RWANDA FDA
Rwanda Food and Drugs Authority

RWANDA FDA GUIDELINES ON APPEALS AND COMPLAINTS

NOVEMBER, 2022

Doc. No.: ODG/QMS/GDL/001	Revision Date: 23/11/2022	Review Due Date: 29/11/2025
Revision No.: 1	Approval date: 24/11/2022	Effective Date:30/11/2022

FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) is a regulatory body established by the Law N° 003/2018 of 09/02/2018 determining its mission, organization and functioning. It is committed to providing the highest quality of regulatory services that meet customer requirements.

In this regard, the Authority Issues Guidelines N° ODG/QMS/GDL/001 on Appeals and Complaints to guide customers on how they can appeal against regulatory decisions made and submit a complaint on service rendered or products regulated by the Authority.

Dr. Emile BIENVENU
Director General

GUIDELINES DEVELOPMENT HISTORY

DRAFT ZERO	20/07/2021
ADOPTION BY RWANDA FDA	23/07/2021
STAKEHOLDERS CONSULTATION	NA
ADOPTION OF STAKEHOLDERS' COMMENTS	NA
DATE FOR COMING INTO EFFECT	30/11/2022

Document Revision History

Date of revision	Revision number	Changes made and/or reasons for revision
23/07/2021	0	Initial Issue
23/11/2022	1	1. Include the chapter of complaints 2. Review of timelines to harmonize with other regulatory documents 3. Rearrangement of the entire document 4. Fine-tuning the text in line with updated SOP on document control.

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INTRODUCTION

These guidelines have been developed to provide guidance to applicants who are aggrieved (dissatisfied with) by any regulatory decision of the Authority, or services provided by Rwanda Food and Drugs Authority (Rwanda FDA) or any issues related to products regulated by the Authority.

If any person is aggrieved by any of the above, it is his/her right to lodge an appeal or complaint in line with the provisions in the Rwanda FDA Quality Manual and these guidelines.

SCOPE

A person has a right to lodge an administrative appeal when dissatisfied with a decision of the Authority or complain against services rendered, regulated products or other complaints in the following regulatory functions:

1. Marketing authorization or Registration,
2. Inspection and Licensing of manufacturers, importers, exporters and wholesalers and retailers of regulated products,
3. Regulatory enforcement actions, such as:
   a. Detention and/or seizure of medical products and other regulated products
   b. Recall and withdrawal of medical products and other regulated products
   c. Disposal of medical products and other regulated products
   d. Fines imposed,
4. Control of clinical trials of medical products,
5. Control of promotion and advertisement of regulated products,
6. Laboratory testing of regulated products,
7. Any other decision made by the Authority that may affect his or her business that is regulated by the Rwanda FDA.

DEFINITIONS

An Administrative Appeal: is a formal request for a review of a regulatory decision or an outcome of an application or any other decisions made or communicated by Rwanda FDA in writing or at any forum**.**

New Material: refers to material or information that was in existence at the time the review team made its decision which, had it been made available before the review had been completed, would have influenced the opinion of the team, and in relation to which an appellant must provide a good reason for not having been provided to the review team.

Complaint: Oral, written or any other form of expression of dissatisfaction made by a customer, client, stakeholder or any member of the public in respect to the operations, policies or activities related to, or incidental to the execution of Rwanda FDA mandate and service delivery.

CHAPTER I. APPEALS

GENERAL REQUIREMENTS

1. Any person who is aggrieved by a regulatory decision made by Rwanda FDA may formally request in writing for Rwanda FDA to reconsider/review the initial decision within 30 working days after the date of notification of the decision.

2. All appeal requests shall be made in writing, and addressed to:

THE DIRECTOR GENERAL
RWANDA FOOD AND DRUGS AUTHORITY
P.O BOX: 1948 KIGALI_RWANDA

3. The aggrieved person shall ensure that the appeal request includes the following:

- The appeal letter, dated and signed by the aggrieved person or entity requesting for the review of the regulatory decision or an outcome of an application or any other decisions made by the Authority;
- A copy of the initial decision notification letter (or other evidence of notification) stating clearly the regulatory decision for which the appeal is requested;
- Any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why review is requested;
- The list of grievances from the decision and other issues to be analysed again;
- The motivation for each grievance or problem indicating the errors committed and the way in which they must be modified on the basis of the law and the means of proof and the claim;
- A description of how the interests of the aggrieved person are affected by the regulatory decision.
- The motivation for additional claim if any

It is important to ensure that all information and documents that an appellant wishes Rwanda FDA to consider, is provided with the request to the Authority since it shall not consider any information provided after the submission of the request unless the information is provided in response to a request from the Rwanda FDA.

APPEAL APPLICATION REVIEW

Upon review of the appeal application, the Authority shall give response in writing of the outcome of the appeal application, which shall include a statement of reasons (i.e. findings, references to evidence and reasons for the decision). The response shall be addressed to the aggrieved person within 30 working days after submitting an appeal application.

In the event that the aggrieved person is a third party (i.e. the applicant was not the person to whom the regulatory decision was issued by the Authority), Rwanda FDA shall also notify in writing, the person to whom the regulatory decision was issued (e.g. the Market Authorization Holder (MAH) of the product, Sponsor of a Clinical Trial, etc.) a communication that a request for review has been received by Rwanda FDA.

An administrative appeal of a regulatory decision may result in one of the following:

1. Endorse the regulatory decision;
2. Revoke the regulatory decision in whole or in part;
3. Revoke and substitute the regulatory decision with a new decision.

ENDORSING THE REGULATORY DECISION

Where upon review the Authority decides to uphold the regulatory decision, the regulatory decision shall remain unchanged.
It is however possible that upon review, the Authority may have come to the same conclusion as the regulatory decision but for different reasons.

REVOKING THE REGULATORY DECISION

Where upon review the Authority decides to overturn a regulatory decision, the regulatory decision would be reversed as though the regulatory decision was never made.

REVOKING AND SUBSTITUTING THE REGULATORY DECISION WITH A NEW DECISION

Where upon review, Rwanda FDA decides to vary all or part of the regulatory decision, the regulatory decision would be partially or entirely replaced (substituted) by a new decision.

The Authority may assess the initial decision as being partially or entirely incorrect at the time it was made or as being partially or entirely irregular in light of procedure, new material or additional information made available to the Authority upon review of the initial decision.

If the initial decision is one of which is required to be published on Rwanda FDA's website (such as a decision to register a product or revoke/cancel/suspend a product registration, facility license, etc.), and Rwanda FDA upon revision of the regulatory decision decides to revoke and substitute the regulatory decision, the particulars of the current decision shall be published.

WITHDRAWING APPEAL APPLICATION

An aggrieved person may withdraw his/her request at any time before the Authority convenes a committee to review the regulatory decision. Withdrawal of an appeal application should be notified in writing to the Director General within a period of ten (10) working days of submitting the appeal.

APPEAL TO THE SUPERVISORY AUTHORITY

In case the feedback on the decision appealed does not satisfy the aggrieved person, or the aggrieved person wishes to appeal against Rwanda FDA to an independent Authority, she/he may appeal to the supervising Authority of Rwanda FDA, the Honourable Minister of Health.

CHAPTER II. RWANDA FDA CUSTOMER COMPLAINTS

Customer complaints may arise from services rendered or products regulated by the Authority Complaints can be recorded by the customers on the Rwanda FDA Customer Complaints form (Doc. No: ODG/QMS/FOM/012) found on Rwanda FDA website, or Rwanda FDA reception desk, or Rwanda FDA Quality Control Laboratory (QCL), or Rwanda FDA Port of entry offices.

The filled customer complaints can be submitted physically or courier or posted to Rwanda FDA head office or Rwanda FDA QCL or Rwanda FDA port of entry offices. The filled Customer Complaints form can also be sent to central secretariat's email (centralsecretariat@rwandafda.gov.rw or complaints@rwandafda.gov.rw).

The feedback to the complainant after investigation can be provided through appropriate communication channel.

TIMELINES

Request for appeal against decision(s) made by the Authority must be made within thirty (30) working days after the date of notification of the decision.

Acknowledgement of receipt of the appeal / complaint shall be made by the Authority within 2 working days.

Feedback from the Authority to the aggrieved / appellant person shall be made within 30 working days after submitting an appeal application.

Withdrawal of an appeal application from the Authority should be made within ten (10) working days after submission.

ENDORSEMENT OF THE GUIDELINES

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Date	24/11/2022	24/11/2022	24/11/2022