RWANDA FDA
Rwanda Food and Drugs Authority
P.O. Box 1948 Kigali
info@rwandafda.gov.rw
www.rwandafda.gov.rw

APPLICATION FORM FOR REGISTRATION OF DOMESTICALLY MANUFACTURED HIGH RISK FOODS FOR GENERAL PURPOSES

New/renewal application:
(Fill in product registration number if renewing)**.....**

1.0 Particulars of food

1.1 Brand Name/Trade Name/Trade Mark: .....

1.2 Common name/Product Name: .....

1.3 Brief description of the physical characteristics of the food (form, colour etc.): .....

.....

1.4 Intended end user (infants, young children, pregnant women, immune compromised, old age, diabetic or general population). State any other conditions or contraindications if any:

.....

1.5 Type of materials for the packaging container and liner if any (Describe primary, secondary and tertiary packaging material where applicable): .....

.....

1.6 Type of materials for closure /cap/crown/seal and liner if any: .....

1.7 Retail packaging unit in weight, volume, or number: .....

1.8 Shelf life (month)/where applicable: .....

1.9 Shelf life after opening of container if applicable: .....

1.10 Precautions for use: .....

.....

1.11 Important Notice: ……..……..

.....

1.12 Instructions for use:.....

.....

1.13 Recommended storage conditions before opening: .....

1.14 Recommended storage conditions after opening if applicable**:** .....

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1.15 Standard used in the manufacture of the product: .....

.....

2.0 Particulars of manufacturer

2.1 Name (company/person): .....

2.2 Name of the country where the company was incorporated: .....

2.3 Postal Address: .....

2.4 Physical address (country, town/city, street Plot No: .....

.....

2.5 Phone: .....

2.6 Fax: ….....

2.7 E-Mail: .....

3.0 Particulars of the Trade Mark Holder/If Applicable

3.1 Name (company/person): .....

3.2 Name of the country where the company was incorporated: .....

3.3 Postal Address: .....

3.4 Physical address (country, town/city, street Plot No: .....

.....

3.5 Phone: .....

3.6 Fax: ….....

3.7 E-Mail: .....

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4.0 Raw materials, Ingredients & Additives used

List of raw materials, ingredients and/or additives in descending order of proportion, quantities per unit of the food and purpose of use

4.1 Raw Materials

S/N	Name	Proportion (e.g. %, ppm, unit/mass or volume)	Purpose of use
01			
02			
03			
04			
05			
06			
07			
08			
09			
10			

4.2 Ingredients & Additives

S/N	Name	Proportion (e.g. %, ppm, unit/mass or volume)	Purpose of use
01			
02			
03			
04			
05			
06			

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07			
08			
09			
10			

5.0 Certification by the applicant

I, ……

The…… (Position in the company) and a duly authorised representative of ……..... do hereby certify that all the information filled in this form and all the accompanying documents are true and correct to the best of my knowledge and confirm that the information referred to in this application is available for proof.

Signature: ……

Date: ……

Official Stamp/Seal: ……

……

For official use only

Name of receiving officer: ……

Date: ……

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NOTES:

- **Important Notice**: Means an annotated model that grant, warn or impede the user by a conveying notice that aims to explain a usefulness information to the beneficiaries/consumer.

- **Instructions for use:** Means a defined prolific information of the food product on its label as a technique, user manual, video, written and/or pictorial information accompanying a food product to inform the user about the appropriate and safe use of that particular food product.

- **HIGH RISK FOODS FOR GENERAL PURPOSES;** Milk and milk products, Meat and meat products, Fish and fish products, Eggs and eggs products, Spices, Soups, Sauces, Salads, Processed vegetables and vegetable products, Ready to eat savouries, Composite foods, Potable water, herbal tea, hibiscus blossom tea.

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CHECKLIST OF SUBMITTED APPLICATION DOCUMENTS

LIST OF REQUIRED DOCUMENTS	Mandatory/Optional	Provided (Yes/No)
An application letter requesting for product registration addressed to the DG of Rwanda FDA.	**Mandatory**	
A duly filled Application form	**Mandatory**	
Proof of payment for product's registration (Consider the regulation governing service fees, Tariff and Fines that can be found on www.rwandafda.gov.rw , publications window in the Technical Regulations Portal) to one of Rwanda FDA's accounts highlighted on the bottom of the Authority's website.	**Mandatory**	
Premise license issued by Rwanda FDA	**Mandatory**	
Certificate of Company/Business Registration from RDB	**Mandatory**	
Certificate of Mark Registration from RDB	**Mandatory**	
Notarised mutual agreement when a Trademark holder is not the manufacturer	**Mandatory where applicable**	
Credentials of the production manager (Academic qualifications, training certificates, and his/ her work contract showing the duties, etc.)	**Mandatory**	
A production Flow Chart with detailed description of the method of preparation, mentioning the quality and quantity of the starting materials used, manufacturing formula, critical control points, Quality Control Steps, specifications at each stage with processing conditions, packaging instructions and labelling procedures.	**Mandatory**	
Hazard Analysis and Critical Control Points (HACCP) review reports /Plan in case no safety certificate such as ISO, HACCP, FSSC is available	**Mandatory**	

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Test Reports or Certificates of Analysis that shows the critical parameters performed by any recognised laboratory (respective to the sample batches submitted for registration), it shall include Tested Parameters, Tested Results, and Acceptable Limits as per the product applicable standard.	**Mandatory**	
A Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE) free certificate, if the raw material is from animal source and contains; gelatine, magnesium stearate, lactose etc. (where applicable)	**Mandatory where applicable**	
Stability Study report showing how you determined the shelf life; this must be conducted on three consecutive batches and on the declared storage temperature. The report shall have a study protocol, conditions, and results at regular intervals	**Mandatory**	
In-Use Stability Study report	**Optional**	
A Copy/ Mock-up of the current label.	**Mandatory**	
Two sample of the product packaged in the final package ready for the market or two mock samples	**Mandatory**	
Any other conformity such as HACCP, ISO, FSSC, Etc.	**Optional**	
Proof of application for GMP inspection with proof of payment. The fee is prescribed in the Regulation Governing Rwanda FDA Service fees, Tariff and Fines	**Mandatory**	

Note: Note: The application dossiers are submitted via email at info@rwandafda.gov.rw and samples are submitted to the Reception of Rwanda FDA Headquarters.