

REQUIREMENTS FOR APPLICATION FOR REGISTRATION OF IMPORTED HIGH RISK FOOD

Note:

- Payment of product registration fees shall be made through iRIMS system based on the system generated proforma invoice;
- Three samples of the product packaged in the final package ready for the market shall be provided at Rwanda FDA head office reception, Nyarutarama, Kigali;
- Application for GMP inspection by Rwanda FDA is a mandatory requirement and it shall be made through iRIMS system.

High risk foods: Food supplements, infant formula, follow on formula, follow up formula, complementary food, food intended for special medical purpose, food for weight control, processed milk and milk products, processed meat and meat products, processed fish and fish products, processed eggs and eggs products, spices, soups, sauces, processed vegetables and vegetable products, ready to eat savories, composite foods, packaged water for direct human consumption.

LIST OF REQUIRED DOCUMENTS	Mandatory/Optional
Premises license issued by Rwanda FDA for the Local Technical Representative's warehouse.	Mandatory
A Notarized Power of Attorney from the manufacturer/Marketing Authorization Holder (MAH) appointing the Local Technical Representative (LTR).	Mandatory where applicable
Notarised mutual agreement when a Trademark holder is not the manufacturer.	Mandatory where applicable
Valid Manufacturing License of the manufacturer from the country of origin.	Mandatory
Valid international certificate of food safety management such as GMP, ISO, HACCP, FSSC, etc.	Optional
A detailed Process Flow Chart.	Mandatory
Test Reports or Certificates of Analysis that shows the critical parameters performed by any recognised laboratory, it shall	Mandatory



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include Tested Parameters, Tested Results, and Acceptable Limits as per the product applicable standard.	
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
Any genuine scientific research to support any structural or functional claim on the product label.	Mandatory for food supplements and food for weight control
BSE, TSE free certificate if the raw material is from animal source And contains gelatin, magnesium stearate.	Mandatory for food supplements
Radiation free certificate, GMO free certificate, health certificate/ veterinary certificate, dioxin free certificate, melamine free certificate.	Mandatory for infant formula, follow on formula, follow up formula
Any other food safety management certificates.	Optional

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