



**GUIDELINES FOR REGISTRATION AND LICENSING OF
FOOD PREMISES**

RWANDA FDA
Rwanda Food and Drugs Authority

FEBRUARY, 2022

GUIDELINE DEVELOPMENT HISTORY

| | |
|---|--------------------|
| DRAFT ZERO | 07/05/2019 |
| ADOPTION BY RWANDA FDA | 13/05/2019 |
| STAKEHOLDERS CONSULTATION | 13/05/2019 |
| ADOPTION OF STAKEHOLDERS' COMMENTS | 13/05/2019 |
| REVISION N°: 0 | 13/05/2019 |
| REVISION N°:1 | 29/09/2021 |
| STAKEHOLDERS CONSULTATION | 08/11/2021 |
| ADOPTION OF STAKEHOLDERS' COMMENTS | 12/11/2021 |
| EFFECTIVE DATE | 20/ 02/2022 |

DOCUMENT REVISION HISTORY

| Date of revision | Revision number | Changes made and/or reasons for revision |
|-------------------------|------------------------|--|
| 07/05/2019 | 0 | Guideline for registration and licensing of food premises. |
| 14/09/2021 | 1 | <ol style="list-style-type: none"> 1. Chapter I was amended by adding the scope, the classification of food premises and the products regulated by Rwanda FDA. 2. Chapter II is renamed APPLICATION LICENSING & INSPECTIONS instead of Licensing Requirements 3. Chapter 5. The administrative sanctions and fines were added. 4. Formats of operational license as well as updated requirements for premises licensing are added. |

RWANDA FDA
Rwanda Food and Drugs Authority

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

FOREWORD

Rwanda Food and Drugs Authority (RWANDA FDA) is a regulatory body established by Law N° 003/2018 of 09/02/2018. One of the functions of RWANDA FDA is to regulate matters related to quality and safety of food for the purpose of protecting the public from health hazards associated with consumption of unsafe food, as stated in Article 3 (13).

The achievement of this goal depends on the awareness and adherence to the law by all key players dealing with products regulated under the Law N° 47/2012 of 14/01/2013 relating to the regulation and inspection of Food and Pharmaceutical Products in its Article 3 (paragraph 1 and 2) stipulates the modalities for registration of premises and licensing of food business respectively.

All dealers in the food business should prioritize consumer's health, thus take reasonable steps to ensure that the food supplied to the community is safe, of good quality, and ensure that premises for manufacturing, storage, distribution and selling are well constructed, secured and maintained in a way that the safety and health of consumers is assured. All premises involved should be registered with Rwanda FDA.

These guidelines are developed to provide guidance on application requirements for premises registration and licensing. Any dealers involved in manufacturing, storing, import or export, sale, packaging, distribution, supply, transport of food will be able to prepare the required application documents in line with the requirements of these guidelines and therefore minimize unnecessary queries. Implementation of these guidelines will therefore speed up provision of quality service to the clients.


Dr. Emile BIENVENU
Director General



RWANDA FDA
Rwanda Food and Drugs Authority

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

TABLE OF CONTENTS

GUIDELINE DEVELOPMENT HISTORY1

TABLE OF CONTENTS3

ABBREVIATIONS AND ACCRONYMS.....5

DEFINITION OF TERMS.....6

CHAPTER 1. INTRODUCTION8

1.1. SCOPE8

1.2. CLASSIFICATION OF FOOD PREMISES.....8

1.2.1. FOOD MANUFACTURING FACILITIES8

1.2.2. FOOD OUTLETS8

1.2.2.1. WHOLESALERS OF FOOD PRODUCTS8

1.2.2.2. RETAILERS OF FOOD PRODUCTS8

1.3. FOOD PRODUCTS REGULATED BY RWANDA FDA9

CHAPTER 2. APPLICATION REQUIREMENTS FOR PREMISE REGISTRATION AND OPERATIONAL LICENSE.....10

2.1. GENERAL APPLICATION REQUIREMENTS10

2.2. TYPES OF APPLICATIONS10

2.2.1. NEW APPLICATION FOR PREMISE REGISTRATION10

2.2.2. RENEWAL FOR PREMISE REGISTRATION10

2.2.3. VARIATION OF REGISTERED PREMISE11

2.2.4. RE- INSPECTION OF FOOD PREMISE11

2.3. REQUIREMENTS FOR NEW PREMISE LICENSING11

2.3.1. PREREQUISITE TO APPLY FOR REGISTRATION AND LICENSING OF FOOD MANUFACTURING PREMISES11

2.3.2. REQUIREMENTS TO APPLY FOR REGISTRATION AND LICENSING OF FOOD MANUFACTURING PREMISES12

2.3.3. LICENSE TO OPERATE A WHOLESALE OF FOOD PRODUCTS.....13

2.3.4. LICENSE TO OPERATE A RETAIL OF FOOD PRODUCTS.....13

2.3.5. LICENSE TO OPERATE A RESTAURANT AND RELATED FOOD BUSINESSES..13

2.3.6. LICENSE TO OPERATE A WHOLESALE OR RETAIL OF FOOD SUPPLEMENTS AND/OR INFANT FORMULA SHOP BUSINESSES.....14

2. 4. RENEWAL OF PREMISE LICENSE15

2.5. VARIATION OF REGISTERED PREMISE15

2.6. REJECTION OF APPLICATION.....16

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

| | |
|---|-----------|
| CHAPTER 3. INSPECTION OF PREMISES FOR SUITABILITY | 17 |
| 3.1. LOCATION OF PREMISES FOR FOOD PREMISES | 17 |
| 3.2. BUILDING DESIGN OF PRODUCTION AREAS..... | 17 |
| 3.3. FOOD EQUIPMENT, UTENSILS AND FOOD CONTACT SURFACE | 18 |
| 3.4. PERSONNEL | 18 |
| 3.5. STORAGE FACILITIES..... | 18 |
| 3.6. SANITATION AND HYGIENE..... | 19 |
| 3.7. DOCUMENTATION AND RECORD KEEPING | 19 |
| 3.8. REGULAR WATER SUPPLY | 19 |
| 3.9. CONTAINERS TO BE CLEANED | 20 |
| 3.10. DESCRIPTIVE MATERIALS TO BE KEPT SECURE..... | 20 |
| 3.11. FIRE-FIGHTING EQUIPMENT..... | 20 |
| 3.12. WEIGHING, MEASURING, TESTING AND RECORDING EQUIPMENT TO BE CHECKED..... | 20 |
| 3.13. QUALITY CONTROL AREAS | 20 |
| 3.14. RECALLS, REJECT AND WITHDRAWAL OF PRODUCTS | 20 |
| 3.15. REGULATORY ACTIONS..... | 21 |
| CHAPTER 4. ADMINISTRATIVE SANCTIONS AND FINES | 22 |
| REFERENCES..... | 23 |
| ANNEXES | 24 |
| ANNEX 1. LIST OF REQUIREMENTS FOR PREMISE REGISTRATION AND LICENSING OF FOOD PREMISES | 25 |
| ANNEX 2. APPLICATION LETTER FORMAT AND APPLICATION FORM FOR PREMISE REGISTRATION AND LICENSING OF FOOD PREMISES..... | 33 |
| ANNEX 3. FORMAT OF PREMISE INSPECTION REPORT | 36 |
| ANNEX 4. NARRATIVE REPORT FORMAT..... | 38 |
| ANNEX 5. FORMATS OF LICENSES | 41 |
| END OF THE DOCUMENT | 46 |

RWANDA FDA
Rwanda Food and Drugs Authority

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

ABBREVIATIONS AND ACCRONYMS

Rwanda FDA: Rwanda Food and Drugs Authority

RDB: Rwanda Development Board

RCA: Rwanda Cooperative Agency



RWANDA FDA
Rwanda Food and Drugs Authority

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

DEFINITION OF TERMS

The following definitions are given for the purpose of these guidelines:

“**Authority**” means RWANDA FOOD AND DRUGS AUTHORITY, or the acronyms Rwanda FDA established under the Law N^o 003/2018 of 09/02/2018.

“**Business**” includes professional practices and any activity carried on by a person or a body of persons in relation to products regulated under this Law N^o 47/2012 of 14/01/2012

“**Director General**” means the Chief Executive of the RWANDA FOOD AND DRUGS AUTHORITY appointed under Article 7 of the Law N^o 003/2018 of 09/02/2018

“**Equipment**” mean machines, instrument, apparatus, utensil, or appliance, other than a single use item, used or intended to be used in or in connection with food handling and include any equipment used to or intended to be used to clean food.

“**Food**” means any item other than pharmaceutical, cosmetic and tobacco used as food or drink for human beings and includes any substance used in manufacture or treatment of food.

“**Food manufacturing facilities**” means premises where operations involve production, preparation, and processing, formulating, filling, refining, transformation packing, packaging, or re-packaging of food.

“**Food outlets**” means premises where food is stored, sold, distributed, displayed for sale, or exhibited

“**Handling**” includes the making, processing, producing, collecting, extracting, processing, storing, transporting, delivering, preparing, treating, preserving, packing, cooking, thawing, serving, or displaying of food.

“**Inspector**” means any officer appointed, authorized or recognized under the Law N^o 003/2018 of 09/02/2018.

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

“**Premises**” includes building structures, basements, and vessels and in relation to any building including part of a building and any cartilage, forecourt, yard or places of storage used in connection with the building or part of that building and in relation to a vessel means ship, boat, aircraft and includes a carriage or receptacle of any kind.

“**Sell**” means sell by wholesale or retail and include import, offer, exhibit, keep, expose, display, transmit, consign, convey or deliver for sale or authorize, direct or allow a sale, or prepare or possess for the purpose of sale and batter or exchange supply or dispose of to any person whether for a consideration or otherwise.



| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

CHAPTER 1. INTRODUCTION

1.1. SCOPE

This guideline shall be used for submission of documentation for registration and licensing of food premises. It describes the types of applications of food premises and food products regulated by Rwanda FDA, the minimum licensing requirements for registration, the procedures for approval and refusal of application, renewal of registration and variation of registered food premises, general requirements of any premise and administrative sanctions and penalties.

1.2. CLASSIFICATION OF FOOD PREMISES

Food premises are classified in two major categories namely facilities for food manufacturers premises, and food outlets which includes wholesalers and retailers of food products.

1.2.1. FOOD MANUFACTURING FACILITIES

Rwanda FDA classifies food manufacturing facilities based on production capacity. The criteria of classifying large scale and small-scale food manufacturing facilities are determined by national food value chain actors.

1.2.2. FOOD OUTLETS

Rwanda FDA classifies food outlets according to their plant size, the source of goods, the quantity of food products and their role in the supply chain of food products.

1.2.2.1. WHOLESALERS OF FOOD PRODUCTS

These are food businessmen conducting business ideally in bulks of food products from manufacturers and/or distributors; store them in warehouses prior to reselling to other businesses especially retailers. Wholesalers include food importers, food distributors and food warehouses. Any wholesaler involved in manufacturing/restaurant activities will be considered as a manufacturer/ restaurant.

1.2.2.2. RETAILERS OF FOOD PRODUCTS

These are food dealers that sell processed food products from wholesalers and resell directly to consumers as the end-user for consumption and not for resale. They encompass supermarkets, canteens, boutiques, kiosk, food catering, drop shipping and any other of the kind.

In this category, we also find food processing facilities that process food preserved for short-term /or cooked food with a short shelf life and sell directly to consumers.

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

These include hotels kitchen, restaurants, snack bars, cafeteria, smoothies, milk shop, drinking water shop, public barbeques, food truck/van, street food vendors and any of the kind. Any retailer involved in wholesale/manufacturing activities will be considered as a wholesaler or a manufacturer.

1.3. FOOD PRODUCTS REGULATED BY RWANDA FDA

In reference to Law N° 003/2018 of 09/02/2018, Rwanda FDA has been mandated to regulate processed foods, fortified foods, food supplements and animal feeds.

Processed foods are defined as food products transformed from their original state to extend/prolong their shelf life, packaged, labeled complying to all specified standards, and ready for consumption. In other words, any food other than a raw agricultural commodity that has been subjected to processing including but not limited to canning, cooking, freezing, dehydration, and milling or changed in nutritional composition with fortifying, preserving or preparing in a different way.

A list of main processed foods includes but not limited to:

- a) Cereals and cereal products (maize flour, rice, wheat flour, ...)
- b) Alcoholic beverages (beer, wine, liquors etc....)
- c) Non-alcoholic beverages (soft drinks, juice etc. ...)
- d) Drinking water
- e) Coffee and tea products
- f) Milk and milk products (fermented milk, yogurt, ...)
- g) Bakery products and pastries (bread, donuts, ...)
- h) Processed meat products and fish products
- i) Animals feeds
- j) Edible salt, sweeteners, honey, and confectionaries
- k) Fats and oils
- l) Spices, soups, sauces, salads and proteins, processed vegetables, processed fruits
- m) Infant formulae, complementary foods for infants
- n) Food supplements
- o) Cooked food

Any organization or company intended to manufacture/process, store, distribute and retail any food falling into these categories or any food product which will be defined by Rwanda FDA shall request authorization.

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

CHAPTER 2. APPLICATION REQUIREMENTS FOR PREMISE REGISTRATION AND OPERATIONAL LICENSE

2.1. GENERAL APPLICATION REQUIREMENTS

2.1.1. Any organization, a company or individual, who intends to do business related to processed food for human and animal consumption either production, packaging/re-packaging and labeling, storage, and distribution shall apply for registration of premise and license of carrying out such a food business.

2.1.2. In order to adhere to the legal requirements, the applicant has to follow the instructions prescribed in these guidelines. These guidelines are available from RWANDA FDA headquarter office or via the official website of Rwanda FDA.

2.1.3. All applications should be sent to Rwanda FDA via the electronic system.

2.1.4. An application for premise registration either processing facility or food outlet shall be made according to the details provided below;

2.2. TYPES OF APPLICATIONS

For the purposes of submission of premises registration dossier to Rwanda FDA, applications are classified into four categories as follows:

2.2.1. New application for premise registration

New application is any application requesting for registration in Rwanda FDA for the first time with intention to open a food premise. Such license has a validity of one year. The premise license grants the authorization to manufacture food products but does not translate into authorization to sell the products. Therefore, after approval for premise license, the applicant should obtain product license before release products on market.

The duration for processing applications for manufacturing facilities and food outlets should not exceed 30 working days from the application date unless they don't comply.

2.2.2. Renewal for premise registration

Any application for renewal of a registered premise is considered as license renewal. This application shall be made at least one (1) month before the expiry of existing registration.

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

2.2.3. Variation of registered premise

Application for any change made in the registered premise is considered as variation of the license. Any change shall be communicated to Rwanda FDA. These changes may be change of ownership, change of responsible technician, change of location, additional line of production, opening a new branch or any other change different from the previously submitted application.

2.2.4. Re- inspection of food premise

Re-inspection shall be carried out after unsuccessful initial premise licensing inspection(s), and will attract an inspection fee in addition to the application fee paid. Applicants shall notify Rwanda FDA of changes made to comply with the set recommendations, by submitting the following requirements;

- 1) Re-inspection application letter addressed to the Director General of Rwanda FDA, mentioning the proposed dates.
- 2) The proof of payment of prescribed re-inspection fees
- 3) A Corrective and Preventive Actions (CAPA) report, detailing what has been implemented with respective visual proof and timelines for non-implemented recommendations.

2.3. REQUIREMENTS FOR NEW PREMISE LICENSING

2.3.1. PREREQUISITE TO APPLY FOR REGISTRATION AND LICENSING OF FOOD MANUFACTURING PREMISES

Applicants should fulfill the prerequisites as detailed below prior to new application for premise licensing. Applicants should apply for:

A. Site location approval

The Authority shall approve the site location for food product manufacturers after satisfactory review of the following preliminary documents:

- 1) Letter of intent
- 2) Site master plan (indicating the location /plan of the premise and the surroundings activities)
- 3) Environmental impact assessment

B. Architectural Plan Approval;

The applicant shall submit the following documents:

- 1) Approval letter for site location from the Authority
- 2) Architecture plan showing but not limited to the following:

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

- i) Production process flow chart.
- ii) Sanitation facilities (Clean water and waste water treatment system)
- iii) Mechanical ventilation /Air handling unit /Heat, Ventilation and Air Conditioning (HVAC).
- iv) Construction and process materials (food grade material)
- v) Finishing materials (food production floor, ceiling and walls should be seamless, easy to clean).

2.3.2. REQUIREMENTS TO APPLY FOR REGISTRATION AND LICENSING OF FOOD MANUFACTURING PREMISES

A complete application for opening and/or operating a food manufacturing premise shall include the following documents:

1. Application letter addressed to Director General (See format, annex 2, p.34)
2. A duly filled application form for premises registration of food premise. (See annex 2, p.35)
3. Certificate of Rwanda Development Board (RDB) or Certificate of Rwanda Cooperative Agency (if applicable) showing the owner or representative of the company, the exact current physical location and scope.
4. Identity card or Passport of the representative (Owner, Managing Director, or any legal representative of the premise).
5. Recent passport photo of the representative (owner, managing director or any legal representative).
6. Proof of Payment of prescribed fees to Rwanda FDA Accounts
7. Most recent Plant layout / architectural site plan.
8. Process flowchart(s) of the products.
9. Lease contract of the premise of at least one year (if applicable)
10. Notarized degree of qualified responsible technician or notarized equivalence of degree if the degree was issued abroad.
11. Curriculum vitae of the responsible technician.
12. Contract of the technician with the company (of at least one year).
13. Commitment letter of the technician attesting the assurance of food safety addressed to Director General of Rwanda FDA.
14. Identity card or passport of the responsible technician
15. Recent passport photo of the responsible technician.

Note:

1. The qualified technician should have at least a bachelor's degree in Food sciences, Food Microbiology or Biotechnology. However, other qualifications, or other educational levels of study may be accepted after analysis and approval by the Authority.

2. The above requirements shall also apply to applicants engaged in reprocessing, partial processing including but not limited to food fortification, packaging and re-packaging.

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

2.3.3. LICENSE TO OPERATE A WHOLESALE OF FOOD PRODUCTS

A complete application for opening and/or operate a wholesale of food products shall include the following documents:

1. Application letter addressed to Director General (See format, annex 2, p.34)
2. A duly filled application form for premises registration of food premise (See annex 2, p.35)
3. Certificate of Rwanda Development Board (RDB) or Certificate of Rwanda Cooperative Agency (if applicable) showing the owner or representative of the company.
4. Identity card or Passport of the representative (Owner, Managing Director or any legal representative of the premise).
5. Recent passport photo of the representative (owner, managing director or any legal representative)
6. Proof of payment of the prescribed fees to Rwanda FDA Accounts
7. Lease contract of the premise of at least one year (If applicable)

Note: The space should be suitable and exclusively reserved for food products.

2.3.4. LICENSE TO OPERATE A RETAIL OF FOOD PRODUCTS

A complete application for opening and/or operating a retail of food shall include the following documents:

1. Application letter addressed to Director General (See format, annex 2, p. 34)
2. A duly filled application form for premises registration of food premise (See annex 2, p. 35)
3. Certificate of Rwanda Development Board (RDB) or Certificate of Rwanda Cooperative Agency (if applicable) showing the owner or representative of the company.
4. Identity card or Passport of the representative (Owner, Managing Director or any legal representative of the premise).
5. Recent passport photo of the representative (owner, managing director or any legal representative)
6. Proof of Payment of the prescribed fees to Rwanda FDA accounts.

Note: The space should be suitable and exclusively reserved for food products.

2.3.5. LICENSE TO OPERATE A RESTAURANT AND RELATED FOOD BUSINESSES

A complete application for opening and/or operate a Restaurant or related businesses shall include the following documents:

1. Application letter addressed to Director General (See format annex 2, p. 34)
2. A duly filled application form for premises registration of food premise (See annex 2, p.35)
3. Certificate of Rwanda Development Board (RDB) or Certificate of Rwanda Cooperative Agency (if applicable) showing the owner or representative of the company.

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

4. Identity card or Passport of the representative (Owner, Managing Director or any legal representative of the premise).
5. Recent passport photo of the representative (owner, managing director or any legal representative)
6. Proof of Payment of the prescribed fees to Rwanda FDA Accounts
7. Lease contract of the premise of at least one year (if applicable)
8. Qualification of the Specialized personnel
7. Curriculum Vitae of responsible specialized personnel
8. Contract of specialized personnel
9. Identity card or Passport of specialized personnel
10. Recent passport photo of specialized personnel

Note: The specialized personnel should have at least a diploma of food processing or culinary arts. However, other qualifications, or other educational levels of study may be accepted after analysis and approval by the Authority.

2.3.6. LICENSE TO OPERATE A WHOLESALE OR RETAIL OF FOOD SUPPLEMENTS AND/OR INFANT FORMULA SHOP BUSINESSES

A complete application for opening and/or operate a wholesale or retail of food supplements/ infant formula shall include the following documents:

1. Application letter addressed to Director General (See format, annex 2, p. 30)
2. A duly filled application form for premises registration of food premise (See annex 2, p. 31)
3. Certificate of Rwanda Development Board (RDB) or Certificate of Rwanda Cooperative Agency (if applicable) showing the owner or representative of the company
4. Identity card or Passport of the representative (Owner, Managing Director or any legal representative of the premise).
5. Recent passport photo of the representative (owner, managing director or any legal representative)
6. Proof of Payment of the prescribed fees to Rwanda FDA Accounts
7. Lease contract of the premise with at least one year (if applicable)
8. A Degree of the Responsible Technician (notarized)
9. A Valid License to Practice Profession of the Responsible Technician (notarized)
10. Curriculum Vitae of Responsible Technician
11. Professional agreement or Contract of Responsible Technician
12. Written commitment of the Responsible Technician.
13. Identity card or Passport of Responsible Technician
14. Recent photo passport of Responsible Technician

Note:

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

Guideline for Registration and Licensing of Food Premises

1. For establishments dealing with retail of food supplements, the premise shall have a minimum space of 40m² as which can be separated into a minimum sales area of 30m² and 10m² for storage in Kigali and secondary cities; For the rest of the country, for retail of food supplements, the premise shall have a minimum space of 30m² which that can be separated into a minimum sales area of 20m² and 10m² for storage.
2. For wholesale of food supplements, the premise shall have a minimum space of 70m² which that can be separated into a minimum sales area of 20m² and 50m² for storage.
3. The premise of food supplements should a standard alone premise or the products may be sold in pharmacy.
4. The qualified technician should have at least a bachelor's degree in Nutrition with a valid license to Practice the Profession. However, other qualifications, or other educational levels of study may be accepted after analysis and approval by the Authority.

2.4. RENEWAL OF PREMISE LICENSE

- 2.4.1. An authorization shall be renewed after one year from the date it was issued.
- 2.4.2. The applicant must apply for renewal of license at least one (1) month before the expiration date.
- 2.4.3. Renewal of premise license shall be done through Rwanda FDA official email or electronic system by submitting the updated version of the documents required for new application with the original license of the previous year. (See annex 3)
- 2.3.4. Dealers who shall delay to renew their licenses beyond the expiration date shall be required to pay the prescribed fee together with administrative fines described in the regulation related to the regulatory service, tariff/fees and fines. Failing to do so, the premises shall be closed down.

2.5. VARIATION OF REGISTERED PREMISE

- 2.5.1. Application for change of location (shift of premises), change of type of business, trade name of the premises, ownership, change of responsible technician, additional line of production, additional branch, suspension or termination of premise operations or any other change of registered premises shall be addressed to the Director General.
- 2.5.2. Change of location or type of business shall be treated as a new application. Therefore, the application procedure for new premise as prescribed in these guidelines shall apply.

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

2.5.3. The rest of variations of the operational license shall be done by submitting the updated version of the documents required for specific variation with the original license, specifying the current variation made.

2.5.4. Before receipt of notification for any changes made, the applicant shall be required to pay the respective service fees.

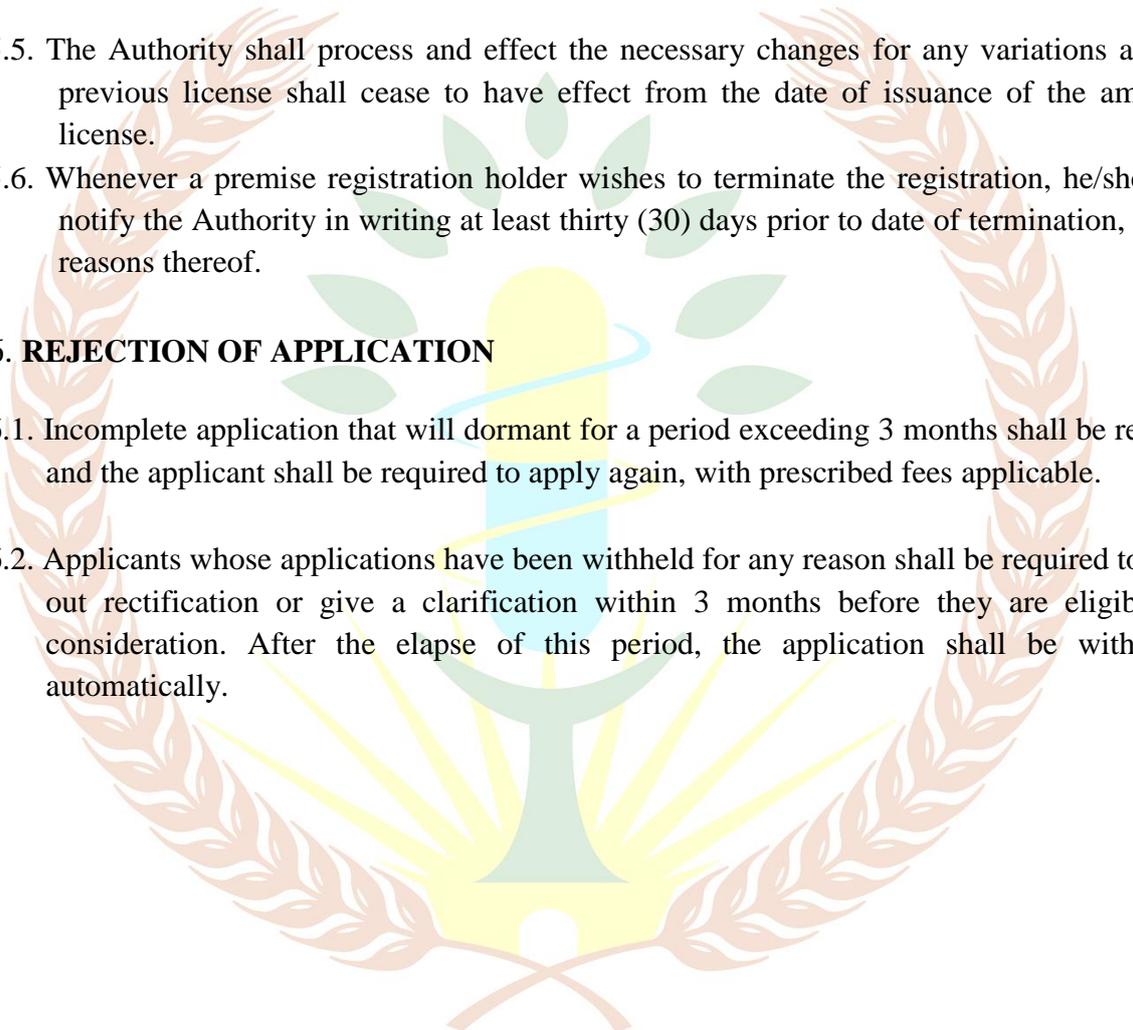
2.5.5. The Authority shall process and effect the necessary changes for any variations and the previous license shall cease to have effect from the date of issuance of the amended license.

2.5.6. Whenever a premise registration holder wishes to terminate the registration, he/she shall notify the Authority in writing at least thirty (30) days prior to date of termination, giving reasons thereof.

2.6. REJECTION OF APPLICATION

2.6.1. Incomplete application that will dormant for a period exceeding 3 months shall be rejected and the applicant shall be required to apply again, with prescribed fees applicable.

2.6.2. Applicants whose applications have been withheld for any reason shall be required to carry out rectification or give a clarification within 3 months before they are eligible for consideration. After the elapse of this period, the application shall be withdrawn automatically.

The logo of the Rwanda Food and Drugs Authority (FDA) is centered on the page. It features a stylized sun with rays emanating from a central point, set against a background of green leaves and a brown laurel wreath. Below the logo, the text "RWANDA FDA" is written in large, bold, green capital letters, and "Rwanda Food and Drugs Authority" is written in smaller, brown capital letters below it.

RWANDA FDA
Rwanda Food and Drugs Authority

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

CHAPTER 3. INSPECTION OF PREMISES FOR SUITABILITY

The Authority shall inspect the premises to determine suitability of the food premises. The premises that do not comply with the requirements for suitability shall not be eligible for premises licensing. Food premises requirements include, but not limited to the following;

3.1. LOCATION OF PREMISES FOR FOOD PREMISES

- 3.1.1 The food premise shall be a permanent nature, located away from sites or activities that emit obnoxious material like fumes, dust, smoke, offensive trade or breeding sites for vermin.
- 3.1.2. The food premise should have sufficient space for the carrying out and supervision of the necessary operations.
- 3.1.2 Physical address of the premise where the business is to be carried out shall be clearly indicated in the application form to include plot and house numbers, street, district, province and coordinates as this will facilitate easy reach during supervision and inspection.
- 3.1.4. The food premise should be located within commercial or industrial area.

3.2. BUILDING DESIGN OF PRODUCTION AREAS

- 3.2.1. The food premises shall be designed for the intended purpose and shall have no direct link with any business or occupation that may lead to contamination of food.
- 3.2.2. The premises shall be of suitable layout, constructed to facilitate easy maintenance and sanitation and good flow of operations.
- 3.2.3. The food premises and facilities installed shall have:
 - a) Sufficient space for placement and storage of materials, which are necessary for sanitary operations.
 - b) Adequate space, either by partition, location or other effective means for those operations, which may cause contamination of food;
 - c) Sufficient lighting and ventilation to enable all operations to be carried out satisfactorily and safely.
 - d) Maximum protection against rodents, birds, vermin etc.
 - e) The floor, walls and ceiling of food premises shall be adequately seamless cleanable and maintained in a clean and good state of repair.
 - f) The fixtures, ducts and pipes shall not be suspended over areas where drips or condensate may contaminate food and raw materials or food contact surfaces.
 - g) Aisles or working spaces between equipment and walls shall be unobstructed and of sufficient width to allow employees to perform their duties without contaminating the food or food contact surface with their clothing or personal contact.

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

3.3. FOOD EQUIPMENT, UTENSILS AND FOOD CONTACT SURFACE

- 3.3.1. Every utensil and equipment used in food premises shall be suitable for their intended use and food grade; well designed and adequately cleanable and proper maintenance of cold chain for frozen products.
- 3.3.2. Every food contact surface shall be smooth and impervious, free from pits, crevices and loose scale, non-toxic, and capable of withstanding repeated cleaning disinfection and sanitization.
- 3.3.3. Utensils, crockery, cutlery, and other equipment coming in contact with food shall be sufficient in number to enable adequate sanitization before reuse. Single service articles shall be stored in appropriate containers and handled, dispensed, used and disposed to prevent contamination of food or food contact surfaces.
- 3.3.4. There shall be transportation/ channeling means for food products that limits human interaction and/ or cross-contamination risk, and they shall be made in food grade materials.

3.4. PERSONNEL

- 3.4.1. Every food premise should present the Managing Director and Responsible technician (if applicable).
- 3.4.2. The responsible technician should present the degree or certificate with required qualification.
- 3.4.3. The premise shall have trained personnel from a recognized institution.
- 3.4.4. Any person who owns a food business shall ensure that persons suffering from communicable diseases shall not be involved in handling of food or food contact surfaces.
- 3.4.5. Thorough medical examination for food handlers shall be carried out prior to employment and after every six months.
- 3.4.6. Medical examination records for each worker shall be kept properly and accessible for inspection. The records shall be kept and maintained for not less than two years.
- 3.4.7 Any responsible technician wishing to resign from his/her responsibilities shall inform the authority with a resignation letter signed by both the employer and the employee. This shall result into suspension of production until a new responsible technician is hired.

3.5. STORAGE FACILITIES

- 3.5.1. Storage facilities shall protect products from deterioration and the specified storage conditions shall be monitored and maintained accordingly.
- 3.5.2. Controlled storage environment/facilities e.g. air conditions, refrigeration for cold chain products shall be made available and monitored using suitable temperature recording devices and records reviewed and filed.
- 3.5.3. All food products shall be stored off the floor in well-fitted shelves or pallets.

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

3.5.4. Storage facilities for grains should be monitored for humidity, temperature and pests and records should be kept properly.

3.6. SANITATION AND HYGIENE

All food premises shall be provided with adequate and easily accessible sanitary conveniences to cater separately for both genders, for employees and/or customers.

3.6.1. There shall be adequate and readily available potable water supply; hot and cold running water to be used for the intended operation or use.

3.6.2. There shall be a proper system of waste disposal.

3.6.3. There shall be provision of protective gears and occupation health facilities.

3.6.4. Food handlers shall be clean in person and shall avoid unhygienic practices such as smoking, sneezing and coughing over food, nose picking, finger licking, talking over food etc.

3.6.5. There shall be adequate provision for hand washing facilities with hot and cold running water, nail brushes and disinfectant liquid soap. To avoid recontamination of hands there shall be automatic or elbow or foot operated water taps.

3.6.6. Doors may be designed to open by pushing from all sides or self-operating doors to avoid contaminating the food handler's hands.

3.7. DOCUMENTATION AND RECORD KEEPING

Any person who owns a food business shall make available the following documents/records:

- a) Food import licenses and/or purchasing documents
- b) Sanitation and fumigation documents
- c) Ledger book or an appropriate inventor control system
- d) Visitors' book
- e) Sales receipts (wholesalers)
- f) Inspection log book
- g) Medical examination records where applicable
- h) Complaints handling book
- i) Register for expired/ recalled / rejected/ withdrawn food products
- j) Food Hygiene Regulation
- k) Standard of the product being manufactured

3.8. REGULAR WATER SUPPLY

- 1) The premises shall have a regular and sufficient supply of water.
- 2) Water treatment plants and distribution systems should be designed, constructed and maintained so as to ensure a reliable source of water of an appropriate quality.

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

- 3) The chemical and microbiological quality of water used in production should be specified and monitored.
- 4) Water for injections should be produced, stored and distributed in a manner which prevents microbial growth, for example by constant circulation at a temperature above 70°C.

3.9. CONTAINERS TO BE CLEANED

All processing containers, vessels and utensils shall be cleaned and labeled as such before they are stored and shall be rechecked for cleanliness before being issued out to the manufacturing areas.

3.10. DESCRIPTIVE MATERIALS TO BE KEPT SECURE

- 1) All product labels, printed packaging and descriptive materials shall:
 - a. Be stored in a secure manner; and
 - b. Be accessed by only authorized personnel.
- 2) Proper records shall be kept for the labels, printed packaging and descriptive materials issued, to avoid any mix-up.

3.11. FIRE-FIGHTING EQUIPMENT

The premises shall have sufficient fire-fighting equipment which shall, at all times, be in good condition and readily accessible.

3.12. WEIGHING, MEASURING, TESTING AND RECORDING EQUIPMENT TO BE CHECKED

The equipment used for weighing, measuring, testing and recording shall be subjected to recorded checks for accuracy in accordance with a regular set schedule.

3.13. QUALITY CONTROL AREAS

- 1) Quality Control laboratories shall be separated from production areas. This is particularly important for laboratories for the control of biological, microbiological and radioisotopes, which shall also be separated from each other.
- 2) Quality Control laboratories shall be designed to suit the operations to be carried out in them. Sufficient space shall be given to avoid mix-ups and cross- contamination. There shall be adequate suitable storage space for samples and records.
- 3) Separate rooms may be necessary to protect sensitive instruments from vibration, electrical interference, humidity, etc.

3.14. RECALLS, REJECT AND WITHDRAWAL OF PRODUCTS

- 3.8.1. The applicant shall show a capacity to prompt and effective system of traceability and recall from the market of products known or suspected to be defective or hazardous,

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

- 3.8.2. In case of recall of product initiated by the dealer himself, the Authority shall be notified of the reason for recall.
- 3.8.3. Recall operations shall be capable of being initiated promptly, at least down to the level of retailers.
- 3.8.4. The distribution records shall be readily available to the person(s) responsible for recalls and they shall contain sufficient information related to the product, e.g. Name of product, Manufacturer, Dates of Manufacture and Expire, and Batch Number.
- 3.8.5. The disposal of recalled/rejected/withdrawn products from the market shall be effected within one month after completion of exercise. Disposal exercise shall be carried under supervision of Rwanda FDA Inspectors/ Food Inspectors and representatives from other Government Institutions.

3.15. REGULATORY ACTIONS

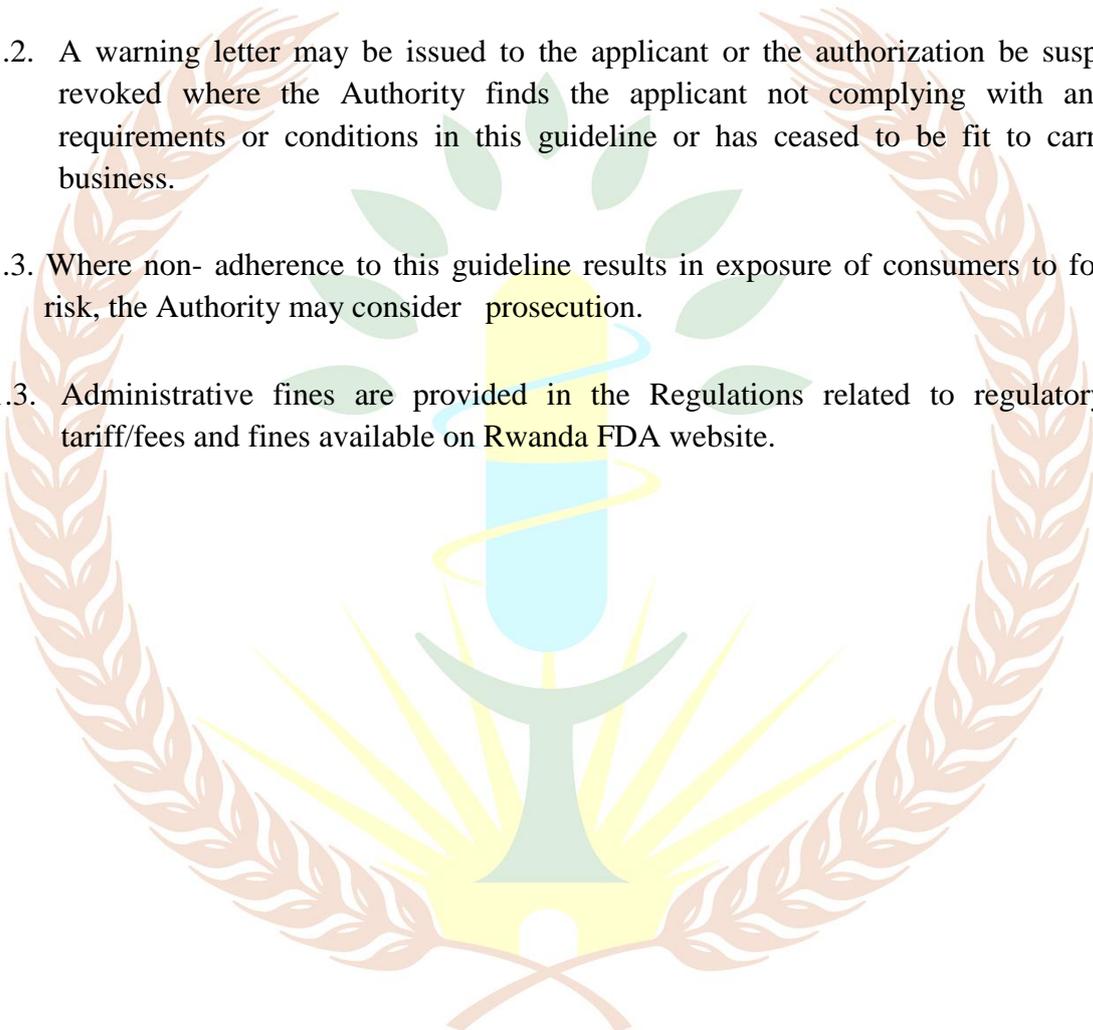
- a) The following section provides the regulatory actions that shall be taken by the Authority when making decisions on the inspections findings.
- b) The Authority shall take the regulatory actions based on Minor, Major and Critical category of non-compliances:
 - 1^o Referred to the inspection findings, **minor non-compliances** imply a recommended corrective action within a given time frame and are requested for compliance reports.
 - 2^o Referred to the inspection findings, **major non-compliances** imply issuing a warning letter, recommend corrective action within a given time frame, recommend temporary withdrawal or suspension of operational license, request for comprehensive compliance report, follow-up inspection to verify implementation if necessary.
 - 3^o Referred to the inspection findings, **critical non-compliances** imply temporarily closure of the establishment, permanent withdrawal/revocation of operational license, not granting the operational license.
- c) The above- mentioned non-compliances shall be detailed in other regulatory documents (e.g.: Standard Operating Procedures).

RWANDA FDA
Rwanda Food and Drugs Authority

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

CHAPTER 4. ADMINISTRATIVE SANCTIONS AND FINES

- 4.1.1. The authority shall cancel, suspend or withdraw the license to operate a food processing premise/ food outlet if:
- a) The circumstances under which it was licensed no longer exist
 - b) The grounds on which it was licensed are later found to be false or any provision under which it was licensed has been contravened.
- 4.1.2. A warning letter may be issued to the applicant or the authorization be suspended or revoked where the Authority finds the applicant not complying with any of the requirements or conditions in this guideline or has ceased to be fit to carry on the business.
- 4.1.3. Where non- adherence to this guideline results in exposure of consumers to food safety risk, the Authority may consider prosecution.
- 4.1.3. Administrative fines are provided in the Regulations related to regulatory service tariff/fees and fines available on Rwanda FDA website.

The logo of the Rwanda Food and Drugs Authority (FDA) is centered on the page. It features a stylized green and blue emblem with a yellow sunburst at the base, all enclosed within a circular wreath of golden-brown leaves. Below the logo, the text "RWANDA FDA" is written in large, bold, green capital letters, and "Rwanda Food and Drugs Authority" is written in smaller, orange-brown capital letters below it.

RWANDA FDA
Rwanda Food and Drugs Authority

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

REFERENCES

1. Law n° 003/2018 of 09/02/2018 establishing Rwanda food and drugs authority and determining its mission, organization and functioning.
2. Rwanda FDA. 2019. Guideline for registration and licensing of food premises. Rev.0
3. TFDA. 2011. Guidelines for registration and licensing of food premises.
4. FDA Ghana. 2013. Guideline of Licensing of Manufacturing facility (Revised on 20th April 2020).



| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

ANNEXES

1. LIST OF REQUIREMENTS FOR PREMISE REGISTRATION AND LICENSING OF FOOD PREMISES
2. APPLICATION LETTER AND APPLICATION FORM FOR PREMISE REGISTRATION AND LICENSING OF FOOD PREMISES
3. FORMAT OF PREMISE INSPECTION REPORT
4. NARATIVE REPORT FORMAT
5. FORMATS OF LICENSES



| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |



**ANNEX 1. LIST OF REQUIREMENTS FOR PREMISE REGISTRATION
AND LICENSING OF FOOD PREMISES**

RWANDA FDA
Rwanda Food and Drugs Authority

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |



RWANDA FDA

Rwanda Food and Drugs Authority

P.O. Box 1948 Kigali

info@rwandafda.gov.rw

www.rwandafda.gov.rw

QMS N^o: DIS/CKL/082
Revision No: 0
Effective Date: 21/02 2022
Ref. Doc: Guidelines
DIS/GDL/005

| 0.A. SITE LOCATION APPROVAL | | |
|---|-----|----------------------|
| Premise name : | | Date : .../.../..... |
| Documents | YES | NO |
| 1 Letter of intent | | |
| 2 Site master plan (indicating the location /plan of the premise and the surroundings activities) | | |
| 3 Environmental impact assessment | | |

| 0.B. ARCHITECTAL PLAN APPROVAL | | |
|--|-----|----------------------|
| Premise name : | | Date : .../.../..... |
| Documents | YES | NO |
| 1 Approval letter for site location from the Authority | | |
| 2 Architecture plan showing but not limited to the following: | | |
| 3 i) Production process flow chart. | | |
| ii) Sanitation facilities (Clean water and waste water treatment system) | | |
| iii) Mechanical ventilation /Air handling unit /Heat, Ventilation and Air Conditioning (HVAC). | | |
| iv) Construction and process materials (food grade material) | | |
| v) Finishing materials (food production floor, ceiling and walls should be seamless, easy to clean). | | |

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |



RWANDA FDA

Rwanda Food and Drugs Authority

P.O. Box 1948 Kigali

info@rwandafda.gov.rw

www.rwandafda.gov.rw

QMS N^o: DIS/CKL/067
Revision No: 1
Effective Date: 21/02 2022
Ref. Doc: Guidelines
DIS/GDL/005

| I. REQUIREMENTS FOR PREMISE REGISTRATION AND LICENSING OF FOOD MANUFACTURING PREMISE | | | New application | Renewal | Change ownership | Change technician | Change location | Additional line | Additional branch |
|--|---|----|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Documents | YES | NO | | | | | | | |
| Premise name: | | | <input type="checkbox"/> |
| Date : .../.../..... | | | | | | | | | |
| 1 | Application letter addressed to Director General | | <input type="checkbox"/> |
| 2 | A dully filled application form for premises registration and licensing of food premise | | <input type="checkbox"/> |
| 3 | Certificate of RDB / RCA | | <input type="checkbox"/> |
| 4 | The Identity Card/Passport of the Managing Director or representative | | <input type="checkbox"/> |
| 5 | Recent photo passport of the managing Director or representative | | <input type="checkbox"/> |
| 6 | Proof of Payment of the prescribed fees to Rwanda FDA Account. | | <input type="checkbox"/> |
| 7 | Most recent plant layout/ architectural site plan | | <input type="checkbox"/> |
| 8 | Process flowchart(s) | | <input type="checkbox"/> |
| 9 | Lease contract of the premise at least one year (if applicable) | | <input type="checkbox"/> |
| 10 | Certificate of qualified personnel (notarized) or equivalent degree of technician (notarized) | | <input type="checkbox"/> |
| 11 | Curriculum vitae of the responsible technician | | <input type="checkbox"/> |
| 12 | Copy of work contract between employer and responsible technician | | <input type="checkbox"/> |
| 13 | Letter of commitment of the responsible technician | | <input type="checkbox"/> |
| 14 | Identity Card/Passport of the responsible technician | | <input type="checkbox"/> |
| 15 | Recent photo passport of the responsible technician | | <input type="checkbox"/> |
| 16 | Original license | | <input type="checkbox"/> |

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |



RWANDA FDA

Rwanda Food and Drugs Authority

P.O. Box 1948 Kigali

info@rwandafda.gov.rw

www.rwandafda.gov.rw

QMS N^o: DIS/CKL/079
 Revision No: 0
 Effective Date: 21/02/2022
 Ref. Doc: Guidelines
 DIS/GDL/005

| REQUIREMENTS FOR RE – INSPECTION | | |
|--|-----|----|
| Premise name: Date :/...../..... | | |
| Documents | YES | NO |
| 1 Re-inspection application letter addressed to the Director General of Rwanda FDA, mentioning the proposed dates. | | |
| 2 The proof of payment of prescribed re-inspection fees | | |
| 3 A Corrective Actions and Preventive Actions (CAPA) report, detailing what has been implemented with respective visual proof and timelines for non-implemented recommendations. | | |

RWANDA FDA
 Rwanda Food and Drugs Authority

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |



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

QMS N^o: DIS/CKL/081
Revision No: 0
Effective Date: 21/02 2022
Ref. Doc: Guidelines
DIS/GDL/005

| II. REQUIREMENTS FOR PREMISE REGISTRATION AND LICENSING OF WHOLESALE OF FOOD PRODUCTS | | | New application | Renewal | Change ownership | Change location | Additional branch |
|---|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Premise name : | | Date :/...../..... | | | | | |
| Documents | YES | NO | <input type="checkbox"/> |
| 1 | Application letter addressed to Director General | | <input type="checkbox"/> |
| 2 | Application form for premises registration and licensing of food premise | | <input type="checkbox"/> |
| 3 | Certificate of RDB / RCA | | <input type="checkbox"/> |
| 4 | The Identity Card/Passport of the managing Director or representative | | <input type="checkbox"/> |
| 5 | Recent photo passport of the managing Director or representative | | <input type="checkbox"/> |
| 6 | Proof of Payment of prescribed fees to Rwanda FDA Accounts. | | <input type="checkbox"/> |
| 7 | Lease contract of the premise at least one year (if applicable) | | <input type="checkbox"/> |
| 8 | Original license | | <input type="checkbox"/> |

RWANDA FDA
Rwanda Food and Drugs Authority

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |



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

QMS N^o: DIS/CKL/080
Revision No: 0
Effective Date: 21/02 2022
Ref. Doc: Guidelines
DIS/GDL/005

| III. REQUIREMENTS FOR PREMISE REGISTRATION AND LICENSING OF RETAIL OF FOOD PRODUCTS | | | New application | Renewal | Change ownership | Change location | Additional branch |
|---|--|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Premise name: | | | | | | | |
| Date :/...../..... | | | YES | NO | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Documents | | | | | | | |
| 1 | Application letter addressed to Director General | | <input type="checkbox"/> |
| 2 | Application form for premises registration and licensing of food premise | | <input type="checkbox"/> |
| 3 | Certificate of RDB / RCA | | <input type="checkbox"/> |
| 4 | The Identity Card/Passport of the managing Director or representative | | <input type="checkbox"/> |
| 5 | Recent photo passport of the managing Director or representative | | <input type="checkbox"/> |
| 6 | Proof of Payment of prescribed fees to Rwanda FDA Accounts. | | <input type="checkbox"/> |
| 7 | Original license | | <input type="checkbox"/> |

RWANDA FDA
Rwanda Food and Drugs Authority

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |



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

QMS N^o: DIS/CKL/083
Revision No: 0
Effective Date: 21/02 2022
Ref. Doc: Guidelines
DIS/GDL/005

| IV. REQUIREMENTS FOR PREMISE REGISTRATION OF RESTAURANT AND/OR RELATED PREMISES | | | | New application | Renewal | Change ownership | Change technician | Change location | Additional branch |
|--|--|--------------------------------|-----------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Premise name: | | Date :...../...../..... | | | | | | | |
| Documents | | YES | NO | <input type="checkbox"/> |
| 1 | Application letter addressed to Director General | | | <input type="checkbox"/> |
| 2 | A duly filled application form for premises registration of food premise. | | | <input type="checkbox"/> |
| 3 | Certificate of RDB or RCA (if applicable) | | | <input type="checkbox"/> |
| 4 | Identity card or Passport of the representative (Owner, Managing Director or any legal representative of the premise). | | | <input type="checkbox"/> |
| 5 | Recent passport photo of the representative (owner, managing director or any legal representative) | | | <input type="checkbox"/> |
| 6 | Proof of Payment of prescribed fees to Rwanda FDA Accounts. | | | <input type="checkbox"/> |
| 7 | Plant layout | | | <input type="checkbox"/> |
| 8 | Lease contract of the premise of at least one year (if applicable) | | | <input type="checkbox"/> |
| 9 | Qualification of the Specialized personnel | | | <input type="checkbox"/> |
| 10 | Curriculum Vitae of responsible specialized personnel | | | <input type="checkbox"/> |
| 11 | Contract of specialized personnel | | | <input type="checkbox"/> |
| 12 | The Identity card/ passport photo of specialized personnel | | | <input type="checkbox"/> |
| 13 | Recent passport photo of specialized personnel | | | <input type="checkbox"/> |
| 14 | Original license | | | <input type="checkbox"/> |

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |



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

QMS N^o: DIS/CKL/069
Revision No: 1
Effective Date: 21/02 2022
Ref. Doc: Guidelines
DIS/GDL/005

| V. REQUIREMENTS FOR PREMISE REGISTRATION OF WHOLESALE/ RETAIL OF FOOD SUPPLEMENTS AND/OR INFANT FORMULA | | | | New application | Renewal | Change ownership | Change technician | Change location | Additional branch |
|--|---|-----|----|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Documents | | YES | NO | | | | | | |
| Premise name : | | | | | | | | | |
| Date :/...../..... | | | | | | | | | |
| 1 | Application letter addressed to Director General | | | <input type="checkbox"/> |
| 2 | A duly filled application form for premises registration of food premise. | | | <input type="checkbox"/> |
| 3 | Certificate of RDB | | | <input type="checkbox"/> |
| 4 | The copy of Identity Card/Passport of the owner | | | <input type="checkbox"/> |
| 5 | Lease contract of the premise at least one year (if applicable) | | | <input type="checkbox"/> |
| 6 | Proof of payment of the prescribed fees to Rwanda FDA Accounts | | | <input type="checkbox"/> |
| 7 | A Degree of Responsible Technician (notarized) or equivalent degree of technician (notarized) if granted abroad (notarized) | | | <input type="checkbox"/> |
| 8 | A Valid License to Practice the Profession of Responsible Technician (notarized) | | | <input type="checkbox"/> |
| 9 | A Curriculum Vitae of the Responsible Technician | | | <input type="checkbox"/> |
| 10 | Commitment letter of the Responsible Technician. | | | <input type="checkbox"/> |
| 11 | Signed Professional agreement/ Contract | | | <input type="checkbox"/> |
| 12 | The Identity Card/Passport of the Responsible Technician | | | <input type="checkbox"/> |
| 13 | Recent photo passport of the Responsible Technician | | | <input type="checkbox"/> |
| 14 | Original license | | | <input type="checkbox"/> |

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |



**ANNEX 2. APPLICATION LETTER FORMAT AND APPLICATION FORM FOR
PREMISE REGISTRATION AND LICENSING OF FOOD PREMISES**

RWANDA FDA
Rwanda Food and Drugs Authority

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

APPLICATION LETTER

<Company name>
<Province/District/Sector/Cell>
<Street/Plot/Building/ No>
<Telephone>
<Email>

<Date>

<Rwanda Food and Drugs Authority>
<P.O.Box 1948>
<Kigali- Rwanda>

Dear Sir/ Madam,

Subject: Application for premise registration of < company name/ cooperative name>

We are pleased to submit our application dossier for a registration of our premise <company name> registered under TIN number <tin> located in <address>.

The company is directed by <Managing Director (Email/telephone)> and the food products are under responsibility of <Responsible technician (email/ telephone)>.

We are a <manufacture/wholesale/retail> of <food products (types of products)> with brand name <brand name(s)>. We <any other additional information>.

Your sincerely,

<Managing Director name>
<Title>
<Signature>.

RWANDA FDA
Rwanda Food and Drugs Authority

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

Guideline for Registration and Licensing of Food Premises

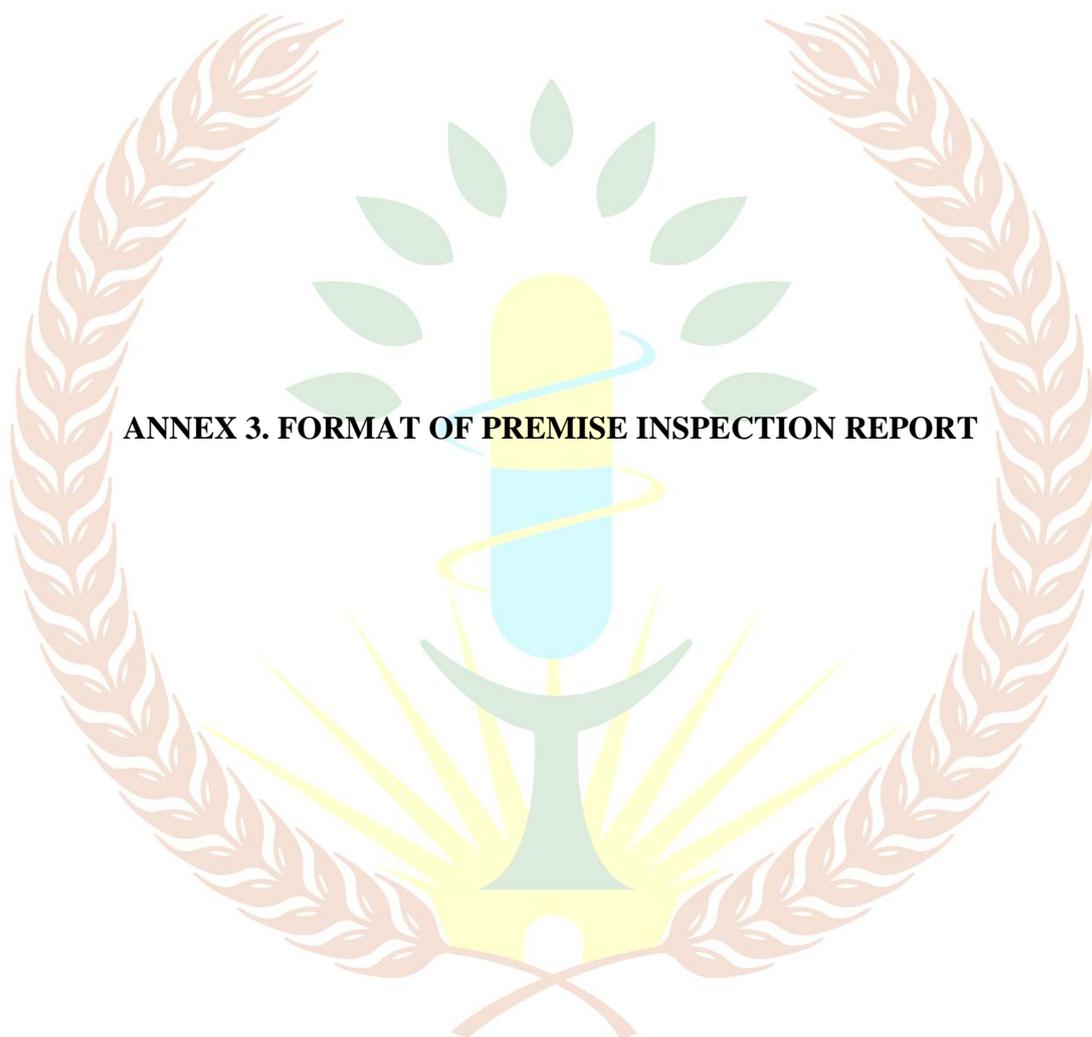


Rwanda Food and Drugs Authority
 Rue. KG 9 Avenue, Nyarutarama Plaza
 P.O. Box 1948, Kigali, Rwanda.
 Email: info@rwandafda.gov.rw
 Website: www.rwandafda.gov.rw
 Tel: +250 789 193 529

Format: DIS/FORM/169
 Revision No: 1
 Effective Date: 20/02/2022
 Ref. Doc: Guidelines
 DIS/GDL/005

| APPLICATION FORM FOR LICENSE OF FOOD PREMISE | | |
|--|---|---|
| Name of Premise: | Application date: //..... (DD / MM/ YYYY) | |
| RDB/ RCA N° : | First Registration date in Rwanda FDA : //..... (DD / MM/ YYYY) | |
| Physical location : (Province/ District/ Sector/Cell) | GPS coordinates: | |
| Official e-mail: | Official Telephone : | |
| Name of Owner : | Position : | |
| Partners' name(s): | | |
| Email of Owner: | Tel. of Owner: | |
| Name of responsible Technician (if applicable): | Qualification: | |
| Email of resp. technician: (if applicable) | Telephone of resp. technician: | |
| Financial resources committed to business : | Prescribed fees : Receipt number : | |
| FACILITY TYPE : (Please tick below) | TYPE OF PRODUCTS (Please tick below) | TYPE OF APPLICATIONS (Please tick below) |
| <input type="checkbox"/> FOOD MANUFACTURER <input type="checkbox"/> LARGE SCALE <input type="checkbox"/> SMALL SCALE & MEDIUM (SME) <input type="checkbox"/> FOOD OUTLET <input type="checkbox"/> WHOLESALE OF FOOD PRODUCTS <input type="checkbox"/> RETAIL OF FOOD PRODUCTS <input type="checkbox"/> RESTAURANT & RELATED <input type="checkbox"/> HOTEL KITCHEN <input type="checkbox"/> BAR & RESTAURANT <input type="checkbox"/> FAST FOOD <input type="checkbox"/> OTHER | <input type="checkbox"/> Cereals products <input type="checkbox"/> Maize flour <input type="checkbox"/> Wheat flour <input type="checkbox"/> Rice <input type="checkbox"/> Alcoholic beverages <input type="checkbox"/> Liquors <input type="checkbox"/> Wines <input type="checkbox"/> Beer <input type="checkbox"/> Plant based alc. beverages <input type="checkbox"/> Non-alcoholic beverage <input type="checkbox"/> Drinking water <input type="checkbox"/> Daily products <input type="checkbox"/> Meat products <input type="checkbox"/> Vegetable products <input type="checkbox"/> Other | <input type="checkbox"/> Site location approval <input type="checkbox"/> NEW APPLICATION <input type="checkbox"/> RENEWAL <input type="checkbox"/> VARIATION <input type="checkbox"/> Change of ownership <input type="checkbox"/> Change of location <input type="checkbox"/> Change responsible technician <input type="checkbox"/> Additional line <input type="checkbox"/> Additional branch <input type="checkbox"/> REINSPECTION <input type="checkbox"/> OTHER |
| Declaration I,, certify that the above information is correct and hereby apply for Premise License in Rwanda FDA for the above-named premises. Applicant signature Date/...../..... | | |
| FOR OFFICIAL USE ONLY: Date Received :/...../..... Approved/ Rejected: A / R. Approval/Rejection date :/...../..... | | |

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |



ANNEX 3. FORMAT OF PREMISE INSPECTION REPORT

RWANDA FDA
Rwanda Food and Drugs Authority

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |



RWANDA FDA
Rwanda Food and Drugs Authority

P.O. Box 1948 Kigali
info@rwandafda.gov.rw
www.rwandafda.gov.rw

PREMISE INSPECTION REPORT CONDUCTED AT
X INDUSTRIES

- I. INTRODUCTION**
- II. OBJECTIVES**
- III. BUILDING**
- IV. EQUIPMENT**
- V. PERSONNEL**
- VI. STORAGE FACILITIES**
- VII. SANITATION AND HYGIENE**
- VIII. DOCUMENTS AND RECORD KEEPING**
- IX. RECOMMENDATION(S)**
- X. APPENDIX(ES)**

Prepared by:

Name, signature, date
Position

Name, signature, date
Position

Reviewed by:

Name, signature, date
Division Manager of FDIC

Approved:

Name, signature, date
Head of Department of FDISM

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |



ANNEX 4. NARRATIVE REPORT FORMAT

RWANDA FDA
Rwanda Food and Drugs Authority

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |



RWANDA FDA
Rwanda Food and Drugs Authority

P.O. Box 1948 Kigali
info@rwandafda.gov.rw
www.rwandafda.gov.rw

NARRATIVE INSPECTION REPORT CONDUCTED AT (LOCATION) DURING THE PERIOD FROM (DATE) TO (DATE)

I. INTRODUCTION

II. OBJECTIVES

III. KEYS FINDING(S) AND RECOMMEDATION(S)

| COMPANY /NAME Product Owned by: Located at: (Province/ District/ Sector / Cell/ Inspection date: | PURP OSE | KEY FINDINGS/ OBSERVATI ON | GENERAL RECOMMEND ATIONS |
|---|--|--|---|
| 1. NAME OF THE COMPANY Product: xxxxxxxxxxxxxxxx Owned by: XXXXX XX XX Located at: / // Inspection date: .../.../... | | | - - - - - |

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |

Guideline for Registration and Licensing of Food Premises

| | | | |
|----|--|--|--|
| 2. | | | |
|----|--|--|--|

GENERAL CONCLUSION

| No | Name of inspectors | Post / Institution | Email | Telephone |
|----|--------------------|--------------------|-------|-----------|
| 1 | | | | |
| 2 | | | | |

Done at XXX, on day/ month/year.

Reviewed by:

Name, signature, date

Division Manager of FDIC

Approved:

Name, signature, date

Head of Department of FDISM

RWANDA FDA
Rwanda Food and Drugs Authority

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |



ANNEX 5. FORMATS OF LICENSES

RWANDA FDA
Rwanda Food and Drugs Authority

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |



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

QMS N°: DIS/FMT/048
Rev. N°: 1
Effective Date: 08/12/2021
Ref. Doc.: DIS/GDL/005

LICENSE OF PREMISE FOR FOOD PRODUCT MANUFACTURING

Issued under Article 9 of the Law N° 003/2018 of 09/02/2018 Establishing Rwanda Food and Drugs Authority and Determining its Mission, Organization and Functioning, and articles 3 &4 of the Law N° 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products.

This is to certify that

License N°: DIS/ /FDA/20_

Name of the Company: Name of the company as on RDB certificate

Company Code: Tin number

Location of the premise: XXXXXX City/Province, XXXXXXXX District,
XXXXXX Sector, XXXXXXXXI, Cell

Name of the Managing Director: Name of managing mentioned on RDB

Telephone N°: (+xxx) xxxxxxxxxxxxxx

Head of Production Department: xxxxxxxxxxxxxxxxxxxxxx

was granted to to carry out the following manufacturing activities:

| Product category | Product type | Manufacturing activities |
|------------------|--------------|---|
| | | Production, packaging, labeling, storage and distribution |

Validity: This license is valid for one (1) year renewable from the date of issuance.

This authorization may be suspended or withdrawn if the conditions under which it was granted are violated. The products are put on market after assessment and registration by Rwanda FDA. The application for renewal of license shall be due one month before its expiry.

Done at Kigali on

Name and signature of Director General + Stamp of the institution
Director General

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |



RWANDA FDA
Rwanda Food and Drugs Authority

P.O. Box 1948 Kigali

info@rwandafda.gov.rw

www.rwandafda.gov.rw

QMS N°: DIS/FMT/142

Rev. N°: 0

Effective Date : 08 Dec 2021

LICENSE TO OPERATE AS WHOLESALE & RETAIL OF PROCESSED FOODS | ANIMAL FEEDS | ...

Issued under Article 9 of LAW N° 003/2018 of 09/02/2018 Establishing Rwanda Food and Drugs Authority and Determining its Mission, Organization and Functioning, and the LAW N° 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products, especially article 3&4,

Ref N°: DIS/ /FDA/20xx

This is to certify that

Name of the Company : Name of the company on RDB/RCA Certificate

Company Code : TIN number

Managing Director : Name of managing mentioned on RDB Certificate

Telephone N° : (+xxx) xxxxxxxxxxxx

was granted the license to operate as wholesaler/ importer/ distributor/ retailer of food products, animal feeds, on the following locations:

Sales room: xxx Province/ City, xxx District, xxx Sector, xxx Cell.

Building/ plot/ street /house no, P.O. Box xxxxxxx, xxxxx,xxxxx

Stock room: xxxxxxxx Province /City, xxx District, xxxxx Sector, xxxxx Cell.

Building/ plot/ street /house no

Validity: This license is valid for one (1) year renewable from the date of issuance

N.B.:

1. This license must be prominently displayed in the premises to which it refers to.
2. Any change made on details of the company name, physical location, management or closure of the premise shall be notified and approved by Rwanda FDA.
3. This license is not transferrable and its misuse will result into suspension or revocation.
4. The application for renewal of license shall be done one month before its expiration.

Done at Kigali on

Name and signature of Director General + Stamp of the institution

Director General

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |



RWANDA FDA
Rwanda Food and Drugs Authority

P.O. Box 1948 Kigali

info@rwandafda.gov.rw

www.rwandafda.gov.rw

QMS N°: DIS/FMT/147

Rev. N°: 0

Effective Date : 21/02/2022

LICENSE TO OPERATE AS RESTAURANT | FAST FOOD ...

Issued under Article 9 of LAW N° 003/2018 of 09/02/2018 Establishing Rwanda Food and Drugs Authority and Determining its Mission, Organization and Functioning, and the LAW N° 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products, especially article 3&4,

Ref N°: DIS/ /FDA/20xx

This is to certify that

Name of the Company : Name of the company on RDB/RCA Certificate
Company Code : TIN number
Managing Director : Name of managing mentioned on RDB Certificate
Telephone N° : (+xxx) xxxxxxxxxxxx
Specialized Personnel : Name of specialized personnel

was granted the license to operate as restaurant of food, on the following locations:

Sales room: xxx Province/ City, xxx District, xxx Sector, xxx Cell.
 Building/ plot/ street /house no, P.O. Box xxxxxx, xxxxx,xxxxx

Stock room: xxxxxxxxx Province /City, xxx District, xxxxxx Sector, xxxxx Cell.
 Building/ plot/ street /house no

Validity: This license is valid for one (1) year renewable from the date of issuance

N.B.:

1. This license must be prominently displayed in the premises to which it refers to.
2. Any change made on details of the company name, physical location, management or closure of the premise shall be notified and approved by Rwanda FDA.
3. This license is not transferrable and its misuse will result into suspension or revocation.
4. The application for renewal of license shall be done one month before its expiration.

Done at Kigali on

Name and signature of Director General + Stamp of the institution

Director General

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |



RWANDA FDA
Rwanda Food and Drugs Authority

P.O. Box 1948 Kigali

info@rwandafda.gov.rw

www.rwandafda.gov.rw

Ref N^o: DIS/ /FDA/20__

LICENSE TO OPERATE A WHOLESALE / RETAIL FOOD SUPPLEMENTS/ INFANT FORMULAE

Reference is made to the **Law N^o 003/2018 of 09/02/2018** establishing Rwanda Food and Drugs Authority and determining its mission, organization and functioning especially in its article 3; and considering the provisions of the **Law N^o 47/2012 of 14/01/2013** relating to the regulation and inspection of food and pharmaceutical products especially in its article 3 & 4;

This is to certify that **NAMES OF ESTABLISHMENT**, registered under company code **TIN NUMBER** is licensed to operate as a retail food supplements shop located in **XXXX** City/Province, **XXXX** District, **XXXX** Sector, **XXXX** Cell.

Names of the Managing Director: **Mr(s)/Ms NAMES OF MANAGING DIRECTOR**

Telephone Number: **+2507xxxxxxx**

Names of responsible technician: **Mr(s) /Ms NAMES OF RESPONSIBLE TECHNICIAN**

Professional bodies Registration N^o: **COUNCIL REGISTRATION NUMBER (If applicable)**

Validity: This license is valid for one (1) year renewable from the date of its issuance.

NB:

1. *This license must be prominently displayed in the premises to which it refers to.*
2. *Any change made on details of the company name, physical location, management or responsible technician shall be notified and approved by Rwanda FDA.*
3. *This license is not transferrable and its misuse will result into suspension or revocation.*
4. *The application for renewal of license shall be done one month before its expiration.*

Done at Kigali on, dd/mm/yyyy

Name and signature of Director General + Stamp of the institution
Director General

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |



RWANDA FDA
Rwanda Food and Drugs Authority

| | | |
|-----------------------|----------------------------|-----------------------------|
| Doc. No.: DIS/GDL/005 | Revision Date: 29/9/2021 | Review Due Date: 20/02/2025 |
| Revision No.: 1 | Effective Date: 20/02/2022 | |