RWANDA FDA
Rwanda Food and Drugs Authority

REGULATIONS RELATED TO REGULATORY SERVICE TARIFF/FEES AND FINES

(Rwanda FDA law N°. 003/2018 of 09/02/2019, Article 9)

Doc. Ref. No.: CBD/TRG/004 Rev_2

ADOPTION AND APPROVAL OF THE REGULATIONS

In EXERCISE of the powers conferred upon Rwanda Food and Drugs Authority by Article N° 9 of the Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning, hereby ADOPTS and ISSUES these Regulations N° CBD/TRG/004 Rev_2 Related to regulatory service tariff/fees and fines, made this 31st day of March, 2021.

Dr. Charles KARANGWA
Ag. Director General

ARRANGEMENT OF THE REGULATIONS

CHAPTER I: GENERAL PROVISION

Article 1: Purpose of these Regulations

The purpose of these Regulations is to establish tariffs or fees and fines for regulatory services rendered by Rwanda Food and Drugs Authority.

Article 2: Citation

These Regulations may be cited as the *''Rwanda FDA regulatory service tariff/fees and fines*''.

Article 3: Application

These Regulations shall apply on all services rendered by Rwanda FDA as well as fines imposed due to their contravention

Article 4: Definitions

1. **"Airing"** means publicize, publish, disseminate, circulate, communicate, spread, promulgate, broadcast an opinion or a subject;
2. "**Authority**" Means Rwanda Food and Drugs Authority or its acronym "Rwanda FDA", established under Article 2 of the Law N^{o} 003/2018 of 09/02/2018 determining its mission, organization and functioning;
3. **"A manufacturer** "means a company that carries out operations such as production, packaging, repackaging, labelling and relabeling of products regulated by Rwanda FDA;
4. **"Food product"** means any article other than drugs, cosmetics and tobacco that has been processed, packed and distributed as food or drink for human consumption;
5. **"Food additive"** is any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by- products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include contaminants or substances added to food for maintaining or improving nutritional quality.
6. **"Food/dietary supplement"** means a product other than tobacco, cosmetics or drugs intended to supplement the diet, and shall include all of the following characteristics:
    a. Contains concentrated source of one or combination of the following: vitamins, minerals, amino acids, essential fatty acids, enzymes and other metabolites, pre

and/or probiotic, natural substances of plant or animal origin with nutritional or physiological function;

b. Intends to be taken orally in the form of tablet, capsule, powder, soft gel, gel cap, pellet, pill, granules or liquid
c. It is not presented for use as a convectional food or as a substitute of a meal or the diet;
d. Labelled and marketed as a food / dietary supplement
e. Does not suggest in any way that the product is meant to diagnose, treat, cure or prevent a disease, disorder, abnormal physical or mental state or a particular physiological function.

7. **"Pharmaceutical product"** means any substance capable of preventing, treating human or animal diseases and any other substance intended for administration to a human being or an animal in order to diagnose diseases, restore, correct or carry out modification of organic or mental functions. It also means products used in disinfecting premises in which food and drugs are manufactured, prepared or stored.
8. **"Medical device"** is any device used in the medical field for the purpose of diagnosis, testing, cure, surgery or health protection;
9. **"Notifications"** means changes in manufacturing or compositions that could have minimal or no adverse effects on the overall safety, efficacy and quality of the finished food or pharmaceutical products;
10. **"Major variation"** means change that could have major effects on the overall safety, efficacy and quality of the finished food or pharmaceutical products;
11. **"Minor variation"** means change that may have minor effects on the overall safety, efficacy and quality of the finished food or pharmaceutical products;
12. **"Retention"** means to maintain market authorization on a register and enable the Authority to carry out inspection and monitor the quality and rational use of the pharmaceutical product or medical device on market;
13. **Food/ Pharmaceutical products registration:** The process of reviewing and assessing the dossier to support a product in view of its marketing authorization, licensing of its imports or exports and granting operational approval;
14. **"Duplicate certificate"** is a certificate issued to replace a certificate, permit or license previously issued by the Authority;
15. **"Tariff/fees":** Includes any charge made or levied in connections with services rendered by the Authority;
16. **"Free on Board" also described as FOB** means a value of a regulated product to be imported into Rwanda;
17. **"Good Manufacturing Practices (GMP)"** means practices prescribed by the Authority for the manufacturing of products to ensure that such products are of good quality, safe and effective for intended use;

18. **"Condemned products"** means products declared not complying with regulatory requirements after assessment/inspection by the Authority.
19. **"Variant"** means a similar product manufactured by the same manufacturing plant using the same ingredient(s) at the same levels but different in food additive or type of packaging materials.
20. **Emergency Situations**: an extraordinary event which is considered to constitute a public health risk to other States through the international spread of disease; and to potentially require a coordinated international response. This definition implies a situation that: is serious, unusual or unexpected; carries implications for public health beyond the affected State's national border; and may require immediate international action.

Article 5: Service Tariff/fees and Fines

The Authority reserves the power to determine the types of services offered to the public, Non-governmental Organizations (NGOs), research institutions, individuals and private institutions. Payment of prescribed fees shall be done in respect of the product and services regulated by Rwanda FDA as stated in the Law 003/2018 of 09/02/2018.

Service tariffs/fees and fines paid under these regulations shall be paid in Rwandan francs or in US Dollars. Exchange of foreign currency into Rwandan Francs is acceptable provided that it is done according to current average rates as determined by National Bank of Rwanda.

Service Tariff/fees and Fines are published on Rwanda FDA website and can be provided to any other natural person or organization on a request.

The Authority may change or vary any service tariff/fees or fines in force at any time. The fees and fines paid under these regulations shall be collected by the Authority and are not refundable or transferable whether an application is successful or not.

The service fees to be paid for FOBs shall be calculated and paid before service is rendered in the actual value of consignment declared by the importer and verified by the Authority.

Service Fees paid for Good Manufacturing Practices (GMP) inspections shall be determined and charged basing on the manufacturing sites of the regulated products.

ANNEX I: LIST OF SERVICES AND THEIR CORRESPONDING FEES

PART 1: REGISTRATION OF REGULATED PRODUCTS (5 years)

	Human and Veterinary Medicines (Domestic)		
Serial Number	**Service**	**Currency**	**Fee**
1	Registration for human medicines	FRW	300,000
2	Registration for veterinary medicines	FRW	200,000
3	Registration of herbal medicines	FRW	50,000
	Human and Veterinary Medicines(Foreign)		
4	Registration for human medicines	USD	1,250
5	Registration for veterinary medicines	USD	600
6	Registration of foreign herbal medicines	USD	250
	Medical devices (Domestic)		
7	Class A	FRW	100,000
8	Class B	FRW	120,000
9	Class C	FRW	200,000
10	Class D	FRW	220,000
	Medical devices(Foreign)		
11	Class A	USD	500
12	Class B	USD	1,500
13	Class C	USD	2,000
14	Class D	USD	2,500
	Registration of In-Vitro Diagnostic Device (IVD)-Domestic		
15	Class A	FRW	120,000

16	Class B	FRW	200,000
17	Class C	FRW	300,000
18	Class D	FRW	400,000
	Registration of IVD (Foreign)		
19	Class A	USD	300
20	Class B	USD	1,000
21	Class C	USD	1,200
22	Class D	USD	1,500

Note 1: Medical Devices are classified basing on their levels of risk
Class A: low risk (examination gloves, tongue depressors)
Class B: low- moderate risk (electronic thermometers, tubes for blood transfusion)
Class C: moderate- high risk (condoms, infusion pumps)
Class D: high risk (cardiac pacemakers, implants, intrauterine device)

For more details, Confer to the guidelines for registration of medical devices.

Note 2: Medical devices and In Vitro Diagnostics (IVDs) made by the same manufacturer, same model with slight differences shall be considered as variant and pay 5% of the registration fee of the main product as defined in the relevant Guidance document

	Registration Medicated Cosmetics and household chemicals (Domestic)		
23	Toothpastes	FRW	150,000
24	Antiseptics	FRW	100,000
25	Detergent powder	FRW	100,000
26	Detergent liquid	FRW	100,000
27	Mosquito coil	FRW	150,000
28	Mosquito spray	FRW	150,000
29	Vector control products	FRW	150,000
30	Soap (toilet and laundry)	FRW	75,000
31	Household chemicals	FRW	150,000
32	Cosmetics	FRW	150,000
	Registration of Medicated Cosmetics and household Chemicals (Foreign)		

33	Toothpastes	USD	250
34	Antiseptics	USD	150
35	Detergent powder	USD	200
36	Detergent liquid	USD	150
37	Mosquito coil	USD	150
38	Mosquito spray	USD	200
39	Vector control products	USD	350
40	Soap (toilet and laundry)	USD	250
41	Cosmetics	USD	250
42	Household chemicals	USD	200
	Registration of Laboratory chemicals, Poisons and Pesticides (Domestic) **Note**: *Grouping shall be made on products with same base. 2-10 (85%), 11-20 (70%), 21-30 (60%), more than 30 (50%)*		
43	Laboratory chemicals	FRW	500,000
44	Poisonous substances	FRW	600,000
45	Pesticides	FRW	500,000
	Registration of Laboratory chemicals, Poisons and Pesticides (Foreign) **Note**: *Grouping shall be made on products with same base. 2-10 (85%), 11-20 (70%), 21-30 (60%), more than 30 (50%)*		
46	Laboratory chemicals	USD	1,250
47	Poisonous substances	USD	1,250
48	Pesticides	USD	1,250
	Fees for Clinical Trials Authorization		
49	Funded Clinical Trial (Phase I)	USD	4,000
50	Funded Clinical Trial (Phase II)	USD	4,000
51	Funded Clinical Trial (Phase III)	USD	3,000
52	Funded Clinical Trial For Research institution (Foreign)	USD	4,000
53	Funded Clinical Trial For Research institution (Domestic)	USD	2,000
54	Application for Amendment of an approved Clinical Trial (Funded)	USD	500

55	Funded Clinical Trial For Academic Research trial (Individual) Domestic	USD	1,000
56	Application to undertake clinical trial for a registered pharmaceutical products or medical devices	USD	2,500
57	Non-Funded Clinical trials (Domestic)	FRW	500,000
58	Application to conduct ectoparasiticides field trials	USD	1,000
	Registration of Food Products (Domestic)		
59	Milk and milk products	FRW	100,000
60	Cereal and cereal products	FRW	75,000
61	Pulses	FRW	50,000
62	Nuts	FRW	50,000
63	Processed Tuber and roots	FRW	50,000
64	Non-alcoholic beverages	FRW	75,000
65	Liquors (final product)	FRW	500,000
66	Beers, Wines and plant-based alcoholic drinks	FRW	250,000
67	Sugar and Honey	FRW	100,000
68	Iodated Salt (edible)	FRW	50,000
69	Fats and Oils	FRW	75,000
70	Tea and Coffee	FRW	100,000
71	Cocoa and cocoa products	FRW	100,000
72	Spices and Herbs	FRW	50,000
73	Vinegar	FRW	50,000
74	Fish and fish products	FRW	100,000
75	Meat and meat products	FRW	100,000
76	Fruits and fruits products	FRW	75,000
77	Drinking/ mineral water	FRW	300,000
78	Vegetable and vegetable products	FRW	50,000
79	Food for infants and follow-up formula	FRW	200,000
80	Food supplements	FRW	250,000

81	Food additives	FRW	400,000
82	Confectionaries	FRW	80,000
83	Fortified foods	FRW	160,000
84	Other processed food products	FRW	120,000
85	Animal feeds	FRW	160,000
86	Animal feed supplements	FRW	100,000
	Registration of Tobacco and Tobacco products		
87	Tobacco and Tobacco products	FRW	1,000,000
	Registration of Food Products (Foreign) Note: *Grouping shall be as follows: 1-20 (100%), 21-50 (85%), 51-100 (70%), more than 100 (55%)*		
88	Milk and milk products	USD	400
89	Cereal and cereal products	USD	300
90	Pulses	USD	250
91	Nuts	USD	300
92	Tuber and roots	USD	250
93	Non-alcoholic beverages	USD	300
94	Liquors (final products)	USD	1,500
95	Beers, Wines and plant-based alcoholic drinks	USD	550
96	Sugar and Honey	USD	200
97	Iodated Salt (edible)	USD	150
98	Fats and Oils	USD	200
99	Tea and Coffee	USD	500
100	Cocoa and cocoa products	USD	500
101	Spices and Herbs	USD	400
102	Vinegar	USD	200
103	Fish and fish products	USD	500
104	Meat and meat products	USD	500
105	Fruits and fruits products	USD	200
106	Drinking/ mineral water	USD	400

107	Vegetable and vegetable products	USD	200
108	Food for infants and follow-up formula	USD	700
109	Food supplements	USD	700
110	Food additives	USD	350
111	Confectionaries	USD	210
112	Fortified foods	USD	700
113	Other processed food products	USD	520
114	Animal feeds	USD	500
115	Animal feed supplements	USD	100

Note:

- *For all food products manufactured within East African Countries with registration or certification marks from regulatory Bodies, a Registration fee is waived.*
- *For food products, the registration fee shall be paid on the main brand and the variants shall pay an equivalent of variation fee equivalent to 5%.*
- *SMEs standing shall be defined by the Ministry in Charge of Commerce and Industry through industrial Policy.*

PART 2: RETENTION/RENEWAL AND VARIATION OF REGISTERED PRODUCTS

#	**Service**	**Pharmaceutical products and medical devices, chemicals, cosmetics, pesticides and poisonous substances. (% of the initial registration fee)**	**Food and tobacco products % of the initial registration fees**
116	Annual Retention	15%	Free
117	Renewal after five (5) years	50%	50%
118	Major Variation	50%	25%
119	Minor Variation	20%	15%

PART 3: INSPECTIONS

#	**GMP Inspection for Pharmaceutical or medical devices manufacturing facilities (Domestic)**		
120	GMP Licensing Per Year	FRW	200,000
121	GMP Licensing of herbal plant Per Year	FRW	200,000
122	Re-inspection of facilities for manufacturing pharmaceutical products and medical devices on request	FRW	100,000
	GMP Inspection for Pharmaceutical or medical devices manufacturing facilities (Foreign) for 5 production lines at one site		
123	East Africa	USD	3,000
124	Rest of Africa	USD	4,000
125	Asia	USD	5,000
126	Europe	USD	6,000
127	America	USD	7,000
128	Australia and New Zealand	USD	6,000
129	Fee for inspection of any additional production line	USD	1,000
	N.B: *GMP Inspection for Pharmaceutical or medical devices manufacturing facilities (Foreign) for 5 production lines at one site shall be Free in case of mutual recognition agreement*		
	GMP Inspection of food manufacturing facility (Domestic)		
130	Local food GMP inspection Per year	FRW	200,000
131	Local food GMP inspection Per year for SMEs	FRW	50,000
	GMP Inspection of food manufacturing facility (Foreign)		
132	East Africa	USD	3,000
133	Rest of Africa	USD	4,000
134	Asia	USD	5,000
135	Europe	USD	6,000
136	America	USD	7,000

137	Australia and New Zealand	USD	6,000
NB: *GMP Inspection of food manufacturing facility (Foreign) shall be Free in case of mutual recognition agreement*			

PART 4: OPERATIONAL LICENSE/PERMIT/CERTIFICATE

138	Medical representative for a foreign company	USD	300
139	Medical representative for a local company	FRW	30,000
140	Approval of regulated products in exhibition or trade fair (where applicable)	FRW	100,000
141	Pharmaceutical manufacturers	FRW	300,000
142	Inspection for additional line for pharmaceutical Product manufacturing	FRW	100,000
143	Inspection for additional line for food products manufacturing	FRW	100,000
144	Pharmaceutical products small compounding facilities	FRW	250,000
145	Food and beverage processing facility	FRW	200,000
146	Food and beverage processing facility with SME status	FRW	50,000
147	Tobacco and tobacco products manufacturer	FRW	200,000
148	Medical devices manufacturer	FRW	200,000
149	Chemicals, poisons and pesticides manufacturer	FRW	200,000
150	Cosmetics manufacturers	FRW	300,000
151	Animal feed manufacturing facility	FRW	200,000
152	Pharmaceutical distributor/importer/wholesaler	FRW	250,000
153	Wholesalers for veterinary products	FRW	250,000
154	Medical devices wholesalers	FRW	250,000
155	Cosmetics wholesalers	FRW	250,000
156	Cosmetics outlets	FRW	200,000
157	Veterinary Pharmacy	FRW	200,000

158	Retail Medical devices outlets	FRW	200,000
159	Retail Pharmacy	FRW	200,000
160	Retail Orthopedic workshop	FRW	200,000
161	Retail food supplements shop	FRW	200,000
162	Retail Optical shop	FRW	200,000
163	Animal feed and feed ingredients wholesale/outlets	FRW	200,000
164	Transfer/Relocation/ Re-inspection a manufacturing premise of regulated products	FRW	200,000
165	Transfer/Relocation/ Re-inspection of a retail/ wholesale premise of regulated products	FRW	100,000
166	Application for additional premise	FRW	150,000
167	Supervision of Safe Disposal of unfit products: Less than 100Kg	FRW	30,000
168	Supervision of Safe Disposal of unfit products: 100-500 Kg	FRW	60,000
169	Supervision of Safe Disposal of unfit products: 501-1000Kg	FRW	100,000
170	Supervision of Safe Disposal of unfit products: Above 1000Kg	FRW	300,000
171	Export permit for regulated products	FRW	25,000
172	Annual operational license renewal for pharmaceutical manufacturers	FRW	200,000
173	Annual operational license renewal for food and beverages manufacturers	FRW	200,000
174	Annual operational license renewal for food and beverages manufacturers with SME status	FRW	Free
175	Annual operational license renewal for tobacco and tobacco products manufacturer	FRW	200,000
176	Annual operational license renewal for medical devices manufacturer	FRW	100,000
177	Annual operational license renewal for chemicals, poisons and pesticides manufacturer	FRW	100,000
178	Annual operational license renewal for pharmaceutical wholesalers/distributors/importers	FRW	100,000
179	Annual operational license renewal for food wholesalers/distributors/importers	FRW	100,000

180	Annual operational license renewal of retail pharmacy	FRW	100,000
181	Annual operational license renewal of Retail Orthopedic workshop	FRW	100,000
182	Annual operational license renewal of Retail food supplements shop	FRW	100,000
183	Annual operational license renewal of Retail Optical shop	FRW	100,000
184	Annual operational license renewal of Retail Orthopedic workshop	FRW	100,000
185	Annual operational license renewal for food selling outlets	FRW	50,000
186	Canteens, contract caterers, snack bars, bakeries, restaurants and hotel restaurants	FRW	100,000
187	Special carriers of regulated products in special conditions (Vehicles, boats/vessels, aircrafts)	FRW	30,000
188	Health certificate /Export permit for food products for every application	FRW	25,000
189	Permit for importation of food products	FoB	0.5%
190	Permit for importation of animal feed and feed ingredients	FoB	0.2%
191	Permit for importation of donated products	FoB	0.2%
192	Permit for importation of donated products in case of official request from Government	FoB	Free
193	Permit for importation of grants products	FoB	0.2%
194	Permit for importation of medical devices (Human)	FoB	2%
195	Permit for importation of Laboratory Reagents	FoB	2%
196	Permit for importation of Food supplements	FoB	2%
197	Permit for importation of medical devices (animal)	FoB	1%
198	Importation of laboratory and household chemicals	FoB	0.5%
199	Permit for importation of laboratory equipment	FoB	1%
200	Permit for importation of pesticides and poisons	FoB	1%
201	Permit for importation of tobacco and tobacco products	Fob	2%

202	Permit for importation of Human medicine (finished products)	Fob	2%
203	Permit for importation of Veterinary medicines (Finished products)	Fob	1%
204	Permit for importation of raw materials and packaging materials for regulated products	Fob	0.2%
205	Permit for importation of machinery	Fob	1%
206	Permit for importation of cosmetics	FOB	1%
207	Permit for importation of machinery for those with investment certificates dealing with regulated products	Fob	Free
208	Samples for registration for regulated products (only 2 packaging items)	Fob	Free
209	Samples for research	Fob	Free
210	Sample for testing in cosmetic shops (1 package per type)	FoB	Free
211	Promotional materials	FoB	Free
212	Verification of consignments for disasters, emergency and outbreaks officially declared by competent Authority	FoB	Free
213	Duplicate-Certificate (Domestic)	FRW	Free
214	Duplicate-Certificate (Foreign)	USD	Free
	Fees for changes in particulars registered with the Authority		
215	Application for change of name, ownership or management of a pharmacy	FRW	Free
216	Application for change of pharmacist or in-charge person during the licensing period	FRW	30,000
217	Application for change of pharmacy technicians	FRW	Free
218	Change of location and/or additional storage space	FRW	100,000
	Administrative fines:- Importation, Sale & Distribution of Unapproved, Substandard & Counterfeit Products		
219	Admin. Fine – Manufacturing, importation, sale, storage & distribution	currency Applicable on the	Double the value of condemned products

	of substandard, Unapproved, Counterfeit/falsified, expired and fraudulent regulated Products	invoice	plus test related costs (when testing is compulsory).
220	Adm. Fines- violation of closure by Rwanda FDA	FRW	500,000
221	Admin. Fine for Airing of Unapproved advertisements	FRW	500,000
122	Disposal charge of condemned products	Applicable currency	Disposal at the owner's cost
223	Admin. Fine for Absence of responsible technical person in an authorized facility dealing with regulated products	FRW	100,000
224	Admin. Fine for Operating without operational license	FRW	1,000,000
225	Admin. Fine for Operating without valid operational license	FRW	100,000
226	Admin. Fine for Closure of the Pharmacy which is officially on duty	FRW	100,000
227	Conducting Unauthorized Clinical trial	FRW	5,000,000
228	Non-adherence to Clinical Trial Authorization Requirements, Timelines/Implementation of Unapproved Protocol/Amendments.	FRW	500,000
229	Airing Expired regulated Products in shelves	FRW	100,000
230	Production without Production/Quality Control Manager	FRW	500,000
231	Transport of regulated products in unacceptable conditions	FRW	200,000
	Fees for vetting/analysis/review of regulated products (prescript/language) promotional materials/Screening of Promotional materials per language		
232	Written materials/scripts per product	FRW	60,000 paid once for the approval of message
233	Written materials with brand name or product name		
234	Audio and video		
235	Renewal of promotional materials		

CHAPTER II: FINAL PROVISIONS

Article 6: Duration for payment of service fees and fines

All services rendered by Rwanda FDA are prepaid and therefore, the payment proof will be among the requirements for application. The fines shall be paid within thirty (30) days from the reception of decision imposing fines. Commitment to pay by instalments for a period of at least three (3) times shall be accepted only for exceptional cases. Any accepted payment in instalments shall not exceed 12 moths.

Article 7: Right to appeal

The manufacturer, seller, distributor, importer or any other person responsible for the condemned regulated products, if not satisfied with the decision of the Authority, may submit his/her appeal to the management of the Authority for review within fifteen (15) calendar days from the date of the reception of the decision. The management of the Authority shall take decision on the appeal within thirty (30) calendar days from the reception of the appeal.

If the appellant is not satisfied with the decision of the management of the Authority, he/she may appeal to the Board of Directors within fifteen (15) calendar days from the reception of the response to the appeal. The Board of Directors shall take a decision on the appeal within thirty (30) calendar days from its reception.

Article 8: Exemption of Regulatory Service Fees

For public health emergencies or in case of mutual recognition agreements, the Authority may exempt regulatory service fees.

Article 9: Forced payment of fines

In case the condemned person or company does not pay the fines imposed, the Authority shall proceed with the seizure of the person or company's property to recover the non-paid fines. The seizure and the public auction of the seized property are conducted by a qualified Court bailiff in accordance with the law on civil, commercial, labor and administrative procedure.

Article 10: Revision of these Regulations

These regulations shall be revised by Rwanda Food and Drugs Authority in case there is a change to the service requirements and any amendment shall be communicated to the public.

Article 11: Commencement

These regulations come into force on the date of signature and publication on the Rwanda FDA website.

Article 12: Repealing Provisions

All Provisions contrary to these regulations are repealed.

End of Document