA	National Drug Authority
WHO	World Health Organization

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**GUIDELINES for REGULATION of FOOD/DIETARY SUPPLEMENTS in
UGANDA
(Version 4, August 2007)**

1.0 GENERAL

These guidelines apply to all Dietary Supplements other than Conventional Pharmaceutical Products, Biological Products, Traditional medicinal products, diagnostic aids, medical appliances and public health chemicals.

Definition:

A food/Dietary Supplement; is a product taken by mouth which contains a dietary ingredient intended to supplement the diet.

- 1.1 All documents are to be submitted typewritten or computer printed in ENGLISH. Where originals are in another language, copies shall be presented together with certified English translations.
- 1.2 Each complete application must contain a complete index to the various appendices and each page of the application dossier must be numbered.
- 1.3 A prescribed application fee shall accompany each complete application form. Subsequent applications to amend any part of the application shall be accompanied by a prescribed fee per change and guidelines on submission of amendment applications shall be followed.

A fee shall be charged annually to retain the nutritional product on the notification list.

- 1.4 Notification procedures shall commence only if the application form with its appendices has been properly completed. Only the information required in the appendices should be furnished.
- 1.5 All documents shall be addressed to:

The Executive Secretary / Registrar,
National Drug Authority, Plot 46-48 Lumumba Avenue
PO Box 23096, Kampala, UGANDA

Phone: (+256) 41-255665 / 347391/ 347392
Fax: (+256) 41-255758
E-mail: ndaug@nda.or.ug

- 1.6 Payment of fees can be made by Bank Transfer to:

National Drug Authority Account no: 0240060034201
Stanbic Bank Uganda Limited, Kampala

or by bank draft in favour of National Drug Authority

- 1.7 All Dietary/Food Supplements marketed in Uganda have to be notified before they are sold and distributed.

2.0 APPLICANT

- 2.1 Application for the notification of a Dietary/Food Supplement shall be made only by:
 - the patent holder
 - the manufacturer
 - a distributor authorised by the manufacturer or patent holder

- an authorised Local Technical Representative (LTR) of the manufacturer or patent holder (see section 5 below)

The name, physical address, telephone number, fax number, and e-mail address of the applicant shall be provided.

3.0 PARTICULARS OF THE DIETARY/FOOD SUPPLEMENT PRODUCT

- 3.1 **Proprietary name** means the (trade or brand) name which is **unique** to a particular Dietary Supplement Product and by which it is generally identified (and by which it is registered in the country of manufacture).
- 3.1.1 All Dietary/Food Supplements shall be notified as per their proprietary Name. The Proprietary Name should not be derived from INN name and should not have an INN stem.
- 3.1.2 If derived from Generic Name should not be similar to the Generic Name.
- 3.1.3 Each dosage form and strength will require a unique Proprietary Name.
- 3.1.4 Each Name used should be distinctive in sound and in writing not to be confused with Names of other Products.
- 3.1.5 The Name should not be misleading e.g. use Protavit for product not containing implied micro or macronutrient. Names which lead to self-diagnosis in conditions requiring professional diagnosis will be considered as misleading.
- 3.1.6 The use of "Umbrella/Brand Naming" is not acceptable, each product type should have it's own unique Name.
- 3.1.7 Any Phrase that implies superiority, speed or better performance over other products shall not be allowed.
- 3.1.8 Meaning of abbreviations, symbols, alpha-numerals must be explained in a covering letter.
- 3.1.9 A proprietary name should not carry prescription information unless otherwise backed with a strong scientifically proven report that support the connotation.
- 3.1.10 When the Name being applied for is identical or very close to already registered Name, applicant shall be advised to change to another Name.
- 3.1.11 Proprietary Names shall not be reserved for applications that have not been yet received.
- 3.2 **Approved / INN / generic name** in relation to a Dietary/Food Supplement means the internationally recognised non-proprietary name of such a product or Name of the micro or macro active or such other name as the NDA may determine.
- 3.3 **Strength** shall be given per unit dosage form or per specified quantity: e.g. mg per tablet, mg per capsule, mg/mL, mg per 5mL spoonful, mg per G, etc.
- 3.4 **Dosage form** shall mean the form in which the Dietary Supplement is presented, e.g. solution, suspension, Tablet, emulsion, Capsules, Sachet, etc.
- 3.5 **Description of the Product** shall mean a full visual description of the Dietary Supplement including colour, size, shape and other relevant features, e.g. 'Orange and white gelatin capsule with marks "Provit", or 'pink film-coated tablets with word "Haemforte" embossed on one side' etc.

3.6 **Labelling:** The applicant shall ensure that the primary (immediate) packaging of the product is labelled according to the law applicable in Uganda. The following minimum information shall be required in English on the label of the immediate packaging:

- (i) brand name where appropriate
- (ii) International non-proprietary name/generic name where it is applicable
- (iii) quantity of active ingredient per dosage unit and % of the Recommended Dietary Allowances (RDA) of each ingredient per dosage unit.
- (iv) total packed quantity in a unit pack.
- (v) date of manufacture
- (vi) date of expiry
- (vii) batch number
- (viii) storage conditions
- (ix) name and address of manufacturer

Due to lack of space, the date of manufacture, address of the manufacturer and storage conditions may be omitted on the primary container if it is a blister or strip pack.

The name of the manufacturer may be substituted with a trade-mark or other symbol. However these details shall appear in full on the secondary packaging.

3.7 **Information leaflet:** Applicants should be encouraged to include Scientific Package Inserts in Dietary Supplements Packs. Package Inserts will ensure that supplements are safely and effectively used under normal conditions of use.

Package inserts should not carry promotional statements and make comparison of its product to other products.

In case of changes in the Scientific package information leaflet after product has been registered, NDA should be notified.

The leaflet shall include the following minimum information:

- i) Proprietary Name
- ii) Approved INN/Generic Name if it's applicable
- iii) Identification: Brief description of the physical appearance of the product.
- iv) Presentation: Dosage form and total quantity presented per unit pack e.g. MI, GM, Number of Tablets e.t.c.
- v) Composition of product's active ingredients, stating name of each active ingredient and content in a unit dose.
- vi) Name of the preservative and unit quantity per dose added into the product.
- vii) Name of Anti-oxidants and unit quantity per dose added into the product.
- viii) Quantity of total alcohol contained in Dietary Supplement products for human consumption.
- ix) Warning in block letters "CONTAINS TARTRAZINE" if tartrazine was added to preparations for human consumption.
- x) Approved Name of any other inactive ingredients contained in the formulation.
- xi) Nutritional benefit of the dietary supplement. The stated nutritional claims must be to educate the users and must not be for promotional purposes.
- xii) Dosage and directions for use:
 - a) indicate dosages and dosage intervals
 - b) dosage regimens for children
 - c) contraindications
 - d) precautions in pregnancy, lactation, renal and hepatic failure etc
 - e) Side effects and Special precautions
 - g) symptoms and treatment of over dosage
 - h) Storage instructions

- i) Shelf-life
- j) name and address of the manufacturer

3.8 **Trade Marks and logos:** Infringements on Trade marks or logos are the concern of the applicant and not NDA.

4.0 PARTICULARS OF THE MANUFACTURER(S) AND ACTIVITY

The name, physical address, telephone number, fax number, and e-mail address of the manufacturer shall be provided.

Where different activities of manufacture of a given product are carried out at different manufacturing sites, the above particulars shall be provided for each site and the activity carried out at the particular site shall be stated as in the examples below.

	Name	Address	Activity
1.	UgaPharma	Plot 4, City Rd, Kampala PO Box 5445, Kampala, Uganda Tel: 222207	Granulation
2.	T.M. Pharmaceuticals	Plot 73, Government Avenue, Nairobi PO Box 3459, Nairobi, Kenya Tel: 222218	Compression Coating
3.	Goodman Limited	GLN, 13LT, London, UK Tel: 235 898 491	Packing

A copy of a valid manufacturing licence shall be provided for each site.

5.0 AUTHORISED REPRESENTATIVE IN UGANDA

A body corporate (company) authorised to handle nutraceuticals or dietary supplements, shall be the applicant's local representative in Uganda with legal authorisation to take full responsibility for the product on behalf of the applicant, and will be answerable to NDA.

This body corporate shall be called the **Local Technical Representative (LTR)**. A copy of the legal authority given to the representative or agent shall be enclosed. Such a body may be:

A business entity dealing in dietary supplements, supervised by a Scientist with an appropriate qualification in Chemistry, Biochemistry, Pharmacy, Nutrition or Food Science or as defined by the Authority.

6.0 SIGNATORY

The signatory shall be a qualified personnel working for and/or authorised by the manufacturer / applicant. The designation and qualification of the qualified personnel shall be stated.

7.0 APPENDIX 1 (Specifications of Packaging Materials & Product Composition)

7.1 SPECIFICATIONS OF THE PACKAGING MATERIAL

The following information shall be provided:

- a) A general description of the container and closure system including primary (inner) and secondary (outer) packaging materials used.
- b) Specifications for primary (immediate) packaging components such as: glass containers, plastic containers, rubber closures.
- c) Evidence of suitability of the container and closure system for the finished product and proof of compatibility of primary packaging components with finished product.

7.2 COMPOSITION OF THE PRODUCT

State the approved / INN /generic name(s) of the active and inactive ingredients in the dietary supplement. Trade names shall not be used.

State quantities of each ingredient per unit dose e.g. mg/tablet, mg/mL, etc.

Where applicable state the Reference text or Reference to official specifications for each ingredient e.g. BP 2004 page 111.

State reason for inclusion of each inactive ingredient in the dietary supplement.

7.3 SUITABILITY OF THE PRODUCT AS A DIETARY SUPPLEMENT

For a product to qualify as a nutritional or dietary supplement, should be conform to the definition of dietary supplement stated in this guideline and in addition should meet the following requirements;

- i. There should not be any medicinal or therapeutic claims in relation to use of the product for treatment or averting of a disease condition.
- ii. The product should not contain any drug substances that are listed one of the Schedules in the National Drug Policy and Authority Statute Cap. 206.
- iii. The product should not contain any substance of known pharmacological activity.
- iv. The recommended overall intake in a day for each micro or macro nutrient content should not be above 200% of each nutrient's RDA's or above acceptable upper tolerable daily intake levels.

(Table for commonly used dietary ingredients and their RDA is provided in Annex II).

8.0 APPENDIX 2 (Chemistry and manufacturing aspects)

8.1 Raw material specifications

Raw material specifications and certificates of analysis shall be given.

Copies of the supplier's or manufacturer's Certificates of Analysis shall be supplied for each raw material as proof of conformance to all declared specifications.

8.2 Details of the procedures involved in the various stages of manufacture, including packaging shall be given. This shall be in the form of a detailed flow diagram.

8.3 Summarised specifications of the final product shall be given, ie. the acceptable limits of all the physical, chemical, biological and (where applicable) microbiological parameters. A full description of analytical and other control procedures carried out to ascertain the final product specifications stated above shall be given.

The Finished product specification should include the following tests;

- 1) Tests for all dietary supplement dosage forms**
 - a) Description
 - b) Identity - test method should be specific for active ingredient(s)
 - c) Assay - test method should be specific and stability indicating for active ingredient(s)
 - d) Impurity limits - to determine the level of degradation products of active ingredients, and active ingredient-exciipient interaction impurities.
- 2) Additional tests for hard gelatin capsules and tablets**
 - a) Dissolution (for relatively water insoluble active ingredients)
 - b) Disintegration (for readily soluble active ingredients)
 - c) Hardness & friability
 - d) Uniformity of weight / uniformity of content
 - e) Water content
 - f) Microbial limits
- 3) Additional tests for oral liquids**
 - a) pH
 - b) Microbial limits
 - c) Antimicrobial preservative content/ preservative efficacy test
 - d) Antioxidant preservative content
 - e) Extractables from primary container
 - f) Alcohol content
 - g) Dissolution of suspensions
 - h) Particle size distribution
 - i) Redispersibility
 - j) Specific gravity
 - k) Water content

All tests should be performed unless development pharmaceuticals studies or process validation prove that they are unnecessary. Such proof should be provided in the application dossier.

9.0 APPENDIX 3 (Registration Status in other countries)

- 9.1 Applicant should provide a registration certificate or authorization to market the product as Dietary supplement in the country of manufacture. (If a dietary supplement is not registered in country of manufacture, a valid explanation must be given)
- 9.2 A copy of the manufacturing licence of the manufacturer shall be provided.

10.0 APPENDIX 4 (of Form NDA: R1)

- 10.1 References to literature shall be precise, quoting the year of publication and the relevant page(s). Photocopies of relevant literature may be attached.
- 10.2 A minimum of two samples of the final product for each package size being applied for must be provided in the form in which it shall appear on the market.

11.0 MONITORING AND CONTROL OF DIETARY SUPPLEMENTS

- 11.1 Each consignment of Nutritional Supplements that is imported into Uganda shall be inspected at the port of entry by NDA Inspectors for physical attributes and only notified dietary supplements shall be accepted.
- 11.2 Each batch of every consignment shall be accompanied by an authenticated certificate of analysis that states;
- i). Name of the food Supplement
 - ii). Batch Number
 - iii). Manufacturing date
 - iv). Packaging Date if different from Manufacturing date
 - v). Expiry date
 - vi). Identification for each micronutrient
 - vii). Assay for each micronutrient
 - viii). Impurity tests
 - ix). Specific tests for applicable dosage form e.g. DT, Uniformity of weight, Friability tests for tablets and pH, viscosity, wt/ml for oral liquid dosage forms.
 - x). Tests for microbial limits
 - xi). Certification that all Excipients used are food grade.
- 11.3 The inspector at the port of entry shall ensure that Dietary supplements are properly labelled with the following minimum labelling requirements.
- Name of the Supplement.
 - quantity per pack.
 - date of manufacture
 - date of expiry
 - batch number
 - storage conditions
 - name and address of manufacturer
 - Direction for usage
 - Name of added nutrients, quantities added per serving dose and % of the added quantity of each nutrient to their RDA values.
- 11.4 Consignments that are of suspected quality shall be sampled for testing at the National Drug Quality Control laboratory (NDQCL) and tested at the Importer's cost. Dietary Supplement batches that fail tests of analysis shall be rejected.

REFERENCES AND RESOURCE LIST:

1. *Guidelines for the registration of Orthodox Medicines in South Africa. Version 5.*
2. A Food Labeling Guide; Reference Values for Nutrition Labeling.
(www.cfsan.fda.gov/~dms/flg-7a.html).
3. Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline.
http://books.nap.edu/execsumm_pdf/6015.pdf.
4. Overview of Dietary Supplements. <http://www.cfsan.fda.gov/~dms/ds-oview.htm> .
5. Dietary Reference Intakes (DRIs): Recommended Intakes for Individuals, Vitamins.
http://www.iom.edu/Object.File/Master/21/372/DRI%20Tables%20after%20electrolytes%20plus%20micro-macroEAR_2.pdf.

1. Fees for dietary supplements notification:

Description	Amount (US\$)
1. New application – imported Human DS	\$500
2. Annual retention – imported Human DS	\$200
3. New application – imported Vet DS	\$300
4. Annual retention – imported Vet DS	\$120
5. New application – Local Human/Vet DS	\$50
6. Annual retention – Local Human/Vet DS	\$20

* DS – Refer Dietary Supplement

2. Amendment Fees (Nutritional Supplements):

Description	Amount (US\$)
A. Amendments for imported Human DS	
1. Change in formulation (Inactive)	\$250
2. Extension of shelf life	\$100
3. New scientific information /literature	\$100
4. Finished product specification	\$100
5. Trade name change	\$50
6. Change in name of manufacturer	\$50
7. Additional pack size	\$50
8. Pack design	
- Primary pack	\$25
- Secondary pack	\$25
9. Change in packing material	\$50
10. Additional accessories	\$25
11. Change of label design	\$25
12. Change of licence holder	\$250
B. Amendments for imported Vet DS (dietary supplements)	60% of the above fees
C. Amendments for locally produced DS (dietary supplements)	Can be exempted

* DS – Refer Dietary Supplement

Annex II: Table of Dietary ingredients & their RDA values

The table below lists some of the most common dietary ingredients with their recommended dietary intake (RDA) values and acceptable maximum daily intake limits as a dietary supplement.

Name of Nutrient	RDA	Acceptable maximum daily intake	Targeted Nutritional benefit
ACETYL CYSTEINE	250 mg	500 mg	Powerful anti-oxidant and cell detoxification co-factor, NAC works to eliminate your body of free radicals and heavy metals.
BETA CAROTENE	5000 IU (of Vitamin A); (3 mg of β -carotene)	10000 IU (of Vitamin A) (6 mg of β -carotene)	Converted to Vitamin A. Acts a tissue anti-oxidant, helping to maintain healthy cells.
BIOTIN	300 μ g	600 μ g	Functions as a Co-enzyme in the metabolism of carbohydrates, fats and proteins.
BORON	*	*	Influences cell membrane structure and function
CALCIUM	1000 mg	2000 mg	Maintenance of healthy bones and teeth. Essential for enzyme activation, nerve impulse transmission and muscle contraction
CHLORIDE	3400 mg	6800 mg	Essential for maintenance of acid/base balance of body fluids. Also influential in the conservation of potassium, which is inefficiently resorbed by the body
CHOLESTEROL	300mg	300mg	Required in small quantities for production of many hormones, vitamin D and bile acids that help to digest fat.
CHROMIUM	200 μ g	400 μ g	Enhances insulin function as glucose tolerance factor
COPPER	2 mg	4 mg	For proper use of iron & haemoglobin in the body. Required for connective tissue formation & oxidation
DIETARY FIBRE	25g	50g	Prevents and relieves bowel problems such as constipation, haemorrhoids, diverticular disease, and irritable bowel syndrome; improve cholesterol levels in the blood; reduces risk of heart disease and risk of diabetes
FLUORIDE	4 mg	8 mg	Component of VitB12. Promotes development of red blood cells.
FOLATE (AS FOLIC ACID)	400 μ g	800 μ g	Required for metabolic reactions during cell division and for regeneration of blood & cells
IODINE	150 μ g	300 μ g	Essential component of Thyroid hormone.
IRON	18 mg	36 mg	Required for maintenance of healthy red blood cells for transport of oxygen.
MAGANESE	2 mg	4 mg	Required for enzymes involved in energy metabolism, bone formation, fat synthesis
MAGNESIUM	400 mg	800 mg	Required for protein synthesis, glucose metabolism and for smooth muscle contraction
MOLYBDENUM	75 μ g	150 μ g	Works with riboflavin in enzymes involved in carbohydrate & fat metabolism.
PANTOTHENIC ACID	10.0 mg	20 mg	Involved in metabolism of fats, proteins & glucose into energy. Helps to maintain healthy skin & mucous membranes.
PHOSPHORUS	1000 mg	2000 mg	Helps to maintain healthy bones. Required for energy metabolic reactions in cells.
POTASSIUM	3500	7000 mg	Involved in muscle contraction, cell development, nerve stimulation, food metabolism, critical for normal functioning of the heart & kidneys
PROTEIN (TOTAL PROTEIN)	56 g	112 g	For building and repair of body tissues.
SATURATED FATTY ACIDS	20g	40g	Involved in cell wall formation and tissue repair.
SELENIUM	70 μ g	140 μ g	Cofactor of glutathione peroxidase and antioxidant enzyme. Works with vitamin E as an antioxidant
SODIUM	2400 mg	4800 mg	Required to regulate blood pressure & blood volume. Also critical for functioning of muscles & nerves
TOTAL CARBOHYDRATES	300g	600g	Metabolised to provide energy. Excess is converted to fat & stored in fat deposits
TOTAL FAT	65g	130g	Used in synthesis of nerve cells & hormones. Excess is stored as an energy reserve (Adipose tissue).
VITAMIN A (RETINOL)	5000 IU; (1500 μ g)	10000 IU; (3000 μ g)	Maintains epithelial tissue in skin and mucous membranes. Required for maintenance of good vision, healthy skin, nails and hair.
VITAMIN B12 (CYANOCOBALAMIN)	6.0 μ g	12.0 μ g	Required for the production of red blood cells. Helps to maintain proper function of nervous system.
VITAMIN B2 (RIBOFLAVIN)	1.7 mg	3.4 mg	Helps to maintain healthy skin. Involved in energy production from protein, fat & carbohydrates.
VITAMIN B3 (NIACIN/ NICOTINAMIDE)	20 mg	40 mg	Involved in protein metabolism and for converting of fats & carbohydrates into energy.

Annex II: Table of Dietary ingredients & their RDA values

Name of Nutrient	RDA	Acceptable maximum daily intake	Targeted Nutritional benefit
VITAMIN B6 (PYRIDOXINE HCL)	2.0 mg	4.0 mg	Helps to maintain healthy skin. Involved in energy production from protein, fat & carbohydrates.
VITAMIN B1 (THIAMINE HCL)	1.5 mg	3.0 mg	Required for release of energy from glucose & transforming of carbohydrates into fat. Required for maintenance of healthy nerve functions.
VITAMIN C (ASCORBIC ACID)	60 mg	120 mg	Forms collagen, required for maintenance of healthy gums, skin & connective tissue. Enhances absorption of Iron from food. Acts as a tissue anti-oxidant, hence helping in maintaining healthy cells.
VITAMIN D3 (CHOLECALCIFEROL)	400 IU; (10.0 µg)	800 IU; (20.00 µg)	Required for maintenance of healthy bones & teeth, controls the utilization of calcium in the body.
VITAMIN E (α- TOCOPHERYL ACETATE)	30 IU	60 IU	Tissue anti-oxidant, protects Vitamin A & un-saturated fatty acids against oxidation in the body.
VITAMIN K3 (MENADIONE)	80 µg	160 µg	For production of blood clotting factors
ZINC	15 mg	30 mg	Cofactor of many enzymes involved in energy metabolism, protein synthesis, immune functions, sexual maturation, sensation of taste & smell.

* RDA value for this item has not been defined