RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Food and Drugs Inspection and Safety Monitoring Department	
Document Type: **Standard Operating Procedure**		Doc. Number	: QMS/SOP/069
RWANDA FDA Rwanda Food and Drugs Authority	Title: **SOP FOR ISSUANCE OF PREMISE LICENSE**	Revision Number	:0
		Revision Date:	:15 May 2021
		Effective Date	:21May 2021
		Review Due Date	:21May 20203

RWANDA FOOD AND DRUGS AUTHORITY STANDARD OPERATING PROCEDURE (SOP) ON ISSUANCE OF PREMISE LICENSE

RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Drugs, Food Inspections and Compliance	
Document Type: **Standard Operating Procedure**		Doc. Number	:QMS/SOP/069
RWANDA FDA Rwanda Food and Drugs Authority	Title: **SOP FOR ISSUANCE OF PREMISE LICENSE**	Revision Number	:0
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1.0 Purpose

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 and food outlets.

3.0 Responsibility

Food and Drugs Inspection and compliance Division

4.0 Accountability

Head of food and drugs and safety monitoring department

5.0 Distribution

5.1 Head of Food and Drugs Inspection and Safety Monitoring Department

5.2. Division Manager, Food Inspections & Compliance Division

5 3. Quality assurance analyst

5.4 Analysts

5.5. Specialists

6.0 PROCEDURES

6.1. Applicants shall lodge 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.

6.2 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.

6.3 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.

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

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

6.6 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.

6.7 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.

6.8 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 to be presented to the committee meeting for deliberation.

6.9 The committee may approve or disapprove the presented application

6.10 If the application has been rejected, Food and Drugs and compliance the Division manager shall inform the applicant giving reason(s) for rejection.

6.11 The applicant for manufacturing facilities shall be required to make Payment for business permits upon registration of their products.

ONLINE APPLICATION

6.1 Applications for premises licensing shall be submitted online by filling relevant application form.

6.2 Applicants shall submit their applications at Rwanda FDA secretariat email at "info@rwandafda.gov.rw"

6.3 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.

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(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.

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7.0 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.

8.0 Document Revision History

Date of	Revision	Document Number	Author(s)	Summary of	Reasons for

RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Drugs, Food Inspections and Compliance	
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revision	number			Changes	revision
				NA	New

	Author	Checked by			Authorized by	Page 7 of 7
Title	Senior Licensing Officers, Drug and Food Inspectorate	Head, Drug Inspectorate Services	Head, Drug Assessment & Registration	Head, Quality Management	Executive Secretary /Registrar	
Signature & Date						

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