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 IMPORTED HIGH RISK FOODS FOR GENERAL PURPOSES

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

1.0 Particulars of packaged product

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): .....

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**:** .....

.....

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

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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: .....

4.0 Particulars of Local Technical Representative (LTR)/If applicable

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

4.2 Name of the country where the company was incorporated (Provide registration certificate):

.....

4.3 Physical address (plot/block No./street/Village/Sector/District/Province/City: .....

4.4 Postal Address: .....

4.5 Country of origin (food to be imported): .....

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4.6 Telephone: ……..….

4.7 Fax: ……...……...

4.8 E-Mail: ….....

4.9 Name of the would be importer (in case the importer is not the local representative): ……....

.....

5. 0 Ingredients and Additives used

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

5.1 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			

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5.2 Ingredients & Additives

S/N	Name	Proportion of use	Purpose of use
01			
02			
03			
04			
05			
06			
07			
08			
09			
10			

6.0 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: ……

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For official use only

Name of receiving officer: ….....

Date: …….....

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 requirements	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 displayed at the bottom of the Authority's website.	**Mandatory**	
A Notarized Power of Attorney from the manufacturer/Market Authorization Holder (MAH) giving the permission to Local Technical Representative (LTR) to apply for product registration with Rwanda FDA on their behalf.	**Mandatory where applicable**	
If the applicant is the Manufacturer/MAH, the latter shall provide a letter appointing the LTR	**Mandatory where applicable**	
Notarised mutual agreement when a Trademark holder is not the manufacturer		
Business registration certificate from Rwanda Development Board (RDB) for LTR	**Mandatory**	
Premise licensing by Rwanda FDA for LTR or warehouses	**Mandatory**	
Valid Manufacturing License in the country of origin	**Mandatory**	
Proof of registration/approval from regulator in the country of origin, or any other valid international certificate of food safety management such as GMP, ISO, HACCP, FSSC, etc.	**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**	
A certificate/ report of analysis for showing critical parameters testing	**Mandatory**	

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Stability study showing how shelf life (for products that have expiry dates) was determined	**Optional**	
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**	

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