RWANDA FDA
Rwanda Food and Drugs Authority

REGULATIONS RELATED TO REGULATORY SERVICE TARIFF/FEES AND FINES

(Rwanda FDA law N^{o}. 003/2018 of 09/02/2019, Article 9)

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_1 Related to regulatory service tariff/fees and fines, made this 1st day of April, 2020.

Dr. Charles KARANGWA
Ag. Director General

ARRANGEMENT OF THE REGULATIONS

ADOPTION AND APPROVAL OF THE REGULATIONS 2
ARRANGEMENT OF THE REGULATIONS 3
CHAPTER I: GENERAL PROVISION 4
ARTICLE 1: PURPOSE OF THESE REGULATIONS 4
ARTICLE 2: CITATION 4
ARTICLE 3: APPLICATION 4
ARTICLE 4: DEFINITIONS 4
ARTICLE 5: TARIFFS/FEES AND SERVICES 6
ANNEX I: LIST OF SERVICES AND THEIR CORRESPONDING FEES 7
PART 1: REGISTRATION OF REGULATED PRODUCTS 7
PART 2: RETENTION/RENEWAL AND VARIATION OF REGISTERED PRODUCTS 11
PART 3: INSPECTIONS 11
PART 4: OPERATIONAL LICENSE/PERMIT/CERTIFICATE 12
CHAPTER II: FINAL PROVISIONS 17
ARTICLE 6: DURATION FOR PAYMENT OF SERVICE FEES AND FINES 17
ARTICLE 7: AGGRAVATING CIRCUMSTANCES 17
ARTICLE 8: RIGHT TO APPEAL 17
ARTICLE 8: FORCED PAYMENT OF FINES 18
ARTICLE 10: REVISION OF THESE REGULATIONS 18
ARTICLE 11: COMMENCEMENT 18
ARTICLE 12: REPEALING PROVISIONS 18

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**: 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 relabelling of products regulated by Rwanda FDA;
4. **Food product**: 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**: 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** 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:** any device used in the medical field for the purpose of diagnosis, testing, cure, surgery or health protection;
9. **Notifications:** 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**: changes that could have major effects on the overall safety, efficacy and quality of the finished food or pharmaceutical products;
11. **Minor variation:** changes 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 :** 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 FBO** 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.

Article 5: Tariffs/fees and services

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.

A person shall pay a fee prescribed in the schedule in respect of the product and services regulated by Rwanda FDA Law 003/2018 of 09/02/2019.

Tariffs/fees and fines paid under these regulations shall be paid in Rwandan francs or in US Dollars

Tariffs and services are published on Rwanda FDA website and can be provided to any other natural person or organization which requests for them.

The Authority may change or vary any 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 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.

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

	Human and Veterinary Medicines (Domestic)		
Serial Number	**Service**	**Currency**	**Fee**
1	Registration for human medicines	FRW	400,000
2	Registration for veterinary medicines	FRW	200,000
3	Registration of herbal medicines	FRW	300,000
	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	1,250
	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
	Registration Medicated Cosmetics and household chemicals (Domestic)		
23	Toothpastes	FRW	300,000
24	Antiseptics	FRW	200,000
25	Detergent powder	FRW	200,000
26	Detergent liquid	FRW	200,000
27	Mosquito coil	FRW	300,000
28	Vector control products	FRW	300,000
29	Soap (toilet and laundry)	FRW	150,000
30	Household chemicals	FRW	300,000
31	Medicated Cosmetics	FRW	300,000
	Registration of Medicated Cosmetics and household Chemicals (Foreign)		
32	Toothpastes	USD	500
33	Antiseptics	USD	300
34	Detergent powder	USD	400
35	Detergent liquid	USD	300
36	Mosquito coil	USD	300
37	Vector control products including pesticides	USD	700
38	Soap (toilet and laundry)	USD	500
39	Medicated Cosmetics	USD	500
40	Household chemicals	USD	400
	Registration of Laboratory chemicals, Poisons and Pesticides (Domestic)		
41	Laboratory chemicals	FRW	500,000
42	Poisonous substances	FRW	600,000
	Registration of Laboratory chemicals, Poisons and Pesticides (Foreign)		
43	Laboratory chemicals	USD	1250
44	Poisonous substances	USD	1250
	Fees for Clinical Trials Authorization		
45	Funded Clinical Trial (Phase I)	USD	4000
46	Funded Clinical Trial (Phase II)	USD	4000

47	Funded Clinical Trial (Phase III)	USD	3000
48	Funded Clinical Trial For Research institution (Foreign)	USD	4000
49	Funded Clinical Trial For Research institution (Domestic)	USD	2000
50	Application for Clinical Trial For Amendment (Funded)	USD	500
51	Funded Clinical Trial For Academic Research trial (Individual) Domestic	USD	1000
52	Application to undertake clinical trial for a registered pharmaceutical products or medical devices	USD	2500
53	Non-Funded Clinical trials (Domestic)	FRW	500,000
54	Application to conduct ectoparasiticides field trials	USD	1000
	Registration of Food Products (Domestic)		
55	Milk and milk products	FRW	200,000
56	Cereal and cereal products	FRW	150,000
57	Pulses	FRW	100,000
58	Nuts	FRW	100,000
59	Processed Tuber and roots	FRW	100,000
60	Non-alcoholic beverages	FRW	150,000
61	Liquors (final product)	FRW	1,000,000
62	Beers, Wines and plant-based alcoholic drinks	FRW	500,000
63	Sugar and Honey	FRW	200,000
64	Iodated Salt (edible)	FRW	100,000
65	Fats and Oils	FRW	150,000
66	Tea and Coffee	FRW	100,000
67	Cocoa and cocoa products	FRW	200,000
68	Spices and Herbs	FRW	100,000
69	Vinegar	FRW	100,000
70	Fish and fish products	FRW	200,000
71	Meat and meat products	FRW	200,000
72	Fruits and fruits products	FRW	150,000
73	Drinking/ mineral water	FRW	300,000
74	Vegetable and vegetable products	FRW	100,000
75	Food for infants and follow-up formula	FRW	200,000

76	Food supplements	FRW	250,000
77	Food additives	FRW	500,000
78	Confectionaries	FRW	100,000
79	Fortified foods	FRW	200,000
80	Other processed food products	FRW	150,000
81	Animal feeds	FRW	200,000
	Registration of Tobacco and Tobacco products		
82	Tobacco and Tobacco products (Domestic)	FRW	1000,000
83	Tobacco and Tobacco products(Foreign)	USD	1500
	Registration of Food Products (Foreign)		
84	Milk and milk products	USD	400
85	Cereal and cereal products	USD	300
86	Pulses	USD	250
87	Nuts	USD	300
88	Tuber and roots	USD	250
89	Non-alcoholic beverages	USD	300
90	Liquors (final products)	USD	1,500
91	Beers, Wines and plant-based alcoholic drinks	USD	550
92	Sugar and Honey	USD	200
93	Iodated Salt (edible)	USD	150
94	Fats and Oils	USD	200
95	Tea and Coffee	USD	500
96	Cocoa and cocoa products	USD	500
97	Spices and Herbs	USD	400
98	Vinegar	USD	200
99	Fish and fish products	USD	500
100	Meat and meat products	USD	500
101	Fruits and fruits products	USD	200
102	Drinking/ mineral water	USD	400
103	Vegetable and vegetable products	USD	200
104	Food for infants and follow-up formula	USD	700
105	Food supplements	USD	700
106	Food additives	USD	350
107	Confectionaries	USD	210
108	Fortified foods	USD	700
109	Other processed food products	USD	520

110	Animal feeds	USD	500

Note:

- For all 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

PART 2: RETENTION/RENEWAL AND VARIATION OF REGISTERED PRODUCTS

#	**Service**	**Pharmaceutical products and medical devices, chemicals, medicated cosmetics, pesticides and poisonous substances. (% of the initial registration fee)**	**Food and tobacco products % of the initial registration fees**
111	Retention	15%	5%
112	Renewal	50%	50%
113	Major Variation	50%	5%
114	Minor Variation	20%	5%

PART 3: INSPECTIONS

#	**GMP Inspection for Pharmaceutical or medical devices manufacturing facilities (Domestic)**		
115	GMP Licensing Per Year	FRW	200,000
116	GMP Licensing of herbal plant Per Year	FRW	200,000
117	Re-inspection of facilities for manufacturing pharmaceutical products and medical devices	FRW	100,000
	GMP Inspection for Pharmaceutical or medical devices manufacturing facilities (Foreign) for 5 product lines at one site		
118	East Africa	USD	3,000
119	Rest of Africa	USD	4,000
120	Asia	USD	5,000
121	Europe	USD	6,000
122	America	USD	7,000
123	Australia and New Zealand	USD	6,000
124	Fee for inspection of any additional production line	USD	1,000

	GMP Inspection of food manufacturing facility (Domestic)		
125	Local food GMP inspection Per year	FRW	200,000
	GMP Inspection of food manufacturing facility (Foreign)		
126	East Africa	USD	3,000
127	Rest of Africa	USD	4,000
128	Asia	USD	5,000
129	Europe	USD	6,000
130	America	USD	7,000
131	Australia and New Zealand	USD	6,000

PART 4: OPERATIONAL LICENSE/PERMIT/CERTIFICATE

132	Medical representative foreign per company	USD	700
133	Approval of regulated products in exhibition or trade fair (where applicable)	FRW	100,000
134	Pharmaceutical manufacturers	FRW	300,000
135	Food and beverage processing facility	FRW	200,000
136	Tobacco and tobacco products manufacturer	FRW	200,000
137	Medical devices manufacturer	FRW	200,000
138	Chemicals, poisons and pesticides manufacturer	FRW	200,000
139	Medicated Cosmetics manufacturers	FRW	300,000
140	Animal feed manufacturing facility	FRW	200,000
141	Pharmaceutical distributor/importer/wholesaler	FRW	250,000
142	Wholesalers for veterinary products	FRW	250,000
143	Medical devices wholesalers	FRW	250,000
144	Medicated Cosmetics wholesalers	FRW	250,000
145	Medicated Cosmetics outlets	FRW	200,000
146	Veterinary Pharmacy	FRW	200,000
147	Retail Medical devices outlets	FRW	200,000
148	Retail Pharmacy	FRW	200,000
149	Retail Orthopedic workshop	FRW	200,000
150	Retail food supplements shop	FRW	200,000
151	Retail Optical shop	FRW	200,000
152	Animal feed and feed ingredients wholesale/outlets	FRW	200,000

153	Transfer/Relocation a premise of regulated products	Frw	150,000
154	Application for change of technical person, owner of registered premise and name of premise		30,000
155	Additional premise	FRW	150,000
156	Supervision of Safe Disposal of unfit products: Less than 100Kg	FRW	30,000
157	Supervision of Safe Disposal of unfit products: 100-500 Kg	FRW	60,000
158	Supervision of Safe Disposal of unfit products: 501-1000Kg	FRW	100,000
159	Supervision of Safe Disposal of unfit products: Above 1000Kg	FRW	300,000
160	Export permit for regulated products	FRW	25,000
161	Annual operational license renewal for pharmaceutical manufacturers	FRW	200,000
162	Annual operational license renewal for food and beverages manufacturers	FRW	200,000
163	Annual operational license renewal for tobacco and tobacco products manufacturer	FRW	200,000
164	Annual operational license renewal for medical devices manufacturer	FRW	200,000
165	Annual operational license renewal for chemicals, poisons and pesticides manufacturer	FRW	200,000
166	Annual operational license renewal for pharmaceutical wholesalers/distributors/importers	FRW	150,000
167	Annual operational license renewal for food wholesalers/distributors/importers	FRW	150,000
168	Annual operational license renewal of retail pharmacy	FRW	100,000
169	Annual operational license renewal of Retail Orthopedic workshop	FRW	100,000
170	Annual operational license renewal of Retail food supplements shop	FRW	100,000
171	Annual operational license renewal of Retail Optical shop	FRW	100,000

172	Annual operational license renewal of Retail Orthopedic workshop	FRW	100,000
173	Annual operational license renewal for food selling outlets	FRW	50,000
174	Canteens, contract caterers, snack bars, bakeries, restaurants and hotel restaurants	FRW	100,000
175	Special carriers of regulated products in special conditions (Vehicles, boats/vessels, aircrafts)	FRW	30,000
176	Health certificate /Export permit for food products	FRW	25,000
177	FOB charge for imported food products	FoB	0.8%
178	FOB charge for imported animal feed and feed ingredients	FoB	0.8%
179	Importation of donated regulated products	FoB	0.2%
180	Importation of medical devices	FoB	2%
181	Importation of laboratory and household chemicals	FoB	1%
182	Importation of pesticides and poisons	FoB	1%
183	Importation of tobacco and tobacco products	FoB	2%
184	Permit for importation of medicine (finished products)	FoB	2%
185	Permit for importation of raw materials and packaging materials for regulated products	FoB	0.2%
186	Verification of consignments for disasters and outbreaks	NA	Free
187	Verification of consignments for Medicated cosmetics	FOB	1%
188	Duplicate-Certificate (Domestic)	RWF	20,000
189	Duplicate-Certificate (Foreign)	USD	30
	Fees for changes in particulars registered with the Authority		
190	Application for change of name, ownership or management of a pharmacy	FRW	50,000
191	Application for change of pharmacist or in-charge person during the licensing period	FRW	40,000
192	Application for change of pharmacy technicians	FRW	20,000
193	Change of location and/or additional	FRW	100,000

	storage space		
Administrative fines:- Importation, Sale & Distribution of Unapproved, Substandard & Counterfeit Products			
194	Admin. Fine – Manufacturing, importation, sale, storage & distribution of substandard, Unapproved, Counterfeit/falsified, expired and fraudulent regulated Products	currency Applicable on the invoice	50% value of the condemned products
195	Admin. Fine for Airing of Unapproved Advertisements	RWF	500,000
196	Disposal charge of condemned products	Applicable currency	Disposal at the owner's cost
197	Admin Fine for Absence of responsible technical person in an authorized facility dealing in regulated products	RWF	100,000
198	Admin Fine for Operating without operational license	RWF	1,000,000
199	Admin Fine for Operating without valid operational license	RWF	100,000
200	Admin Fine for Closure of the Pharmacy which is officially on duty	RWF	100,000
201	Conducting Unauthorized Clinical trial	FRW	5,000,000
202	Non-adherence to Clinical Trial Authorization Requirements Timelines / Implementation of Unapproved Protocol/Amendments.	FRW	500,000
203	Airing Expired regulated Products in shelves	FRW	100,000
204	Production without Production/Quality Control Manager	FRW	500,000
205	Transport of regulated products in unacceptable storage conditions	FRW	200,000
	Fees for vetting/analysis/review of regulated products (per script/language/) promotional materials /Screening of Promotional materials per language		
206	Written materials/scripts per product	FRW	60,000
207	Written materials with brand name or product name	FRW	5,000
208	Audio and video	FRW	60,000

209	Renewal of promotional materials	FRW	10,000

CHAPTER II: FINAL PROVISIONS

Article 6: Duration for payment of service fees and fines

All services rendered by Rwanda FDA are prepared 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. At the discretion of the Authority, commitment to pay fines within agreed period of time shall be accepted.

Article 7: Aggravating Circumstances

In accordance with an analysis backed with proofs, the amount of administrative fines may be increased up to three (3) times due to one or several of the following aggravating circumstances;

a) recidivism;
b) committing an act that causes death;
c) Any other intentional act the Authority may judge harmful to the public

Article 8: 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, must submit his/her appeal to the management of the authority for review within fifteen (15) days from the date of the reception of the decision. The management of the authority shall take decision on the appeal within thirty (30) days from the reception of the appeal.

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

Article 8: 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 publication on the Rwanda FDA's website.

Article 12: Repealing Provisions

All Provisions contrary to these regulations are repealed.

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