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RWANDA FDA Rwanda Food and Drugs Authority	Title: **ISSUANCE OF PREMISE LICENSE**	

	Author	Checked by		Approved by
Title	Drugs Inspections Compliance Analyst	Quality Assurance Analyst	DM/FDIC	HoD/FDISM
Names	Clarisse AYINKAMIYE	Dr. Vedaste HABYALIMANA	Dr. MURINDAHABI M. Marilyn	Alex GISAGARA
Date	16/07/2021	16/07/2021	16/07/2021	16/07/2021
Signature				

1.0 Purpose

The purpose of this SOP is to detail how applications for premise licenses are processed.

2.0 Scope

This Standard Operating Procedure:

2.1 Applies to all applications for licenses of premises dealing with products regulated by Rwanda FDA products.

3.0 Policy

3.1 The Law N° 003/2018 of 09/02/2018 Establishing Rwanda Food and Drugs Authority and Determining its Mission, Organization and Functioning states in:
Article 3 (13) … *"premises used in the manufacture of products regulated by this Law"*

4.0 Responsibility

Food and Drugs Inspection and compliance Division
4.1 The Head of Food and Drugs Inspection and Safety Monitoring is responsible for:

4.1.1 Ensuring that all applications for licensing to operate as a Wholesale or Retail seller of products regulated by Rwanda FDA are processed according to this SOP.
4.1.2 Notifying all applicants and licensees of the decisions of the Authority regarding licensing of premises regulated under the Law.
4.2 The Division Manager of Food Inspections and Compliance is responsible for ensuring that all new applications and applications for renewal of premises licenses received are processed; and that the database is updated accordingly.
4.2.1 Maintaining the database of premises regulated under the Law.

5.0 Abbreviations and Definitions

5.1 "**Law**" Nº 003/2018 of 09/02/2018 Establishing Rwanda Food and Drugs Authority and Determining its Mission, Organization and Functioning
5. 2 "**Medical product"** Includes medicines, vaccines, diagnostics and medical devices.
5.3 Food: any article other than drugs, cosmetics; tobacco used as drink or food for human consumption and includes any substance used in the manufacturing or treatment of food.
5.4 "**Premise**" Means any plot of land, buildings or boats, aircrafts, vehicles, a part of a building, channels, yards, a place of storage, annexed to a building, or part of that building, carriage or receptacle of any kind, whether open or closed.

6.0 Distribution

6.1 Head of Food and Drugs Inspection and Safety Monitoring Department
6.2 Division Manager, Food Inspections & Compliance Division
6.3 Quality assurance analyst
6.4 Analysts
6.5. Specialists

7.0 Safety Precautions

Not applicable to this procedure.

8.0 Materials and equipment

8.1 Regulations and Guidelines for suitability and licensing of premises
8.2 Checklists for receiving applications for premises licenses

9.0 Procedure

9.1 Receipt of hard applications

9.1.1 Applicants shall submit their applications in duplicate at Rwanda FDA head office's registry and a copy of such application shall be stamped "Received" and returned to the applicant as his reference.

9.1.2 The received applications shall be recorded in the register at the central secretariat and a temporary file shall be opened for individual applicants and shall be sent immediately to the Head Food and Drugs and safety monitoring department.
9.1.3 Upon receipt of the applicant's file, the Head of Food and Drugs inspection and safety monitoring department shall scrutinize the application to verify correctness of the information. If satisfied he/she shall assign it to the food, drugs Inspection and compliance Division Manager who shall then assign it to the analyst or specialist for assessment. If not satisfied, then he/she shall inform the applicant for clarification of the application.
9.1.4 The Division Manager of food and drugs inspection and compliance shall organize for inspection of applicants proposed premises.
9.1.5 Inspectors shall conduct inspection to verify compliance to requirements as enumerated in the Inspection Checklist for new premises
9.1.6 The assigned analyst /specialist shall verify the following;

(i) Submission of sample for registration (for the case of licensing of manufacturing facilities);
(ii) Credentials of product process supervisor have been submitted to Rwanda FDA
(iii) Submission of process flow chart and plant flow diagrams.
(iv) Presence of a properly filled application forms for Premise Registration Certificate and inspection checklist, signed by both inspector and applicant.
(v) Payment of premise licensing fee.

9.1.7 If the applicant has fulfilled the above requirements, the assigned analyst/specialist shall forward the application to the committee meeting and the applicant shall be informed on the outcome.
9.1.8 The analyst/specialist assessing, shall go through all the applicant's files and if satisfied a summary report of the applications together with individual applicant's file shall be sent to the Food, Drugs and compliance division manager through the Analyst to be presented to the committee meeting for deliberation.
9.1.9 The committee may approve or disapprove the presented application
9.1.10 If the application has been rejected, Food and Drugs and compliance the Division manager shall inform the applicant giving reason(s) for rejection.
9.1.11 The applicant for manufacturing facilities shall be required to make Payment for business permits upon registration of their products.

9.2 Receipt of applications via emails

9.2.1 Applications for premises licensing shall be submitted online by filling relevant application form.
9.2.2 Applicants shall submit their applications at Rwanda FDA secretariat email at "info@rwandafda.gov.rw"
9.2.3 The received applications shall be recorded in the register at the central secretariat and a temporary file shall be opened for individual applicants and shall be sent immediately to the Head Food and Drugs and safety monitoring department.
9.2.4 Upon receipt of the applicant's file, the Head of Food and Drugs inspection and safety monitoring department shall scrutinize the application to verify correctness of the information. If satisfied he/she shall assign it to the food, drugs Inspection and compliance

Division Manager who shall then assign it to the analyst or specialist for assessment. If not satisfied, then he/she shall inform the applicant for clarification of the application.

9.2.5 The Division Manager of food and drugs inspection and compliance shall organize for inspection of applicants proposed premises.

9.2.6 Inspectors shall conduct inspection to verify compliance to requirements as enumerated in the Inspection Checklist for new premises.

9.2.7 The assigned analyst /specialist shall verify the following;

(i) Submission of dully filled form of premise registration

(ii) Credentials of product process supervisor have been submitted to Rwanda FDA

(iii) Submission of process flow and plant flow diagrams.

(iv) Presence of a properly filled application forms for Premise Registration Certificate and inspection checklist, signed by both inspector and applicant.

(v) Payment of premise licensing fee.

9.2.8 If the applicant has fulfilled the above requirements, the assigned analyst/specialist shall forward the application to the committee meeting and the applicant shall be informed on the outcome.

9.3 The analyst/specialist assessing, shall go through all the applicant's files and if satisfied a summary report of the applications together with individual applicant's file shall be sent to the Food, Drugs and compliance division manager to be presented to the committee meeting for deliberation.

9.4 The committee meeting is chaired by the Head of Department, and the Division Manager of Food and Drugs with the Analysts and specialists once a week.

9.5 The applications are presented and the committee may approve or disapprove the presented application

9.5.1 If the application has been rejected, the specialist prepares the feedback letter with recommendation and submit to the Food and Drugs and compliance the Division manager through the Analyst.

9.5.2 The Division Manager reviews and submit the feedback letter to the Head of Department for review and sent to Director General for approval

9.5.3 If the Application has been approved, the specialist prepares the operational license and submit to the Food and Drugs Division Manager through the Analyst

9.5.4 The Division Manager reviews and submit the operational license to the Head of Department for review and sent to Director General for approval

9.6 The endorsed operational license/ feedback letter is sent to the central secretariat for reference and archiving

9.7 The central secretariat sends the endorsed operational license/ feedback letter to the respective applicant via email

9.8 The feedback letter and operational license must be issued to the applicant within 20 working days from the date of reception of dully completed documents.

10.0 Records

Inspection reports follow up inspection reports, inspection checklists, inspection memorandum forms, certificates, and general correspondences shall be maintained at the registry and the department for five years and then destroyed appropriately.

11.0 References

11.1 Rwanda FDA guidelines for Licensing to Manufacture, to Operate as Wholesale and Retail Seller of Medical Products

12.0 Document Revision History

Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision
16 Jul 2021	0	Rwanda FDA Staff	First Issue

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