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 LOW RISK FOOD

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 Instructions for use: .....

.....

1.10 Recommended storage conditions before opening: .....

.....

1.11 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: .....

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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: .....

4.0 Ingredients & Additives used

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

4.1 Ingredients

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

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04			
05			
06			
07			
08			
09			
10			

4.2 Additives

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

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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: ……..…….....

NOTES

- **LOW RISK FOODS:** Fats and oils, Edible ices, Flours, Processed fruits and fruits products, Confectionaries, Coffee, Tea, Cocoa and their products, Cereals and cereals products, Bakery wares, sweeteners, Non-alcoholic beverages, Alcoholic beverages, Salts and salts substitutes, Vinegars.

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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 licensing issued by Rwanda FDA for Local Technical Representative or distributer warehouses	**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**	

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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**	
Hazard Analysis and Critical Control Points (HACCP) review reports /Plan	**Mandatory**	
Hazard Analysis and Critical Control Points (HACCP) Certificate	**Optional**	
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**	
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**	
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 certificates	**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.