	Title: GUIDELINES FOR THE REGISTRATION OF NUTRITIONAL AGENTS	
Rev No: 02	**Doc No: PBSL/GL/030**	Version no. 03
Issue date: 15 May 2024	**Effective date: 17 May 2024**	Approved by: Registrar

Adopted By PBSL	
Start of public Consultation	
End of public Consultation	
Agreed by QMS committee	
Approved by Board	

Pharmacy Board of Sierra Leone,

PMB 322

Central Medical Stores Compound

New England Ville

Freetown

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ACKNOWLEDGEMENTS

EXECUTIVE SUMMARY

1.0 INTRODUCTION

In pursuance of Section 44 of the Pharmacy and Drugs Act, 2001, these Guidelines are hereby developed to provide information, guidance and strict compliance by all concerned on the procedure and requirements for the registration of nutritional agents in Sierra Leone. These guidelines are applicable to all nutritional agents for use in humans as well as for veterinary use, where applicable.

Nutritional agents form an essential component of life, in that it provides humans and other life forms with nutrients to help support growth, and subsequently improve on the quality of life. Nutritional agents must be of good quality, safe, effective and manufactured in premises that comply with the requirements of current good manufacturing practices (cGMPs). An appropriate regulatory framework is, therefore, required to ensure that these are adequately assured.

This guideline describes the requirements for registration of nutritional agents and explains how applications are made to the PBSL for such registration.

2.0 OBJECTIVE

This guideline has been designed to assist in the following;

- Provide guidance on the technical and other general data requirements for the registration of cosmetic and household chemicals by the Pharmacy Board of Sierra Leone.
- To help facilitate the processes and procedures involved in the registration of cosmetics and household chemicals.
- Promote effective and efficient processes for the evaluation of these applications and the subsequent issuance of Marketing Authorization.

3. SCOPE

In pursuance of Section 44, of the Pharmacy and drugs Act 2001, this guideline is made to provide guidance to applicants on the procedure for registering nutritional agents in Sierra Leone. Applicants are encouraged to familiarize themselves with this document and the above law before completing the registration form.

4.0 SPECIFIC REQUIREMENT

4.1. GENERAL REQUIREMENTS

Registration

a. An application for the registration of nutritional agent shall be made in writing.

b. An application form shall be completed in accordance with the sequence of appendices

dated, signed and stamped by the applicant/license holder. All certificates

accompanying registration documents shall be submitted in English.

c. This shall be submitted in duplicate (hard and (or) soft copy) and accompanied by:

I. A covering letter addressed to the Registrar of the Authority,

II. Samples of the product as specified in the Authority's samples Schedule packed in the

final package ready for sale.

III. A non-refundable fee prescribed in the Authority's approved fees Schedule.

Variation

a) An application for the variation of registration of a product prior to re-registration shall be made to the Authority. This variation shall be approved by the Authority before any importation of the product shall be made into the country.

b) The application shall be accompanied by:

I. Supporting documentation for the variation.

II. Samples reflecting the variation as specified in the Authority's samples Schedule.

III. Non-refundable variation fee as specified in Authority's approved fees Schedule.

Re-Registration

a. An application for the re-registration of a Herbal medicinal product should be made 3 (three) months before the expiration of the registration.

b. The application shall be accompanied by:

I. Supporting documentation for any changes since the product was last registered

II. Samples as specified in the Authority's Sample Schedule.

III. A non-refundable application fee as specified in the Authority's Fee Schedule.

The re-registration shall be approved by the Authority before any importation of the product, other than those used as samples for the purpose of this application, shall be made into the country.

4.2. SPECIFIC REQUIREMENTS

The presentation of the product shall not have any resemblance in spelling and pronunciation of name or packaging to another product that has been previously registered by the Authority.

All samples of oral liquid preparations (solutions, syrups) shall have an appropriate graduated plastic measure included in the final package.

All samples submitted shall conform to labelling regulations in force in Sierra Leone (Refer to Pharmacy Board of Sierra Leone Guidelines for Labelling of Products).

If the product is manufactured on contract basis, evidence of the contract shall be submitted. This information shall be clearly stated on the product label and package insert.

Stability study reports, performed under the conditions specified below shall be submitted:-

a) WHO Zone IV B climatic conditions

Condition	Accelerated	Real Time
Storage Temperature	40 + 2°C	30°C
Relative Humidity	75 + 5 %	70 %
Duration	6 months	Until end of shelf life

b) The stability study shall be conducted in the container closure system in which it will be marketed in Sierra Leone

4. The Authority in considering an application:

a) Shall satisfy itself that the there is need to have the product registered in Sierra Leone.

b) Reserves the right to conduct a Good Manufacturing Practice (GMP) audit inspection

on the manufacturing facility for the product at a fee prescribed by the Authority.

c) May ask the applicant to supply such other information as may be required to enable

it reach a decision on the application.

I. An appeal for the review of an application may be made in writing to the Pharmacy Board of Sierra Leone within four (4) weeks of receipt of any rejection notice.

II. Where the Authority is satisfied that there is the need to register a product and all requirements for its registration have been satisfied, it shall do so and issue to the applicant a certificate of registration, subject to such conditions as may be prescribed by the Authority from time to time.

III. The registration of a product under these regulations, unless otherwise revoked, shall be valid for a period of three (3) years and may be renewed.

IV. No information given in this application shall be disclosed by the Pharmacy Board of Sierra Leone to a third party except:-

a) With the written consent of the Marketing Authorization Holder; or

b) In accordance with the directive of the PBSL; or

c) For the purpose of a legal process under the Pharmacy and Drugs Act, 2001

4. The Authority shall cancel, suspend, or withdraw the registration of a product if:-

a. The grounds on which it was registered is later found to be false; or
b. The circumstances under which it was registered no longer exist; or
c. Any of the provisions under which it was registered has been contravened; or
d. The standard of quality, safety and efficacy, as prescribed in the documentation for registration is not being complied with; or
e. The premises, in which the product or part thereof is manufactured, packaged or stored by or on behalf of the holder of the certificate of

registration is unsuitable for the manufacture, packaging or storage of the food/nutritional supplement.

f. Where the registration of a food/nutritional supplement is suspended, withdrawn or cancelled, the Authority shall cause the withdrawal from circulation of that product and shall accordingly cause the suspension, cancellation or withdrawal to be published in the Gazzette.

4. GLOSSARY

In this guideline, unless the context otherwise states: -

"Authority" means Pharmacy Board of Sierra Leone

"Product" means – a food, dietary or nutritional supplement

"Applicant" means the product owner or licence holder. Representatives of licence holders may not hold themselves as applicants unless they own the product.

"Food/Dietary or Nutritional Agent" means - concentrated sources of nutrients or other substances produced in a pharmaceutical dosage form such as tablets, gelatine capsules (soft or hard), sachets, syrups and powders. Dietary components include herbs, vitamins and minerals (with concentration less than the recommended daily allowance), natural oils, royal jelly, pollen and bee propolis. All these ingredients can be included in dietary supplements on the condition that their sole function is supplementation and improvement of body function.

"Medicinal Purpose" means - use for treating or preventing a disease, diagnosing or ascertaining the presence and extent of a physiological function, contraception, inducing anesthesia, altering normal physiologic function permanently or temporarily in any way in humans.

"Variation" means - a change in the indication(s), dosage recommendation (s), drug classification and/or patient group(s) for a previously registered drug being marketed under the same name in Sierra Leone. A variation also includes, but is not limited to, a change in the product name site of manufacture and/or source of ingredients.

6.0 REFERENCES

1. Guidelines for the registration of food/dietary supplements for Uganda.
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/6014.pdf.
4. Overview of Dietary Supplements. http://www.cfsan.fda.gov/~dms/ds-oview.htm .
4. 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.

6. Institute of Medicine of the National Academics in USA; The Food and Nutrition Board. http:www.iom.edu

7.0 ANNEXES

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