NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

TARIFF

(Effective Date: 1st June 2019)

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A GENERAL

1.0	This tariff is for the interest of the General Public and in particular NAFDAC clients
1.1	All Tariff herein are in Naira except where indicated in US dollars. Please note that fees in US dollars can be paid in the equivalent Naira value.
1.2	Local in this tariff implies services rendered within Nigeria for products manufactured in Nigeria while Foreign implies services rendered for products manufactured outside Nigeria
1.3	For validity period of Certificates/Permits/Registration/Listing and Inspection, please refer to relevant guidelines on https://www.nafdac.gov.ng/resources/guidelines/

B ANCILLARY FEES (e.g., Adverts, Variants, Donated items and Change in Brand Names)

S/No	Description	Local	Foreign
1.0	Advertisement		
1.1	Single Product		15,000.00
1.1.1	Variants (per medium/per concept/per version/per language)		5,000.00
1.2	Corporate Adverts with Company products in display		
1.2.1	2-5 products		29,700.00
1.2.2	> 5 products		70,500.00
1.2.3	Variants (per medium/per concept/per version/per language)		15,000.00
1.3	Consumer Promotion (per medium/per concept/per version/per language)		15,000.00
2.0	Approvals for Donated items/Research purposes/MachineTrials/NGOs		50,000.00

S/No	Description	Local	Foreign
2.1	Certified true copy of NAFDAC documents (per page)		5,000.00
2.2	Change in Brand Name (At company's instance)	80,000.00	118,500.00
2.3	Change in Brand Name (At NAFDAC's instance)		0.00
2.4	Change in Variants	80,000.00	118,500.00
2.5	Change of Agencyship		50% of cost of registration
2.6	Change of Package/Pack Size Extension/label/Design	80,000.00	118,500.00
2.7	Fast Track Approval		Double cost of original activity/item
2.8	No objection Approval for Registered products (each) (max 3 issuance)		300,000.00
2.9	Pharmacovigilance/Post Marketing Fees		10% of cost of Registration fees
2.10	Ports Fast track Scheme Annual Registration fee	50,000.00	NA
2.11	Provisional Administrative Approval	150,000.00	NA
2.12	Data Requests	70,000.00	NA
	EXPLANATORY NOTES Adverts are valid for one(1) year but extended to two (2) years upon payment (double relevant fee) if concept remains unchanged.		

C CLINICAL TRIALS

S/No	Description	Industry-Sponsored / Locally-developed IMP	Industry-Sponsored / Imported IMP	Academic trials
1.0	**Application**	250,000.00	$2,747.25	
1.0.1	Individual	NA	NA	50,000.00
1.0.2	Research Institution	NA	NA	100,000.00
1.1	Dossier/Clinical data review		50,000.00	
1.2	Extension of Study	50,000.00	$2,747.25	20,000.00
1.3	**Inspection**	350,000.00	$5,494.51	
1.3.1	Individual	NA	NA	100,000.00
1.3.2	Research Institution	NA	NA	300,000.00
1.4	Additional Site (per site)			150,000.00
1.5	**Routine Inspection**	350,000.00	$2,747.25	
1.5.1	Individual	NA	NA	100,000.00
1.5.2	Research Institution	NA	NA	300,000.00
1.6	**Substantial Protocol Amendment**	50,000.00	$412.09	

D FACILITY AND PORT INSPECTIONS

S/No	Description	Local	Foreign
1.0	**Cold Room**		
1.1	Micro Scale (Renewable yearly)	30,000.00	NA
1.2	Small Scale (Renewable yearly)	40,000.00	NA
1.3	Medium (Renewable yearly)	80,000.00	NA
1.4	Large (Renewable yearly)	100,000.00	NA

S/No	Description	Local	Foreign
2.0	**Field Trial for Agrochemicals/Premixes (per product)**	500,000.00	NA
3.0	**Food (per line for local; per site for foreign)**		$10,989.01
3.1	Micro Scale (Renewable yearly)	10,000.00	NA
3.2	Small Scale (Renewable yearly)	30,000.00	NA
3.3	Medium/Large Scale (Renewable yearly)	80,000.00	NA
4.0	**Pharmaceuticals (per line for local; per site for foreign)**		$10,989.01
4.1	Production Small Scale (Renewable yearly)	50,000.00	NA
4.2	Production Medium/Large Scale (Renewable yearly)	120,000.00	NA
5.0	**Veterinary Cosmetics, Cosmetics and Herbal Products (per line for local; per site for foreign)**		$10,989.01
5.1	Micro Scale (Renewable yearly)	20,000.00	NA
5.2	Small Scale (Renewable yearly)	30,000.00	NA
5.3	Medium/Large Scale (Renewable yearly)	80,000.00	NA
6.0	**Supermarkets/Warehouse (per site) (Annual Fees)**		
6.1	Small Scale	40,000.00	NA
6.2	Medium/Large Scale	80,000.00	NA
6.3	Mega Scale	150,000.00	NA
7.0	**All other types of Facility inspections***	30,000.00 per product/per activity	NA
8.0	**Office based risk assessment for already inspected foreign sites that contract manufacture (per applicant)**		$6,043.96
9.0	**Inspection at Ports**		
9.1	**All Retail Products (per 20ft container)**		
9.1.1	Donated (Drugs, Medical Devices, Food)	NA	50,000.00
9.1.2	Medical Devices, Vaccines and Biologicals	NA	50,000.00
9.1.3	Registered Orphan Drugs/Antiretrovirals	NA	50,000.00
9.1.4	Registered Over The Counter Drugs	NA	135,000.00
9.1.5	Registered Prescription Only Medicines/Food/Cosmetics/Agrochemicals	NA	67,500.00
9.2	**Chemicals, Packaging Materials and Raw materials**		
9.2.1	Less than 100MT	NA	10,000.00
9.2.2	Less than 1000MT	NA	40,000.00
9.2.3	Less than 2000MT	NA	168,750.00
9.2.4	Less than 4000MT	NA	337,500.00
9.2.5	Above 4000MT	NA	506,250.00
9.3	**Finished Chemicals, Food Raw Materials, Semi-finished Bulk Food and Global Listing for Supermarket operators (1 x 20ft to 10 x 20ft)**	NA	40,000.00
9.4	**Rebagging at the Ports**	NA	400,000.00

S/No	Description	Local	Foreign
	EXPLANATORY NOTES **D** 4.0 and **D** 5.0: line represents line(s) for dosage forms **D** 7.0 All other types of facility inspections including: (i.) Pre-production: Inspection carried out to determine suitability of production facility for pharmaceuticals companies only. (ii.) Coding Inspection: For supervision of NAFDAC Registration number and Mobile Authentication Service codes locally on Imported Products. (iii.) Cold chain: To ensure compliance with temperature control chain. (iv.) Pre-registration Inspection: For product registration (v.) GMP/GHP Reassessment: Full Audit of production facilities (vi.) Follow-up Inspection: For CAPA purposes. (vii.) For-Cause: For Specific concerns (viii.) Foreign Facility Inspections are valid for three years **D** 8.0 The office based risk assessment fee will be charged per applicant where a risk assessment is conducted which does not lead to an inspection. Only manufacturers whose GMP inspections have been carried out satisfactorily qualify to contract manufacture for other parties.		

E FORMS/CERTIFICATES

S/No	Description	Local	Foreign
1.0	Application Forms		2,500.00
1.1	cGMP Certificate		20,000.00
1.2	Cold Room Certification	20,000.00	NA
1.3	**Export Certificates**		
1.3.1	Registered Locally made Products (Per issued Certificate)	10,000.00	NA
1.3.2	Certificate of Free Sales (Per issued Certificate)	25,000.00	NA
1.3.3	Health Certificate (Per issued Certificate)	5,000.00	NA
1.3.4	Export Certificates (Per issued Certificate)	5,000.00	NA
1.4	Product Listing Certificate	40,000.00	NA
1.5	Product Registration Certificate	40,000.00	270,000.00

F LABORATORY ANALYSIS

S/No	Description	Local	Foreign
1.0	**All analysed raw materials**	102,500.00	
2.0	**Bread Registration**		
2.0.1	Micro	5,000.00	NA
2.0.2	Medium/Small/Large	15,000.00	NA
3.0	**Cosmetics**	80,000.00	205,000.00
4.0	**Donated Items**	NA	205,000.00
5.0	**Drugs**		
5.0.1	Orphan Drugs	80,000.00	205,000.00
5.0.2	Over the Counter Drugs (OTC)	80,000.00	300,000.00
5.0.3	Prescription Only Medicines (POM)	80,000.00	205,000.00
5.0.4	Vaccines and Biologicals	80,000.00	205,000.00
5.0.5	Veterinary Drugs	80,000.00	205,000.00
6.0	**Enforcement Samples**	108,000.00	405,000.00
7.0	**Food**	40,000.00	205,000.00
8.0	**Herbals and Nutraceuticals**		
8.0.1	Herbal Extracts	20,000.00	205,000.00
8.0.2	Herbal Supplements/ Vitamins & Minerals	80,000.00	205,000.00
9.0	**Medical Devices**	20,000.00	75,000.00
10.0	**Pesticides and other retail Agrochemicals**	80,000.00	205,000.00
11.0	**Pesticide Formulation**	30,000.00	160,000.00
12.0	**Water Registration**		
12.0.1	Bottle	40,000.00	NA

S/No	Description	Local	Foreign
12.0.2	Sachet	20,000.00	NA
13.0	**Consultancy**		135,000.00
14.0	**Nigeria Customs Service Requests**	135,000.00	NA
15.0	**Training of IT students**		
15.0.1	Three (3) months	7,500.00	NA
15.0.2	Six (6) months	10,000.00	NA
15.0.3	One (1) year	15,000.00	NA

G PERMITS

S/No	Description	Local	Foreign
1.0	**Permit to Import: Agrochemicals and Restricted Chemicals (1st 25 Items) New Applicant**		
1.0.1	Businesses and Manufacturers	169,000.00	
1.0.2	Educational Institutions	68,000.00	
1.1	**Permit to Import: Chemicals and other Raw Materials: (1st 25 Items) New Applicant**	101,250.00	
1.2	**Permit to Import: Chemicals and other Raw Materials: Raw Materials: (1st 25 Items) Renewal**	50,625.00	
1.3	**Permit to Import: Chemicals and other Raw Materials: Additional Raw Materials (25 Items/Page)**	40,500.00	
1.4	**Permit to Import: Controlled Drugs and Chemicals/ Precursor Chemicals/ Solvents and Bulk Narcotics (3 items/page)**		
1.4.1	Businesses and Manufacturers	169,000.00	
1.4.2	Educational Institutions	68,000.00	
1.4.3	Health Institutions and Community Pharmacies	68,000.00	
1.5	**Permit to Clear: Agrochemicals and Restricted Chemicals/Controlled Drugs and Chemicals/ Precursor Chemicals/ Solvents and Bulk Narcotics**		
1.5.1	Businesses and Manufacturers	20,000.00	
1.5.2	Educational Institutions	13,500.00	
1.5.3	Health Institutions and Community Pharmacies	13,500.00	
1.6	**Permit to Import: Active Pharmaceutical Ingredients (APIs) (1 item per permit)**		
1.6.1	Businesses	68,000.00	
1.6.2	Educational Institutions	13,500.00	
1.6.3	Health Institutions and Community Pharmacies	13,500.00	
1.6.4	Manufacturers	5,000.00	
1.7	**Permit to Import Pharmaceutical Grade Excipients (25 items/page)**		
1.7.1	Businesses	99,500.00	
1.7.2	Educational Institutions	40,000.00	
1.7.3	Health Institutions and Community Pharmacies	40,000.00	
1.7.4	Manufacturers	86,700.00	
1.8	**Permit for Service Drugs/Medical Devices:**		
1.8.1	Medical Devices (per product)		10,000.00
1.8.2	Orphan Drugs (per product)		25,000.00
1.8.3	Over The Counter Drugs (per product)		40,000.00
1.8.4	Prescription Only Medicines (per product)		35,000.00
1.8.5	200-250 items (maximum)		8,000,000.00

S/No	Description	Local	Foreign
H	**REGISTRATION**		
S/No	**Description**	**Local**	**Foreign**
1.0	**Animal Feed/Food/Premixes**		
1.1	Imported Class 1*	NA	$4,945.06
1.2	Imported Class 2*	NA	$4,120.88
1.3	Micro*	20,000.00	NA
1.4	Small*	40,000.00	NA
1.5	Medium/Large*	80,000.00	NA
2.0	**Fast Food Listing**		
2.1	1-100 items		1,000,000.00
2.2	101-250 items		2,500,000.00
2.3	251-500 items (max)		5,000,000.00
3.0	**Global/Supermarket listing**		
3.1	1-100 items		1,500,000.00
3.2	101-250 items		3,300,000.00
3.3	251-500 items		7,000,000.00
3.4	501-1000 items		12,000,000.00
3.5	1001-5000 items (max)		20,000,000.00
4.0	**Pesticides/Bio Pesticides and other retail Agrochemicals**	120,000.00	$4,120.88
5.0	**Pharmaceuticals**		
5.1	Cosmetics (per product)		$4,945.06
5.1.1	Micro	20,000.00	NA
5.1.2	Small	50,000.00	NA
5.1.3	Medium/Large	100,000.00	NA
5.2	**Herbal and Nutraceuticals/Alternative Medicines (per product)**		**Full Registration: $4,120.88** **Listing: $1,373.63**
5.2.1	Micro	20,000.00	NA
5.2.2	Small	60,000.00	NA
5.2.3	Medium/Large	160,000.00	NA
5.3	Medical Devices 1*	100,000.00	$2,609.89
5.4	Medical Devices 2*	100,000.00	$3,296.70
5.5	Over the Counter Medicines (OTC)	120,000.00	$4,945.06
5.6	Orphan Drugs	120,000.00	$2,747.25
5.7	Prescription Only Medicines (POM) 1*	120,000.00	$3,846.15
5.8	Prescription Only Medicines (POM) 2*	120,000.00	$3,296.70
5.9	Vaccines/Biologicals	120,000.00	$1,923.08
5.10	Veterinary Medicines and Supplements	120,000.00	$4,120.88
6.0	**Renewal Registration**		
6.1	Registration Renewal		90% of New Registration cost
6.2	Additional source/site or change of source		Same as fees for New Registration
6.3	All locally manufactured products for renewal		Same as fees for New Registration

S/No	Description	Local	Foreign
	EXPLANATORY NOTES **H** 1.0. 10% of the total Registration fee is to process for permit to import; 80% is Processing fee which attracts 5% VAT and 10% of the total Registration fee is for Certificate **H** 1.1. Imported Class 1: Food products that can be manufactured in Nigeria; **H** 1.2. Imported Class 2: Food products with no existing manufacturing facility in Nigeria **H** 5.1.1. Micro Enterprises cannot register more than five (5) products. **H** 5.3. Medical Devices 1: Others except items in Medical Devices 2 **H** 5.4 Medical Devices 2: Diapers and Sanitary Pads **H** 5.7. POM1: Medicines that can be manufactured in Nigeria; **H** 5.8. POM2: Medicines with no existing manufacturing facility in Nigeria **H** 6.0 Information on Product renewal are as follows (i) Product licenses are renewed every five (5) years (ii) Listing Certificate are renewed every two (2) years (iii) Any product with expired registration license is considered an unregistered product.		

I	INVESTIGATION CHARGES		
S/No	**Description**	**Local**	**Foreign**
1.1	Clinical Trial CAPA Failure		350,000.00
1.2	Dispensing of Chemicals and raw materials in containers other than the original/primary container without authorization		1,350,000.00
1.3	Drug Hawking		67,500.00
1.4	False Declaration and concealment of imported products		1,687,500.00
1.5	Importation without a Clean Report of Inspection & Analysis (CRIA)*		1,000,000.00
1.6	Labeling Lapse/Change (per product)		537,500.00
1.7	Late Renewal of Registration License/Listing Certificate	156,250.00	537,500.00
1.8	Marketing without Listing Certificate/Importation without Permit (per category)/Use of expired license		843,750.00
1.9	Non Endorsement of shipping documents		675,000.00
2.0	Non-compliance with Good Manufacturing, Hygiene, Distribution and Storage Practices		2,000,000.00
2.1	Possession/Importation of unauthorized labelled packaging materials		1,250,000.00
2.2	Production without Production/Quality Control Manager*		200,000.00
2.3	Sale and Distribution of diverted products meant for relief organisations		5,000,000.00
2.4	Sale of Drugs without Issuance of sales Receipt / Invoice		200,000.00
2.5	Sale of expired Regulated Products		1,500,000.00
2.6	Tampering with products on Hold/Unauthorised Removal of "Hold" Label		3,375,000.00
2.7	Triggered Clinical Trial Alert		1,000,000.00
2.8	Unauthorized Advert (per concept/medium/per product)		168,750.00
2.9	Unauthorized breaking of container seal		135,000.00

S/No	Description	Local	Foreign
3.0	Unauthorized Clinical trial		5,000,000.00
3.1	Unauthorized Clinical Trial protocol		300,000.00
3.2	Unregistered products (per product)	5,000,000.00	5,000,000.00 per product/per container
3.2.1	Micro	200,000.00	NA
3.3	Registered products (with formulation issues)	5,000,000.00	5,000,000.00 per product/per container
3.3.1	Micro	200,000.00	NA
3.4	Infringements leading to Prosecution	Please see explanatory notes below	

EXPLANATORY NOTES

ı 1.5

(i.) All regulated products from China

(ii.) All medicines from India and China

ı 2.1. This infringement would require seizure and destruction of labelled packaging materials intended for product counterfeiting

ı 2.2. Applies only to small, medium and large enterprises

ı 3.2. Entails the following infrigements:

(i.) Importation, production, sale of unregistered products in commercial quantity (Seizure and Destruction of medicines after payment of administrative charge)

(ii.) Importation above quantity approved in permit/registration purposes

(iii.) Service Drug/Medical Devices Scheme

(iv.) Use of unapproved Packaging Materials

(v.) Unauthorized change of location/source/contract manufacture

ı 3.3. Unauthorized change of formulation/use of unauthorized additives/non compliance with mandatory food fortification will require product recall after payment of administrative charge.

ı 3.4. The following infringements shall warrant prosecution:

(i.) Importation of Prohibited regulated products;

(ii.) Use of false, forged or unauthorized use of NAFDAC documents;

(iii.) Obstruction and assault of officers on duty;

(iv.) Counterfeiting of regulated products

(v.) Alteration of Date Markings