


Format: QMS/FMT/002 Revision No: 1 Effective Date: 20 June 2022	Department/Division	Food and Drugs Inspection and Safety Monitoring/Food and Drugs Inspection & Compliance
Document Type: Requirements		Doc. No : FDISM/FDIC/CKL/059
 RWANDA FDA Rwanda Food and Drugs Authority	Title: Requirements to license Cosmetics, Household Pesticides, Household Chemicals and Laboratory Chemicals Premises.	Revision Number : 0
		Revision Date: : 17/04/2023
		Effective Date : 28/04/2023
		Review Due Date : 27/04/2026
		Ref Doc. : FDISM/FDIC/GDL/009

Documents required for a manufacturer

1. Application letter addressed to the Director General of Rwanda FDA.
2. Duly filled application form: Application form for premise licensing of cosmetics, household pesticides, household chemicals and laboratory chemicals.
3. Certificate of domestic company registration issued by Rwanda Development Board or equivalent
4. Architectural plan of the site.
5. Product process flowchart (s).
6. Environment impact assessment report.
7. Proof of payment of the prescribed fees.
8. List of products to be manufactured.
9. Lease/rent contract of the premise/house.
10. Notarized copy of Degree (and equivalence if applicable) of Responsible Technician.
11. Notarized Valid License of the responsible technician to Practice Profession issued by Recognized Professional Councils in Rwanda if applicable.
12. Notarized degrees of the key personnel to be involved in the manufacturing process, quality control and quality assurance.
13. Valid Contract between the Managing Director of the manufacturing plant and the responsible technician in case the Managing Director is not the responsible technician.
14. Copy of the identity card or passport of both the Managing Director and the responsible technician.
15. Written commitment of the technician, to respect the laws and regulations relating to the manufacturing practices performed and oversight the quality of products being manufactured.
16. Signed resignation letter/proof of service delivered issued by the last employer of responsible technician, if applicable.
17. Curriculum vitae of the responsible technician.

Documents required for a wholesaler, an importer or retail of laboratory chemicals

1. Application letter addressed to the Director General of Rwanda FDA.
2. Duly filled application form: Application form for premise licensing of cosmetics, household pesticides, household chemicals and laboratory chemicals.
3. Certificate of domestic company registration issued by Rwanda Development Board or equivalent.
4. Lease/rent contract of the premise/house.
5. Evidence of payment of prescribed fees to Rwanda FDA Accounts.
6. Notarized copy of Degree (and Equivalence if applicable) of responsible technician.

7. Notarized valid license to Practice Profession issued by Recognized Professional Councils in Rwanda if applicable.
8. Contract between the managing director and the responsible technician in case the Managing Director is not the responsible technician.
9. Copy of the identity card or passport of both the managing director and the responsible technician.
10. Written commitment of the technician to respect the laws and regulations relating to the management of chemicals.
11. Signed resignation letter/proof of service delivered issued by the last employer of responsible technician, if applicable.
12. A detailed curriculum vitae of the responsible technician.

Documents required for wholesaler, importer or retail of cosmetics, household pesticides and household chemicals

1. Application letter addressed to the Director General of Rwanda FDA.
2. Duly filled application form: Application form for premise licensing of cosmetics, household pesticides, household chemicals and laboratory chemicals.
3. Certificate of domestic company registration issued by Rwanda Development Board or equivalent.
4. Lease/rent contract of the premise/house.
5. Evidence of payment of prescribed fees to Rwanda FDA Accounts.
6. Copy of the identity card or passport of the Managing Director.
7. A recent passport-size photo.

Documents required for operational license renewal

1. Application letter addressed to the Director General of Rwanda FDA.
2. Duly filled application form: Application form for premise licensing of cosmetics, household pesticides, household chemicals and laboratory chemicals.
3. Notarized degree (or equivalence if applicable) of the responsible technician.
4. Recent operational license of the establishment issued by Rwanda FDA.
5. Written commitment of the responsible technician, to respect relevant laws and regulations and oversight the quality of products being handled where applicable.
6. Certificate of domestic company registration issued by Rwanda Development Board or equivalent.
7. Evidence of payment of prescribed fees.
8. Notarized valid license to practice profession of the responsible technician personnel where applicable.
9. Contract between the establishment and the responsible technician in charge where the managing director is not the responsible technician.
10. Copy of the identity card or passport of both the managing director and the responsible technician.

Documents required for relocation or additional storage space of the licensed premises

1. Application letter addressed to the Director General of Rwanda FDA.
2. Duly filled application form: Application form for premise licensing of cosmetics, household pesticides, household chemicals and laboratory chemicals.
3. Original operational license of the establishment issued by Rwanda FDA.
4. New Certificate of domestic company registration issued by Rwanda Development Board or equivalent.
5. Evidence of payment of prescribed fees.
6. Lease contract for the establishment.

Documents required for the change of the responsible technician of the licensed premises

1. Application letter addressed to the Director General of Rwanda FDA.
2. Duly filled application form: Application form for premise licensing of cosmetics, household pesticides, household chemicals and laboratory chemicals.
3. Original operational license of the establishment issued by Rwanda FDA.
4. Certificate of domestic company registration issued by Rwanda Development Board or equivalent.
5. Evidence of payment of prescribed fees.
6. Notarized degree (or equivalence if applicable) of the responsible technician.
7. Notarized valid license to practice profession of the responsible technician where applicable.
8. Contract between the establishment and the responsible technician in charge where the managing director is not the responsible technician.
9. Written commitment of the responsible technician, to respect relevant laws and regulations and oversight the quality of products being handled.
10. Copy of the identity card or passport of both the managing Director and the responsible technician.
11. Signed resignation letter/proof of service delivered of the outgoing responsible technician
12. Signed resignation letter/proof of service delivered issued by the last employer of the incoming responsible technician, if applicable.
13. A Detailed curriculum vitae of the responsible technician.

Documents required to change the ownership of the licensed premises

1. Application letter addressed to the Director General of Rwanda FDA.
2. Duly filled application form: Application form for premise licensing of cosmetics, household pesticides, household chemicals and laboratory chemicals.
3. Original operational license of the establishment issued by Rwanda FDA.
4. Notarized sales agreement between former and new owner.
5. New and/or updated Certificate of domestic company registration issued by Rwanda Development Board or equivalent.
6. Notarized degree (or equivalence degree) of the responsible technician where applicable.
7. Notarized valid license to practice profession of the responsible technician where applicable.
8. Contract between the establishment and the responsible technician in charge where the managing director is not the responsible technician.
9. Copy of the identity card or passport of both the new managing director and the responsible technician.

Documents required to change the name of the licensed premises

1. Application letter addressed to the Director General of Rwanda FDA.
2. Duly filled application form: Application form for premise licensing of cosmetics, household pesticides, household chemicals and laboratory chemicals.
3. Original operational license of the licensed premise issued by Rwanda FDA.
4. Certificate of domestic company registration issued by Rwanda Development Board or equivalent.

Documents required to close the licensed premises

1. Application letter addressed to the Director General of Rwanda FDA.
2. Dully completed application form: Application form for premise licensing of cosmetics, household pesticides, household chemicals and laboratory chemicals.
3. Original of the premise registration certificate issued by Rwanda FDA.
4. Recent operational license issued by Rwanda FDA.
5. A list of closing stock of products and its intended use.

All the above stated requirements are submitted to the following official email: info@rwandafda.gov.rw

Done at Kigali on. 24 / 04 / 2023

Dr. Emile BIENVENU
Director General