TABLE OF CONTENTS

FOREWORD .................................................................................................................. iii
INTRODUCTION .......................................................................................................... iv
DEFINITIONS OF TERMS ............................................................................................ v
CHAPTER ONE ........................................................................................................... vii
  1.0 REQUIREMENT FOR PREMISES REGISTRATION AND OPERATIONAL LICENSE...... vii
  1.1 GENERAL REQUIREMENTS ................................................................................. vii
  1.2 SPECIFIC APPLICATION REQUIREMENTS ........................................................ vii
CHAPTER TWO .......................................................................................................... viii
  2.0 PROCEDURE FOR APPLICATION OF PREMISES REGISTRATION AND OPERATIONAL LICENSE ................................................................. viii
  2.1 APPLICATION PROCEDURES .............................................................................. viii
  2.2 VALIDITY OF FOOD PREMISES REGISTRATION CERTIFICATE AND OPERATIONAL LICENSE .......................................................... viii
  2.3 RENEWAL OF OPERATIONAL LICENSE ............................................................. viii
  2.4 NOTIFICATION FOR SHIFTS OF PREMISES, CHANGE OF OWNERSHIP OR ANY ALTERATION AND TERMINATION OF PREMISES REGISTRATION BY HOLDER OF REGISTRATION CERTIFICATE ............................................................. viii
CHAPTER 3 ................................................................................................................. ix
  3.0 GENERAL FOOD PREMISES REQUIREMENTS .................................................... x
  3.1 LOCATION ........................................................................................................... x
  3.2 EQUIPMENT, UTENSILS AND FOOD CONTACT SURFACE ................................................. x
  3.4 PERSONNEL ....................................................................................................... x
  3.5 STORAGE FACILITIES ......................................................................................... x
  3.6 SANITATION AND HYGIENE .............................................................................. x
  3.7 DOCUMENTATION AND RECORD KEEPING ................................................... x
  3.8 RECALLS, REJECT AND WITHDRAWAL ............................................................ x
REFERENCES ............................................................................................................ xiv
ANNEX I : APPLICATION FOR REGISTRATION OF PREMISES .................................. xvi
DIS/FMT/028 ............................................................................................................ xvii
ANNEX II : CERTIFICATE OF REGISTRATION FOR FOOD PREMISES .................. xix
DIS/FOM/030 ............................................................................................................ xix
ANNEX III : APPLICATION FOR LICENSE ................................................................ xix
DIS/FMT/029 ............................................................................................................ xix
ANNEX IV : LICENSE ............................................................................................... xx
Issued on..............Fees paid in Rwf , ........................................................................... xx

Doc. No.: DIS/GDL/005  Revision Date: 07/05/2019  Review Due Date: 13/05/2022
Revision No.: 0  Effective Date: 13/05/2019
FOREWORD

The Rwanda Food and Drugs Authority (RWANDA FDA) is a regulatory body established by the 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 the consumption of food, especially in its article 3(13).

The achievement of this goal depends on the awareness and adherence to the law by all key players dealing in one way or another with products regulated under the Law. The Law no 47/2012 of 14/01/2013 relating to the regulation and inspection of Food and Pharmaceutical Products in its Article 3(par. 1 and 2) stipulates the modalities for registration of premises and licensing of food business respectively.

All dealers in food business should have their prime concerns of the consumer’s health. Therefore, dealers should take reasonable steps to ensure that the food supplied to the community is safe, of good quality, and at the same time they should ensure that registered 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.

These guidelines are developed to provide guidance on application requirement for premises registration and licensing. Food manufacturers and distributors will be able to prepare the required application document in line with the requirements of the guidelines and therefore minimize unnecessary queries. Therefore, implementation of these guidelines will speed up provision of quality service to the clients.

Director General
RWANDA FOOD AND DRUGS AUTHORITY

Doc. No.:DIS/GDL/005 Revision Date: 07/05/2019 Review Due Date: 13/05/2022
Revision No.:0 Effective Date:13/05/2019
INTRODUCTION

Registration of premises for dealing with food businesses is a prerequisite requirement prior to commencing of such businesses. This requirement is stipulated under Article 3 and 4 of the Law N° 47/2012 of 14/01/2013. The legislation prohibits the use of any premises for the manufacture, sale, sell, supply or storage of food unless the premises have been registered by the RWANDA FOOD AND DRUGS AUTHORITY (Rwanda FDA) for that purpose.

Registration of premises and licensing of food businesses shall not be considered as the sole means of controlling the operations of such premises. However, there are other valuable means of aid in enforcing relevant legislation, such as adherence to good hygienic practices, good storage practice and good distribution practice that ensure day-to-day operations of these premises are in line with the laws and regulations. Basing on these grounds, the Authority is empowered to suspend or revoke the registration certificate and license of any premises found operating contrary to the law.

These guidelines are divided into three chapters; Chapter one explains the general requirements, specific application requirements, language to be used and payment of fees for the business license. Chapter two highlights on the application procedures for selling outlets, manufacturing facilities and validity of the issued premises registration certificate and business license. Moreover, notifications for a shift of premises, change of ownership or any alteration, and termination of premises registration have been elaborated in chapter two. The General food premises requirement has been emphasized in chapter three.

Therefore, these guidelines have been developed to guide food dealers on the requirement for registration, licensing and operation of their businesses as per the Law N° 47/2012 of 14/01/2013 and food regulations.
DEFINITIONS OF TERMS

The following definitions are given for the purpose of these guidelines

1. Authority
   Means the RWANDA FOOD AND DRUGS AUTHORITY or the acronyms Rwanda FDA established under the Law No 003/2018 of 09/02/2018.

2. Business
   Includes professional practice and any activity carried on by a person or a body of persons in relation to products regulated under the Law No 47/2012 of 14/01/2013.

3. Director General
   Means the Chief Executive of the RWANDA FOOD AND DRUGS AUTHORITY appointed under Article 7 of the Law No 003/2018 of 09/02/2018.

4. 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.

5. Food
   Means any article other than drugs, cosmetics and tobacco used as food or drink for human consumption and includes any substance used in manufacturing or treatment of food.

6. Food manufacturing facilities
   Means premises where operations involve production, preparation, processing, formulating, filling, refining, transformation packing, packaging or re-packaging of food.

7. Food outlets
   Means premises where food is stored, sold, distributed, displayed for sale or advertise

8. Handling
   Includes the making, manufacturing, producing, collecting, extracting, processing, storing, transporting, delivering, preparing, treating, preserving, packing, cooking, thawing, serving or displaying of food.

9. Inspector
   Means any officer appointed, authorized or recognized under the Law No 003/2018 of 09/02/2018.

---

Doc. No.: DIS/GDL/005 | Revision Date: 07/05/2019 | Review Due Date: 13/05/2022
Revision No.: 0 | Effective Date: 13/05/2019
10. Premises

Includes building structures, basements and vessels and in relation to any building includes a 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.

11. Sell

Means sell by wholesale or retail and include import, offer, advertise, keep, expose, display, transmit, consign, convey or deliver for sale or authorise, direct or allow a sale, or prepare or posses for the purpose of sale and batter or exchange supply or dispose of to any person whether for a consideration or otherwise.
CHAPTER ONE

1.0 REQUIREMENT FOR PREMISES REGISTRATION AND OPERATIONAL LICENSE

1.1 GENERAL REQUIREMENTS

1.1.1 Any person who intends to carry out a business of food for human consumption shall apply to RWANDA FDA for registration of premises and licence of carrying out such food business.

1.1.2 In order to adhere to the legal requirements, the applicant is obliged to obtain guidelines for application for registration of food premises and licensing of business and follow the instructions prescribed in these guidelines. These guidelines will be obtained from the RWANDA FDA headquarter office or www.rwandafda.gov.rw

1.1.3 The food premises and businesses shall include the following:
   i) Food manufacturing facilities
   ii) Food outlets

1.1.4 Payment of fees shall be made through RWANDA FDA, National Bank of Rwanda (BNR) account number 1000047658 in Rwandan Francs (FRW) and 1000047666 in USD. All bank charges shall be borne by the applicant.

1.1.5 All the prescribed information and communications regarding the application shall be made either in English or Kinyarwanda

1.2 SPECIFIC APPLICATION REQUIREMENTS

1.2.1 Food manufacturing facilities
   A complete application shall include the following
   i) A duly filled in application forms for premises registration and license
   ii) Process flow chart
   iii) Plant layout
   iv) Certificate of qualified personnel
   v) Letter of commitment of the qualified personnel for supervision of manufacturing facilities

1.2.2 Food outlets

The applicant shall submit a duly filled in application forms for premises registration and license
CHAPTER TWO

2.0 PROCEDURE FOR APPLICATION OF PREMISES REGISTRATION AND OPERATIONAL LICENSE

2.1 APPLICATION PROCEDURES
2.1.1 All applications for registration of food premises and license to operate food business or renewal of license shall be made to the Director General, Rwanda FDA in prescribed application forms for registration of premises (DIS/FOM/029) and for license/license (DIS/FOM/030).

2.1.2 The application shall be submitted to RWANDA FDA Head Quarter.

2.1.3 Upon receipt of complete application and payment of necessary fees, acknowledgement receipt should be issued to the applicant.

2.1.4 The plan, design and construction of the premises shall comply with the requirements of Food Hygiene Regulations.

2.1.5 The applicant may seek advice and consultation from the authority as regards to compliance with the Food Hygiene regulation.

2.1.6 When the construction or renovation is complete, the inspector shall conduct a thorough pre-registration inspection using an appropriate inspection checklist for that particular business give his observations and recommendation on the suitability of the premises in the application form.

2.1.7 The inspectors shall make sure that all information required in the appropriate inspection checklists is properly filled, signed and stamped by both applicant and the inspector.

2.1.8 Upon receipt of duly filled in application forms, inspection checklist and all other necessary documents, Director General shall scrutinize the status of each application, followed by acknowledging receipt.

2.1.9 The Director General may approve, withhold or reject any application and provide reason(s) for decision of withhold or rejection.

2.1.10 For manufacturers whose application for premises registration have been approved, will be issued a notification letter allowing them to carry out trial run to obtain samples for product registration. Upon successful registration of the product, a premises registration certificate and operational license license shall be issued to the applicant.

<table>
<thead>
<tr>
<th>Doc. No.:DIS/GDL/005</th>
<th>Revision Date: 07/05/2019</th>
<th>Review Due Date: 13/05/2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision No.:0</td>
<td>Effective Date:13/05/2019</td>
<td></td>
</tr>
</tbody>
</table>
2.1.11 Applicants whose applications have been withheld for any reason shall be required to carry out rectification or give a clarification within 6 months before they are legible for consideration. After the elapse of this period, the application shall be withdrawn automatically.

2.1.12 The Authority upon satisfaction that the premise complies with legal requirements shall issue premises registration certificate and operational license to the applicant.

2.1.13 Premises registration certificate and operational license for food outlet business shall be issued without submission of sample for registration

2.2 VALIDITY OF FOOD PREMISES REGISTRATION CERTIFICATE AND OPERATIONAL LICENSE

2.2.1 The registration of premises shall be valid provided that the following conditions are met:
   i) The operational license is renewed.
   ii) The premises comply with the conditions under which it was registered.
   iii) There is no change of ownership, business name, location or any alteration of registered premises.
   iv) The Authority has not suspended, cancelled, revoked or amended premises registration.
   v) Premises registration holder has not terminated his/her registration.

2.2.2 The license shall be annually renewed unless suspended, cancelled or revoked by the Authority.

2.2.3 Every Food operational license issued by the Authority shall expire on the 30th Day of June every year.

2.3 RENEWAL OF OPERATIONAL LICENSE

2.3.1 The Authority shall start to receive applications for renewal of license three (3) months before 30th June.

2.3.2 Renewal of operational license shall be done through RWANDA FDA headquarter offices by submitting duly filled in form RWANDA FDA 02, a copy of the previous operational license and the payment of respective fee.

2.3.3 Dealers who shall delay to renew their licenses beyond 30th September every year shall be required to pay the prescribed fee together with a 25 % penalty. Contrary to that, registration certificate shall be revoked and the premises closed down.
2.4 NOTIFICATION FOR SHIFT OF PREMISES, CHANGE OF OWNERSHIP OR ANY ALTERATION AND TERMINATION OF PREMISES REGISTRATION BY HOLDER OF REGISTRATION CERTIFICATE

2.4.1 Notification for change of location (shift of premises), change of type of business, trade name of the premises, ownership or any other change of registered premises, shall be made to the Director General.

2.4.2 Notification for change of location and type of business shall be treated as a new application. Therefore, the application procedure for new premises as prescribed in these guidelines shall apply.

2.4.3 Upon receipt of notification for change of name, ownership or any other alteration the applicant shall be required to pay the respective fees.

2.4.4 The Authority shall process and effect the necessary changes.

2.4.5 Premises registered by the Authority shall cease to have effect upon the expiration of thirty days from the date of change of ownership of the business.

2.4.6 Whenever a Premises 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.
CHAPTER 3

3.0 GENERAL FOOD PREMISES REQUIREMENTS

General food premises requirements include, but not limited to the following:

3.1 LOCATION

3.1.1 The food premises shall be located away from sites or activities that emit obnoxious material like fumes, dust, smoke, offensive trade or breeding sites for vermin.

3.1.2 Physical and postal address of the premises where the business is to be carried out shall be clearly indicated in the application form to include plot and house numbers, street, district and Province as this will facilitate easy reach during supervision and inspection.

3.2 PREMISES DESIGN

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 and constructed to facilitate easy maintenance and sanitation.

3.2.3 The food premises and facilities installed shall have:

i) Sufficient space for placement and storage of materials, which are necessary for sanitary operations;

ii) Adequate space, either by partition, location or other effective means for those operations, which may cause contamination of food;

iii) Sufficient lighting and ventilation to enable all operations to be carried out satisfactorily and safely;

iv) Maximum protection against rodents, birds, vermin etc.

v) The floor, walls and ceiling of food premises shall be adequately cleanable and maintained in a clean and good state of repair.

vi) 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.

vii) Aisles or working spaces between equipment and walls shall be unobstructed and of sufficient width to allow employees to perform their duties without contaminate the food or food contact surfaces with their clothing or personal contact.

3.3 EQUIPMENT, UTENSILS AND FOOD CONTACT SURFACE

3.3.1 Every utensil and equipment used in food premises shall be suitable for their intended use; well designed and adequately cleanable and proper maintenance of cold chain for frozen products.

<table>
<thead>
<tr>
<th>Doc. No.: DIS/GDL/005</th>
<th>Revision Date: 07/05/2019</th>
<th>Review Due Date: 13/05/2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision No.: 0</td>
<td>Effective Date: 13/05/2019</td>
<td></td>
</tr>
</tbody>
</table>
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.

3.4 PERSONNEL
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.
3.4.1 Thorough medical examination for Food handlers shall be carried out prior to employment and after every six months.

3.4.2 There shall be properly trained personnel from a recognized Institution.

3.4.3 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.

3.5 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

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 sexes, 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 re-contamination 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 food handler’s hands.

3.7 DOCUMENTATION AND RECORD KEEPING
Any person who owns a food business shall make available the following documents/records:

i) Food import licenses and/or purchasing documents
ii) Sanitation and fumigation documents
iii) Ledger book or an appropriate inventory control system
iv) Visitors' book
v) Sales receipts (wholesalers)
vi) Inspection log book
vii) Medical examination records where applicable
viii) Complaints handling book
ix) Register for expired/recalled/rejected/withdrawn food products
x) Food Hygiene Regulation

3.8 RECALLS, REJECT AND WITHDRAWAL
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.

3.8.2 In case of recall of product initiated by the dealer himself, the Authority shall be notified of the reason of 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.
REFERENCES

(a) The Law No 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority and determining its mission, organisation and functioning

(b) The Law No 47/2012 of 14/01/2013 relating to the regulation and inspection of Food and Pharmaceutical Products

(c) Tanzania Guideline of food premises registration and licensing

(d) Tanzania Food Hygiene Regulations
ANNEX I : APPLICATION FOR REGISTRATION OF PREMISES

RWANDA FOOD AND DRUGS AUTHORITY
APPLICATION FOR REGISTRATION OF PREMISES

Director General,
Rwanda Food and Drugs Authority,
P. O. Box…….,
Kigali

SECTION A: APPLICANT INFORMATION

I / We hereby apply for registration of my/our existing/ new premises in accordance with the Law N° 47/2012 of 14/01/2013

1. Name of applicant..........................................................................................................................................

2. Postal address........................................ Tel, No........................................ Fax ........................................
e - Mail.....................................................................................................................................................

3. Full name(s) of Partner(s) and Directors(s)
...........................................................................................................................................................................

4. Business situated at/lying between Plot /Vessel/ Truck No...........................................................
   Street/Village/Sector............................................... District/Province/City

5. Premises to be registered for the business of ..............................................................................................

6. The business will be under the supervision of a authorised person, Mr /Ms /Mrs. /Dr. / Prof (Full name)........................................................................................................ whose qualification
   is........................................ and his/her registration number(if any) is...................... of......... (Year).

<table>
<thead>
<tr>
<th>Doc. No.:DIS/GDL/005</th>
<th>Revision Date: 07/05/2019</th>
<th>Review Due Date: 13/05/2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision No.:0</td>
<td>Effective Date:13/05/2019</td>
<td></td>
</tr>
</tbody>
</table>
(Please attach a copy of registration certificate and acceptance/commitment letter from the authorised person)

7. The proposed name of the premises is.................................

8. My/ Our financial resources committed for this business amount to.................................

9. If my/our premises is registered and licensed, I/We shall keep it in hygienic condition and good state of repair as required under the above mentioned Law and Regulations made there under.

10. I/we have not been convicted of any offence relating to any provision of the Law No 47/2012 of 14/01/2013 and Regulations made there under or any other written law related to the business being applied for within 12 months immediately preceding this application and have not been disqualified from holding a license/certificate and my license is/is not suspended.

11. Fees in Rwandan francs/us dollars/Euro.......................... Receipt No.......................... of.................................

N.B. False declaration constitutes an offence.

Date..........................
Signed..........................

Applicant

SECTION B: RWANDA FDA INSPECTOR REMARKS

(Delete which inapplicable)

I (name) Mr./Mrs./Ms./Dr./Prof.......................... Rwanda FDA Inspector, hereby certifies that, I have inspected the above mentioned premises in Section A as per attached inspection checklist and found that it complies/does not comply with the standards prescribed for registration of premises.

Please give reason, if(s) it does not comply.................................

...........................................................................................................................................................................................................................................................................

Name of Inspectors(s)
Signatures
Date
1. .......................................................... ..........................
2. .......................................................... ..........................
3. .......................................................... ..........................

Doc. No.:DIS/GDL/005  Revision Date: 07/05/2019  Review Due Date: 13/05/2022

Revision No.:0  Effective Date: 13/05/2019
ANNEX II: CERTIFICATE OF REGISTRATION FOR FOOD PREMISES

This is to certify that the premises owned by M/S..........................which is located , in.............................................House ..........................n° Street............ Village.........../Cell............../Sector.........../District.........../Province................../City............... have been registered to be used as........................................ for preparation/selling/packing/carrying/advertising/storing/manufacturing of..... with Premises Registration No............

Subject to the following conditions:

1. The premises and the manner in which the business is to be conducted must conform to the Law n° 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority and determining its mission, organisation and functioning, Law N° 47/2012 of 14/01/2013 relating to the regulation and inspection of Food and Pharmaceutical products or any other written law related to the premises registration at all times failing of which this certificate shall be suspended or revoked.

2. Any change in the ownership, name and location of the registered premises shall be approved by the Authority.

3. This certificate is not transferable to other premises or to any other person

4. This certificate shall be displayed visibly in the registered premises.

.........................................................
Date

.........................................................
Signature of Director General and stamp

Doc. No.:DIS/GDL/005  Revision Date: 07/05/2019  Review Due Date: 13/05/2022
Revision No.:0  Effective Date:13/05/2019
ANNEX III: APPLICATION FOR LICENSE

Rwanda Food and Drugs Authority
APPLICATION FOR LICENSE

Director General,
Rwanda Food and Drugs Authority,
P. O. Box..........., 
Kigali

PART I:

1. We hereby apply for renewal/ a new licence to manufacture, sell, pack, store or distribute the following: .................................................................

1. Name of applicant.................................................................

2. Postal address............................. Tel, No............................ Fax.................................
E-mail......................................................................

3. Full name(s) of Partner(s) and Directors(s)
......................................................................................
..............................................................................
.................................................................

4. Premises situated at/lying between Plot /Vessel/ Truck No........................................
Street/ Village/ Sector............................................District / Province/City

5. Premises registered for the business of.................................................................

6. Premises Registration No...........................................of(year)..................................................................

7. Existing License No...........................................Dated.........................Expiring on............................... 

8. Fees in Rwandan francs/US Dollars/Euro..................................................
Receipt No...........................................of.................................................................

Doc. No.: DIS/GDL/005     Revision Date: 07/05/2019     Review Due Date: 13/05/2022
Revision No.: 0     Effective Date: 13/05/2019
PART II: APPLICABLE FOR MANUFACTURERS ONLY

PRODUCT REGISTRATION STATUS

I wish to manufacture the following item whose registration status is shown below:

<table>
<thead>
<tr>
<th>S/N</th>
<th>Common/ Generic Name</th>
<th>Trade Name</th>
<th>Registration No.</th>
<th>For official use only</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Use additional sheets of paper if space provided is insufficient.

PART III: APPLICANT DECLARATIONS

1. If my/our business is licensed I/We shall keep the premises in hygienic condition and good state of repair as required under the above mentioned Law and Regulations made there under.

2. I/we have not been convicted of any offence relating to any provision of the Law N° 47/2012 of 14/01/2013 and Regulations made there under or any other written law related to the business being applied for within 12 months immediately preceding this application and have not been disqualified from holding a license/certificate and my/our license is/is not suspended.

N.B. False declaration constitutes an offence.

..................................................
Date

..................................................
Signature of Applicant and stamp

Doc. No.:DIS/GDL/005  Revision Date: 07/05/2019  Review Due Date: 13/05/2022
Revision No.:0  Effective Date: 13/05/2019
FOR APPROVAL ONLY

Registration granted/not granted because: ____________________________

Registration No. __________________ Approved by Management meeting No. __________________
of ____________________________

Date __________________ Signature of Director General and stamp

<table>
<thead>
<tr>
<th>Doc. No.: DIS/GDL/005</th>
<th>Revision Date: 07/05/2019</th>
<th>Review Due Date: 13/05/2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision No.: 0</td>
<td>Effective Date: 13/05/2019</td>
<td></td>
</tr>
</tbody>
</table>

01 × 26
ANNEX IV : LICENSE

RWANDA FOOD AND DRUGS AUTHORITY

LICENSE

License No. ...............

License is hereby granted to M/S. ..........of P.O.Box. ...............to
Manufacture/Prepare/Pack/ Sell (Retail & Wholesale)/Store/Carry/Advertise.......... at the premises situated
at Province/city.............District.............sector.............Cell.............Village.............street.............
Plot No. .............and Registration No. ...............

This License shall have and continue to have effect from and including the day when it is issued until
it ceases to have effect on 30th June. ........................................

Issued on.............Fees paid in Rwf, ..................................

Receipt No...........................
Dated..............................

Date..............................

.................................................................
Signature of Director General and Stamp

CONDITIONS

1. This License is not valid during the period of suspension, revocation or cancellation of
registration of the premises in respect of which it was issued.
2. This License is not transferable without a written approval of the Authority.

<table>
<thead>
<tr>
<th>Doc. No.: DIS/GDL/005</th>
<th>Revision Date: 07/05/2019</th>
<th>Review Due Date: 13/05/2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision No.:0</td>
<td>Effective Date: 13/05/2019</td>
<td></td>
</tr>
<tr>
<td><strong>Author</strong></td>
<td><strong>Authorised by</strong></td>
<td><strong>Approved by</strong></td>
</tr>
<tr>
<td>-----------</td>
<td>----------------</td>
<td>----------------</td>
</tr>
<tr>
<td><strong>Title</strong></td>
<td>Drug and Food Inspection &amp; Compliance Division Manager</td>
<td>Head of Food and Drugs Inspection &amp; Safety Monitoring Department</td>
</tr>
<tr>
<td><strong>Name</strong></td>
<td>Munyambamu Joseph</td>
<td>Alex Gikumana</td>
</tr>
<tr>
<td><strong>Signature</strong></td>
<td><img src="signature.png" alt="Signature" /></td>
<td><img src="signature.png" alt="Signature" /></td>
</tr>
<tr>
<td><strong>Date</strong></td>
<td>15/05/2019</td>
<td>13/05/2019</td>
</tr>
</tbody>
</table>