

GUIDELINES FOR CONTROL OF PROMOTION, ADVERTISEMENT AND MARKETING OF FOOD PRODUCTS IN RWANDA

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FOREWORD

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 mission of Rwanda FDA, especially in its Article 8, paragraph 11, is to regulate and analyse information used in the promotion, advertising, and marketing of regulated products.

Considering the provisions of the technical regulations No CBD/TRG/017 governing the promotion and advertising of regulated products, the Authority issues these Guidelines for control of promotion, advertisement and marketing of food products in Rwanda.

Food Promotion is regarded as an important means of creating awareness and disseminating information to the food dealers and general public. All food promotions are designed and prepared in such a way to persuade consumers to make choice of buying/using them. On the other hand, food promotion may be unethical, false, mislead the public and hence may have effect on the health of consumers if not controlled.

These Guidelines for promotion of food products have been developed to describe the scope and provide minimum requirements for authorization of promotion of food products and food supplements. Therefore guidelines stipulate, among others, elements of advertisement, marketing and promotion, restrictions therein, basic requirements, stakeholder's responsibilities and the application procedures for obtaining approval to advertise and promote regulated products.

It is our hope that food promotion stakeholders will find this document useful and easy to follow.

Dr. Emile BIENVENU Director General

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DEFINITIONS

In these guidelines:

- "Advertisement" means a form of communication through the media about products, services or ideas by an identified sponsor which is used to encourage, persuade or manipulate an audience (viewers, readers or listeners) to continue with or take some new action.
- "Advertising" means anything that is aimed or designed to promote the supply, sale or use of a product whether or not for financial gain, and it includes but not limited to written communication materials (for instance a notice, circular, handouts, wrappers, catalogues, bill boards, posters, newspapers, magazines, digital and social media or other promotional document), oral and audio materials (word of mouth, records, tapes, radio, ...) and visual announcement (films, video recordings, television, internet, electronic media, interactive data systems, ...).
- "Marketing" means to promote, distribute, sell, or advertise regulated products, or/and creating a relationship of the public and/or with information services regard to regulated products.
- "Appropriate fee" means the fee prescribed in the Regulations No CBD/TRG/004 related to regulatory service tariff/fees and fines.
- "Authority" means Rwanda Food and Drugs Authority (Rwanda FDA).
- "Applicant" means any advertisement agent, distributor, manufacturer or the sponsor of the advertised product.
- **"Food products"** are any animal, plant or mineral products that have been processed or transformed from their original state and are intended for human or animal consumption.
- "Food dealers" means manufacturers, importers, exporters, distributors (wholesalers and retailers) of food.
- "General public" means any person considered as a client or potential client.
- "Health professional" means any technical personnel involved in matters of human health or nutrition.
- **"Law"** means Law No. 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning.
- "Light and Sound mode of promotion" includes any promotion adverts with light and sound effects such as broadcast over television, cinema advertisements, videos, radio, or any audio-visual material. The messages may be contained in radio cassettes, Video cassette, Compact Discs, Digital Video discs, Video Compact Discs, Digital Videos, memory cards, etc.

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- "Manufacture" means all operations involved in the production of food from one or more ingredients and includes preparation, processing, filling, transforming, packaging and repackaging and labelling of food.
- "Manufacturer" means a person, company or organization that is engaged in manufacture of food.
- "Misleading information" means information that gives a wrong idea or impression.
- "Media" means newspaper, magazine, medical/journal, television, radio, internet, posters, handbills, cinema, point of sale material, digital and social media, any form of projected light and sound recordings or any of such means of communication.
- "Non-registrable food products" are products that have less than two (2) months of shelf life such as bakery products (breads, donuts, etc.)
- **"Promotion"** is any communication that attempts to influence people to buy or use food products. It is the publicizing of a product so as to increase public awareness or sales using of audio-visual, oral or written material through advertising, sales promotion, direct marketing publicity, trade shows, promotional meetings, participation in exhibitions, giving samples, personal selling, etc.
- "Promotional material" means any representation concerning the attributes of a product conveyed by any means for the purpose of encouraging the usage of a product.
- "Promotional samples" are mode of promotion which involve supply of free food samples to the dealers and consumers.
- "Promotional meetings" include workshops, conferences, seminars and symposium that are organized or sponsored by any company or under its control targeting the food dealers or any other person for the purpose of promoting food products or its launching.
- **"Promotional campaigns"** are campaigns that are directed to the general public with a view to providing information, promoting awareness or education about a particular food products. They also include Government controlled programs that are coordinated by other Ministries, Departments and/or Agencies.
- "Protected persons" means infants, young children, pregnant women, lactating women, care givers, guardians of infants and/or young children.
- "Regulated product" means processed foods, pharmaceutical products, vaccines, human and veterinary processed foods and other biological products used in clinical as drugs, food supplements, food fortificant, fortified foods, poisonous substances, herbal medicines, medicated cosmetics, medical devices, tobacco and tobacco products.
- "Sales Promotions" are any activity with the purpose of introducing, publicizing or promoting the sale of a food product e.g. price-off, banded offers. It also includes giving discounts and banding of

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different pack sizes of the same product within the same range, with or without a discount distribution of food samples.

"Stakeholders" means Food Dealers, Public institutions, Media and General Public.

"Still mode of promotion" includes any promotion adverts in written form or in print media such as magazines, newspapers, journals, diaries, calendars, flyers, brochures, billboards, posters, branding on vehicles, buildings, benches and other print publications.

"Trade fair/exhibition" is an event organized to demonstrate particular products of a company or organization to prospective customers.

"Web-based mode of promotion" includes any promotion adverts on websites social networks including blogs, etc.

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CHAPTER I: INTRODUCTION

1.1 Scope of these guidelines

According to the law N° 003/2018 of 09/02/2018 establishing Rwanda FDA, especially in its article 8, paragraph 11, the Authority is mandated to regulate and analyse information used in the promotion, advertising and marketing of products regulated under this Law and in its article 9 which give the powers of Rwanda FDA is formulate regulations and guidelines for regulating the manufacture, import and export, distribution, sale and use of regulated products under this Law;

Control of promotion of food products aims at ensuring that the public receives correct information about the products to help them make an informed decision on the choices and use of food products. It also includes protecting consumers from false, misleading or deceptive promotions that would create erroneous impression regarding products they consume.

These guidelines highlight general conditions and requirements as well as specific requirements for promoting food products to the public, procedures for submission of application to promote regulated products. They apply to the product promotion, advertisement and marketing by all manufacturers, wholesalers, retailers, dealer's applicants and/or anyone wishing to promote, advertise or market food products locally processed or imported in Rwanda.

The product promotion, advertisement and marketing must be aligned with the intended uses (indications), as per its registration. This can be in any forms or media, including but not limited to:

- a) Aerial promotions such as on hot air balloons
- b) Booklets
- c) Cinema commercials
- d) Consumer leaflets
- e) Direct mail materials
- f) Internet materials, including press releases intended for internet publication
- g) Onpack statements
- h) Outdoor advertising, including billboards, advertisements on wall fences and motor vehicles
- i) Point of sale materials
- j) Posters

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- k) Print advertisements
- 1) Promotional aids including those used for direct selling activities
- m) Sales promotions
- n) Telephone help lines
- o) Television and radio commercials
- p) Using social media platforms
- q) Sports, art and other sponsorships

1.2 Prohibitions on Promotion, Advertisement and Marketing

The applicants shall adhere to the general requirements for advertisements of food products. He/she shall not be allowed to:

- a) Advertise, promote or market an unregistered food product
- b) Advertise, promote or market any regulated product unless the advertisement or promotion has the clearance and approval issued by the Authority.
- c) Advertise, Promote or market a food product in a manner that is, directly or by implication, misleading or calculated to mislead the population.
- d) Carry out regulated product launch unless a written prior approval or clearance by the Authority has been received.
- e) Sale, distribute or market food products for non-authorized or not licenced establishments or personnel.
- f) Target advertising material to children under 18 years old.
- g) Promote Breast Milk substitutes beyond provisions of the regulation marketing of breast milk substitutes.
- h) Denigrate or attack unfairly any competitive products
- i) Promote that one product is better than (or equivalent to) another of a different brand is prohibited. Promotion should not raise doubt about the quality of similar food products which could bring or exploit fear or distress to individual or community.

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- j) Use any language that brings or is likely to mislead or deceive or create fear or distress to individuals or community.
- k) Encourage inappropriate or excessive use
- 1) Use the names or logos of the Authority and any of our professional groups
- m) Promote a food product as a preventive or cure for a disease, disorder or an abnormal physical state. Promotion bearing nutrition claims such as 'high', 'rich', 'source of', 'low', 'less', 'reduced', 'free' and/or 'zero' in a particular type of nutrient shall be accompanied by scientific proof.
- n) Make any false or misleading claims or representations
- o) Make an advertisement that imitates the general layout, text, slogans or visual presentation or devices of the advertisement of food products of other companies.

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CHAPTER II: REQUIREMENTS FOR PROMOTION, ADVERTISEMENT AND MARKETING OF FOOD PRODUCTS

2.1 General requirements

The importance of promotion, advertisement and marketing is not only informing, teaching or reminding the consumer of the existence of goods, it creates benefits in consumer minds and secures product loyalty over substitutes and competitors.

The following are general requirements for promotion, advertising and marketing of food products:

- a) Any person who wishes to promote or advertise food products must ensure the product is registered or authorised by the Authority.
- b) Any message used for promotion of food products must be approved by the Authority prior to dissemination.
- c) Language on promotional adverts should be among official languages used in Rwanda simple-to-understand, easily comprehensive and should not bring fear or distress to the public.
- d) The applicant should apply for approval of promotional materials before importing them by submitting the mock-up or design to the Authority for review.
- e) The content of promotional materials must be designed in such a way that it is clear and that the material or message are in line with the product being promoted. Presented information should be factually correct and those facts should not be exaggerated in any way
- f) Live Presenter Mentions shall be restricted to message and scripts approved by the Authority.
- g) Promotion shall be objective, without relying solely on the feelings or opinions of the advertiser and shall refer to limitations that are relevant to the claims made for the product.
- h) Promotion shall not state or imply that a product is "an adequate source of all essential nutrients".
- i) A promotion should not directly or indirectly refer to the fact that a product is registered or authorised by the Authority. It shall not refer to the Law or contain any statement which expressly or implicitly suggests that the use of the product is endorsed by the Authority. Promotion shall not in any way discourage the public from seeking further information or advice of a nutritionist or any other expert.
- j) Promotion shall not bring public impression that health could be affected by not taking the product.

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- k) Promotion bearing health claims like nutrient function claim that describe the physiological role of the nutrient in growth, development and normal functions of the body can be used subject to Rwanda FDA approval.
- 1) All claims shall be complete, truthful, not misleading and shall be backed up by tangible proof.
- m) Any advertisement that is framed in such a manner as to exploit the superstitious beliefs and/or calculated to play on the emotions of consumers to induce fear in them to purchase the advertised article is prohibited.
- n) Any additional information in the already approved promotion material shall be considered as a new application.
- o) Where a promotion script contains more than one product, there should be tangible proof to back up claims made for each product so as not to confuse the audience.
- p) Marketing communications should not allow any form of discrimination that is based on race, ethnicity, national origin, age, gender, disability, sexual orientation, and religion.

2.2 Specific requirements

2.2.1. Specific requirements for alcoholic beverages

In addition to the general requirements for the advertisement of food products, these requirements apply to the alcoholic beverages.

- 2.2.1.1 The advertisement shall contain Statutory or Health Warnings as follows:
 - a) Not for sale to persons under 18 years old
 - b) Not recommended for pregnant women,
 - c) Any other Health Warnings that may be prescribed by the Authority. Ex: "Drink Responsibly"
- 2.2.1.2 Conventional symbols with the same meaning are allowed for the above.
- 2.2.1.3 Health Warnings when shown on Television, Print and Social media shall be legible.
- 2.2.1.4. The minimum specifications for these Health Warnings are as follows:
 - a) In an advertisement, Health Warnings must be placed in a visible place
 - b) Health Warnings must not be less than thirty percent (30%) of the biggest font size.

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- c) Health Warnings shall run as crawls for Television and Social media advertisement.
- d) The Health Warnings should run for the entire duration of the TV and social media advertisement.
- e) Where Health Warnings are read on TV and Radio media they shall be clear, audible and well-paced.
- 2.2.1.5. All hotels and bars selling alcoholic beverages shall display Health Warnings on their premises. Health Warnings must also be displayed in all specific stores and trucks of alcoholic beverages.
- 2.2.1.6. An advertisement shall not promote or depict excessive consumption of alcohol. Offering samples or gifts must be done in a controlled way to avoid causing overconsumption and/or overdose.
- 2.2.1.7 An advertisement shall not imply that consumption of alcoholic beverage is required for:
 - a) Social or professional achievement;
 - b) Personal success:
 - c) Any sporting activity;
 - d) Sexual powers;
 - e) Resolution of social, physical or personal problems;
- 2.2.1.8 No advertisement shall enhance or promote vices, general misconduct or be offensive to public policy.
- 2.2.1.9 Advertising shall not associate consumption to any activity which requires care and skill or elements of physical danger.
- 2.2.1.10 A character in alcoholic beverage advertisement must not be shown to be in control of motorized equipment after consumption.

Sponsorship

- 2.2.1.11 Alcoholic Beverage companies providing sponsorship shall not sell, offer as prizes, give out samples of their products and/or distribute promotional materials to participants of programs organized for persons below 18 years old and the vulnerable groups.
- 2.2.1.12 Where an Alcoholic Beverage Company sponsors a program, a well-known personality,

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sporting activity, festival and any other function, an advertisement or publicity event that promotes the product must be submitted to the Authority for approval.

2.2.1.13 Product endorsement by persons used in advertisement shall not directly suggest that the consumption of any alcoholic beverage has contributed to the success of their particular endeavours.

Advertisement targeted at minors

- 2.2.1.14 Advertising shall not appeal, either directly or indirectly, to persons under the legal drinking age (18 years), or be placed in media that are targeted specifically at such persons.
- 2.2.1.15 Children's songs, cartoon characters etc., or the imitation thereof shall not be used in alcoholic beverage advertising.
- 2.2.1.16 Alcoholic beverages shall not be advertised in children magazines, newspapers, journals or media targeted specifically at such persons.
- 2.2.1.17 Alcoholic beverage advertisements shall not run during the airing of movies specifically dedicated to persons under 18.

2.2.2 Specific requirements for energy drinks

- 2.2.2.1 All energy drink advertisements shall include the following;
- a) 'Excessive drinking can be detrimental to health',
- b) 'Not Recommended for persons under 18 years old, Lactating Mothers, Pregnant Women and People Sensitive to Caffeine'
- c) Any other Health Warnings as prescribed by the Authority
- 2.2.2.2 Advertisement of energy drinks shall not contain statements or illustrations that have the potential to lead to the abuse or excessive consumption of the product.
- 2.2.2.3 Energy drinks shall not be advertised as substitute for rest, remedy for fatigue, sexual non-performance or any other physical non-performance.

2.2.3 Specific requirements regarding informational or educational materials on Breast Milk Substitute.

Informational or educational materials, whether oral, written, audio, visual, or digital that refer to infant feeding shall:

a) contain only accurate and scientifically based information and shall not use any illustration or text that encourages bottle feeding or discourages breastfeeding;

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- b) be available in any official language;
- c) not give an impression or create a belief that a designated product is equivalent to, comparable with or superior to breast milk or to breastfeeding;
- d) contain the name or logo of the designated product and the name of the manufacturer or distributor.;
- e) clearly and conspicuously explain each of the following:
 - i. the benefits and superiority of breastfeeding;
 - ii. the value or benefits of exclusive breastfeeding for the first six (6) months of life followed by sustained breastfeeding for up to twenty four (24) months and above;
- iii. how to initiate and maintain exclusive and sustained breastfeeding;
- iv. why it is difficult to reverse a decision not to breastfeed;
- v. the importance of introducing complementary foods at the age of six (6) months;
- vi. how and why any introduction of bottle feeding or early introduction of complementary foods negatively affects breastfeeding;
- vii. that complementary foods can easily be prepared at home using local ingredients; the social and financial implication of the use of breast-milk substitutes and the difficulty of resuming breastfeeding after even partial use of substitutes.
- viii. Labels should be designed to provide the necessary information about the appropriate use of the product, and so as not to discourage breast-feeding.

2.2.4 Specific requirements regarding the mode of promotion

There are different modes which are used to promote food products to the general public. Promotion through these should follow requirements:

- 2.2.4.1 Information including pictorial presentation used in **Still mode of promotion** should be clear to the reader and not in any way that violate the Authority's ethics.
- 2.2.4.2 The Message conveyed and/or images presented through **Light and Sound mode of promotion** should be in simple language and clear to the audience and not in any way that violates the Authority's ethics.

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- 2.2.4.3 The information including pictorial and web links **using Web-based mode of promotion** should:
 - a) Be clearly visible, readily legible and uneditable by web visitors;
 - b) Ideally be access restricted particularly on alcoholic products before publishing/airing;
 - c) Not suggests in any way that the product is meant to diagnose, treat, cure or prevent a disease particularly for food supplements promotion.
- 2.2.4.4 **Sales Promotions** on food products are allowed provided that the product is still safe for consumption or the advertiser writes in letters of bigger font size than the one used for promotional message, the remaining shelf-life of the food products.

2.2.4.5 **Promotional Samples** are allowed provided that:

- a) Samples are not distributed to protected persons;
- b) Distributed samples are not in the category of high risk foods for special nutritional purpose such as infants and follow-up formulae and food supplements;
- c) Samples are not encouraging overconsumption or overdose;
- d) Not in any way that violate the Authority's ethics.

2.2.4.6 Promotional meetings can be conducted provided that:

- a) The application is submitted to Rwanda FDA at least 2 weeks before the meeting and approval is granted;
- b) The application is accompanied by samples of all materials and products to be used in the meeting for promotional activities;
- c) The contents of presentations at symposia or seminars are factual, accurate, and not biased towards any particular company's products.

2.2.4.7 Promotional campaigns are allowed provided that:

- a) Official approval is granted by the Authority.
- b) Information provided is correct and complies with other applicable requirements prescribed in this guidelines;

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c) Advertisements to the general public should not contain materials which refer to recommendations by individual scientists or healthcare professionals which could encourage consumption of products;

2.2.4.8 Food promotions at **Trade fair/exhibition** are allowed provided that:

- a) Demonstrators have approval granted by the Authority;
- b) Food products promoted are not intended to protect person and vulnerable groups.

2.2.5 Exceptions

Prior approval may not be required for the following:

- a) Advertisement limited to a manufacturers' corporate advertising, provided information specific to the product is not included.
- b) Advertising within manufacturer's retail, retail stores, and agency stores.

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CHAPTER III: STAKEHOLDERS RESPONSIBILITIES

In order to effectively execute its functions of protecting and promoting public health including management and control of food promotions, the Authority has to work in close cooperation and collaboration with various stakeholders. Stakeholders' involvement in all Rwanda FDA undertakings is of paramount importance for the Authority to attain its vision and mission.

The roles and responsibilities of different Rwanda FDA stakeholders in line with food promotion are outlined hereunder:

3.1 Responsibilities of Food Dealers

Food Dealers include manufacturers, importers, distributors, wholesalers and retailers of food products have following main responsibilities:

- a) Ensure that the promoted food product conforms to safety specifications and have officially acquired marketing authorization issued by the Authority.
- b) Ensure that they obtain permit from the Authority prior promotion of food products.
- c) Ensure that the information provided about their respective products are correct and presented in such a way that is not misleading the consumers.
- d) Ensure that the information provided conforms with the Authority's Regulations on food promotions, advertising and marketing, and other relevant Regulations.
- e) Ensure that they refrain from illegal dealings and malpractices in relation to product promotion activities.
- f) Ensure that they maintain food promotional materials as approved by the Authority.
- g) Report to the Authority any contraventions and/or all defaulters of the laws and regulations related to food promotion; advertising, and marketing.
- h) Collaborate and cooperate with the Authority in sharing information relating to safety of food including food promotion, advertising, and marketing.

3.2 Responsibilities of public Institutions

Public institutions, especially Local Government Authorities and Law enforcement agents, will collaborate with the Authority in enforcing the Rwanda FDA Law especially its article 8 with following responsibilities:

a) Sensitize local leaders and the general public to voluntarily enforce the Authority's Control of Food Promotion Regulations and other related regulations;

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- b) Advocate for voluntary compliance to existing laws, regulations and guidelines particularly on food promotion, advertising, and marketing;
- c) Enforce regulations and implement guidelines on food promotions;
- d) Sensitize and create awareness on the role of all stakeholders in relation to the enforcement of existing laws and voluntary compliance to relevant regulations;
- e) Report to the Authority any contraventions and/or all defaulters of the laws and regulations related to food promotion especially food dealers who deliberately give out exaggerated or misleading information.

3.3 Responsibilities of Media

Media houses and personnel play a great role in informing and educating the public on voluntary compliance with the existing laws and regulations with following responsibilities in advocating requirements for food promotion which includes:

- a) Convey of the right information to the public about do's and don'ts in relation to food promotion control;
- b) Voluntarily comply with the requirements of the Authority's Control of Food Promotion Regulations and guidelines;
- Report to the Authority any contraventions and/or all defaulters of the laws and regulations related to food promotion especially food dealers who deliberately give out exaggerated or misleading information;
- d) Reject airing or publishing any food promotional adverts from dealers who do not have official food promotion/advertisement authorization from the Authority;
- e) Cooperate with the Authority in enforcing the laws by sharing information about public perception on the safety of food products including food promotion as well as their concerns/complaints on food promotion;
- f) To give constructive comments and recommendations on how to effectively and efficiently control food products promotions.

3.4 Responsibilities of General Public

All food promotions, advertisements, and marketing designed and prepared by food dealers intend to persuade community members to make choice of buying/using food products. Hence, the general public is a very important category of stakeholders in ensuring that food dealers comply with laws and food promotion regulations and that they are not deceived by misleading food promotions. The

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- a) Seek, receive and adhere to the right/correct information from the Authority on the quality and safety of promoted food;
- b) Report to the Authority any contraventions and/or all defaulters of the laws and regulations related to food promotion especially food dealers who deliberately give out exaggerated or misleading information;
- c) Cooperate with the Authority in enforcing the laws by sharing information about violation or perception on and safety of food including food promotion as well as their concerns/complaints on food promotion;
- d) Continuously recommend on how food products promotion, advertisements, and marketing can be controlled effectively and efficiently.

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CHAPTER IV: PROCESS FOR APPLICATION AND APPROVAL OF PROMOTION, ADVERTISING AND MARKETING

Promotion, advertising, and marketing of food products regulated by the Authority must comply with the requirements prescribed in the Rwanda Food and Drugs Authority regulation of Control of Food Promotion and Advertisement. These regulations prohibits promotion of any food product except after getting a written approval from the Authority.

4.1 Application requirements

4.1.1 Applicant

An application for approval of food promotion can be made by owner of the promotion who may be a person/company who is:

- a) The manufacturer, importer, or distributor who has registered the product in Rwanda;
- b) Intending to promote a registered food product in Rwanda;
- c) Authorized for distribution of a non-registrable food product in Rwanda and
- d) The owner of a food premise where the food promotion is done or referred to.

4.1.2 Application document

A complete application document for food promotion shall include the following;

- a) A duly signed cover letter; addressed to Director General of the Authority,
- b) Duly filled in application form attached as Annex I or II,
- c) A copy of the Certificate of Registration of the company and of the products to be advertised (issued by Rwanda FDA),
- d) One sample of the product in the approved final package if needed (the sample will be returned back to the applicant),
- e) Samples of all Promotional materials,
- f) Tangible or recognized scientific proof/ facts to back up claims made by the applicant,
- g) Proof of payment of non-refundable application fee as prescribed in the Authority Regulations no CBD/TRG/004 related to regulatory service tariff/fees and fines,

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h) Copy of recognized degree of qualified personnel in areas of food science and technology or related field who approved the message at company level.

4.1.3 Language of application

The Language of application for food promotion shall be Kinyarwanda, English or French and all other communications regarding the application shall be made in any of these three languages

4.1.4 Language of food promotion, advertisement and marketing

The language used in food promotion, advertisement and marketing shall be at least Kinyarwanda, English or French.

4.1.5 Submission of application

The application shall be submitted to the Authority's headquarters or online.

4.2 Processing of application

- a) After receiving a complete application, the Authority will carry out evaluation of food promotion for satisfaction of compliance with the prescribed requirements.
- b) The Authority may, during evaluation of food promotion, require the applicant to make clarifications by submitting additional information and/or related material as the case may be.
- c) Processing of the application for which additional information and/or related material have been required by the Authority will be kept on hold until the applicant submits such additional information.
- d) In the event applicant does not submit, or delays to submit it without presenting a reasonable cause to the Authority, by the end of fourth week from the date when the matter was communicated to the applicant, the application shall be invalid.
- e) Person who may wish to continue with approval of food promotion, for which application has been invalidated, shall be required to submit a fresh application, which will be considered as a new application.

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4.3 Food promotion feedback

The applicant will be informed on the outcome of application within 10 working days. When the application is successful, applicant will be issued with Approval and Authorization letter. In the event that the application fails to satisfy the regulatory requirement, the authority issues the a rejection letter.

Note: If for any reason the holder of promotion authorization makes any change related to a food promotion, shall submit a new application for approval.

4.4 Validity of approved food promotion

- a) The approved food promotion shall be valid for 2 years for high risk foods (example: Breast Milk Substitute, food supplements, ...) and 5 years for other food products.
- b) Promotions that are still in use must be re-certified at the above mentioned interval.
- c) Approvals for promotions on specific events (example: Exhibition, promotional meetings) are excluded from this rule.

4.5 Suspension, Termination of Food Promotion and advertisement

The approved food promotion shall be terminated if there is:

- a) Non re-certification of the approved promotion which exceed validity period;
- b) Non compliance with the set conditions or requirements including but not limited to revocation, suspension or cancellation;
- c) Any alteration of the approved promotion without Authority's approval; and
- d) Request in writing from the holder of the promotion permit.

4.6 Appeal to the regulatory decision

Any person aggrieved by a decision of the Authority in relation to any application for promotion approval, may make representations to the Authority, whereby he/she shall submit information and arguments to convince the Authority to reconsider its decision.

However, if after reconsideration of the application, the Authority still rejects the application, the applicant shall appeal to the Board of Directors.

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4.7 Reference to official legislation/related guidelines

All food promotion to be approved in Rwanda FDA shall comply with;

- a) The Rwanda FDA Regulations $N^{\rm o}$ CBD/TRG/004 related to regulatory service tariff/fees and charges;
- b) Any other relevant Regulations and Guidelines recognized by the Authority.

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CHAPTER V: COMPLAINTS REGARDING FOOD PRODUCTS PROMOTION, ADVERTISING, AND MARKETING

The Authority is particularly keen to receive complaints where promotion, advertising and marketing of food products may have an adverse impact on the public health. It investigates complaints received from anyone who has encountered promotion for food products that in his or her view is misleading, false, deceptive regarding its character, value, quantity, composition, merits and/or safety of such product.

Requirements for submissions of complaints

The following are procedures for submission of complaints regarding food products promotion, advertising, and marketing to the Authority:

- a) Complaints on promoted, advertised or marketed food products identified under these Guidelines shall be made to the Authority in the prescribed Complaint form No: QMS/FOM/052. This form can be obtained from Rwanda FDA headquarters or through the Rwanda FDA website http://rwandafda.gov.rw
- b) A submitted complaint should have details of when and where the promotion advert was seen and if possible a copy of the advertisement (a picture or a recording) together with details of the concerns about the advertisement should be attached;
- c) The Authority will provide feedback of the received food promotion complaints within five
 (5) working days. This time may be extended when statutory action is taken. If the investigation takes longer, the complainant will be updated on progress;
- d) When closing the case the Authority will provide the complainant with details of the outcome; and
- e) Food promotion complaints may be received through:
 - i. Rwanda FDA telephone numbers at headquarters
 - ii. Rwanda FDA email address; and
 - iii. Physical contact/word of mouth conversation at Rwanda FDA offices.

Note: All information received about food promotion complaints will be treated with high confidentiality.

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ENDORSEMENT OF THE GUIDELINES

	Author	Checked by		Approved by
Title	Division manager	Head of Department	Quality Assurance Analyst	Director General
Names	Mr. Lazare NTIRENGANYA	Dr. Eric NYIRIMIGABO	Mr. Theogene NDAYAMBAJE	Dr. Emile BIENVENU
Signature	GE TOPE	Mit S	For Augus	8 (as 30)
Date	21.10.2-22	25/10/2022	25/10/2022	02/11/2022



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ANNEXES

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ANNEXE I: APPLICATION FORM FOR APPROVAL OF PROMOTIONAL MATERIALS

Format: QMS/FMT/00 Revision No: 1 Effective Date: 20 Jur		Department/Division/Office/Unit	Food Monite Monite	oring/	Drugs Pharm Division	acovigilance	and and	Safety Safety
Document Type	: Form		Doc. N	Vo.		: FDISM/PV	SM/FC	OM/010
Bee 111 W	Title:	APPLICATION FORM FOR	Revisi	on Nu	mber	: 01		
	APPI	ROVAL OF PROMOTIONAL	Revisi	on Dat	te	: 19/10/2022		
The state of the s	MAT	ERIALS	Effecti	ive Da	te	: 21/10/2022		
RWANDA FDA Rwanda Food and Drugs Authority			Reviev	w Due	Date	: 20/10/2025		
	•							

1. Applicant Particulars

Name of applicant:	
Address:	
Contact person:	E-mail:
Telephone Number:	Fax Number:
2. Sponsor particulars (if different from app	plicant)
Name of applicant:	
Address:	
Contact person:	
Telephone Number:	
1010 P.10110 1 (01110 011	
3. Product particulars	
Product category (please tick the appropriate	box)
] Medical Device [] Cosmetic [] Food Produ] Herbal Medicines [] Traditional Medicine [acts [] Food Supplements [] Other []
Product Name(s):	
4. Advertisement/Promotion	
Type of Advertisement:	
~ -	

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5. Type of material: (please tick the appropriate box)
Poster [] Leaflet[] Cinema [] Outdoor/ billboard [] In /On Public Transport[] Magazines/ Newspaper [] Litterature [] Radio [] Television [] Other [] please specify
6. This form shall be accompanied by: (Please tick the enclosed requirements)
 [] A copy of the proposed advert (Script, Audio tape, CD, VCD, DVD, Video casette.) [] Current indications of use as indicated on Certificate of Registration (where applicable) [] Valid copy of certificate of product registration [] Valid copy of premise/operational license [] Valid copy of the degree of qualified personnel in charge promotion/ who approves the promotional message [] Copy of any research/ surveys/ data mentioned in advertisement (Note-further evidence to be provided if requested). [] Copy of previous approval (if the advert is a renewal) [] Copy of approval for the use of a restricted / prohibited claim (if applicable). [] Application fee.
Applicant Declaration
I,

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ANNEXE II: APPLICATION FORM FOR PERMIT TO CONDUCT PROMOTION MEETING

Format: QMS/FMT/002 Revision No: 1 Effective Date: 20 June 20	Department/Division/Office/Unit	Food and Drugs Monitoring/ Pharm Monitoring Division	nacovigilance and Safety		
Document Type: Form		Doc. No	: FDISM/PVSM/FOM/011		
	Title: APPLICATION FORM	Revision Number	: 01		
	FOR PERMIT TO CONDUCT	Revision Date	: 19/10/2022		
	PROMOTION MEETING	Effective Date	: 21/10/2022		
RWANDA FDA Rwanda Food and Drugs Authority		Review Due Date	: 20/10/2025		
1. Applicant Particulars					

Name of applicant:
Address:
Contact person:
Telephone Number: E-mail:
2. Type of meetings (tick)
[] Workshop
[] Conferences
Seminar
[] Symposia
[] Exhibitions
Other
3. Responsible Person's Information
3.1 Name of person / company responsible for the event
3.2 Address
3.3 Telephone Number
3.4 Email (if application)
4. Location Information
4.1 Name and location of premises where event is to be
held
5. Dates and Times of Event
C. Dutto una l'inter di Livert
5.1. Start Date/ Time
5.2. End Date/ Time

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Guidelines for Control of Promotion, Advertisement and Marketing of Food Products in Rwanda

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