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

TARIFF

(Effective Date: 31st January 2020)

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SECTION 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 WHICH WILL BE PAID IN THE NAIRA EQUIVALENT RATE.**
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/**
1.4	All tariff are exclusive of Value Added Tax (VAT)
1.5	Please note that asterisks refer you to the Explanatory notes under each section
1.6	**Acronyms:** **CAPA:** Corrective And Preventive Action **cGMP:** Current Good Manufacturing Practice **GDP**: Good Distribution Practice **GHP:** Good Hygiene Practice **GMP**: Good Manufacturing Practice **IMP:** Investigational Medicinal Product **NGO**: Non Governmental Organization

SECTION 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	103,950.00	
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**		
2.0.1	Research purposes	500.00	
2.0.2	NAFDAC Partners	500.00	
2.0.3	NGOs	50,000.00	
3.0	**Certified true copy of NAFDAC documents (per page)**	5,000.00	
4.0	**Change in Brand Name (At company's instance)**	27,500.00	$206.25
4.0.1	Change in Brand Name (At NAFDAC's instance)	0.00	
5.0	**Change in Variants**		
5.0.1	Food/Cosmetics	22,000.00	$1,050.00
5.0.2	Medicines	22,000.00	$614.30
6.0	**Change of Agencyship**	50% of cost of registration	
7.0	**Change of Package label/Design/Pack Size Extension**	21,000.00	$206.25
8.0	**Fast Track Approval***	Double cost of activity	
9.0	**No objection Approval for Registered products (each) (max 3 issuance per annum)**	300,000.00	
10.0	**Pharmacovigilance/Post Marketing Annual Fees**	10% of cost of Registration fees	
11.0	**Ports Fast track Scheme Annual Registration fee**	50,000.00	NA
12.0	**Provisional Administrative Approval***	10,000.00	
13.0	**Request for Statistical Data**	50,000.00	
14.0	**Authorization to open Form M**	500.00	

EXPLANATORY NOTES*

B 1.0 Adverts are valid for one (1) year but extended to two (2) years upon payment (double relevant fee) if concept remains unchanged.

B 8.0 Fast Track Approval is the expedited processing of activity such as Registration, local inspections, analysis, permit issuance etc

B 12.0 Provisional Administrative Approval is granted for NAFDAC Registration Number allocation for pre-printing on packages before registration only.

SECTION C	CLINICAL TRIALS			
S/No	Description	Industry-Sponsored/ Locally-developed IMP	Industry-Sponsored/ Imported IMP	Academic trials
1.0	**Application**	250,000.00	$1,923.00	NA
1.0.1	Individual Self funded (local)	NA	NA	50,000.00
1.0.2	Institutional Grant aided			300,000.00
1.1	Extension of Study	50,000.00	$2,747.25	20,000.00
2.0	**Inspection**	350,000.00	$5,494.51	
2.0.1	Individual Self funded (local)	NA	NA	0.00
2.0.2	Institutional Grant aided			300,000.00
2.0.3	Additional Site	150,000.00	$415.00	150,000.00
3.0	**Substantial Protocol Amendment**	50,000.00	$412.09	

EXPLANATORY NOTES*

C

i. All Clinical Trial fees shall be paid once. Fees paid are non-refundable and non-transferable

ii. For Permit to Import Investigational Medicinal Products for clinical trials, please refer to PERMITS Section

iii. Academic Trials: Are Clinical Studies that is initiated, developed, designed and managed by a qualified sponsor who assumes sole responsibility for the conduct of the trial only to contribute to knowledge of already existing drug, medical device, biologics or medical procedures not for commercial ends.

a. The study is not funded by any for- profit entity (organization) for source of funding of any kind.

b. The outcome or report from the study is used by the applicant for purpose subject to not for-profit sponsor's intellectual property and publication right.

C 2.0.3 Additional site processing fee applies only after authorization of the clinical trial application

C 3.0 Substantial Protocol Amendments: Is a change to the terms of the protocol or any other supporting documentation that is likely to affect to a significant degree, the safety or physical or mental integrity of participants.....the quality or safety of any investigational product used.

SECTION D	FACILITY AND PORT INSPECTIONS		
S/No	**Description**	**Local**	**Foreign**
1.0	**Cold Room**		
1.1	Small Scale (Renewable yearly)	33,000.00	NA
1.2	Medium (Renewable yearly)	68,000.00	
1.3	Large (Renewable yearly)	85,000.00	
2.0	**Field Trial for Agrochemicals/Premixes (per product)***	400,000.00	
3.0	**Food: (PER LINE FOR LOCAL; PER SITE FOR FOREIGN)**		$10,989.01
3.1	Micro Enterprise (Renewable yearly)	11,000.00	NA
3.2	Small Scale (Renewable yearly)	30,000.00	
3.3	Medium/Large Scale (Renewable yearly)	40,000.00	
4.0	**Pharmaceuticals: (PER LINE FOR LOCAL; PER SITE FOR FOREIGN)***		$10,989.01
4.1	Pre-Production: Small Scale	50,000.00	NA
4.2	Pre-Production: Medium/Large Scale	70,000.00	
4.3	Production: Medium/Large Scale (Renewable yearly)	170,000.00	
5.0	**Veterinary Cosmetics, Cosmetics and Herbal Products (PER LINE FOR LOCAL; PER SITE FOR FOREIGN)***		$10,989.01
5.1	Production: Micro Enterprise (Renewable yearly)	15,000.00	NA
5.2	Production: Small Scale (Renewable yearly)	30,000.00	
5.3	Production: Medium/Large Scale (Renewable yearly)	40,000.00	
6.0	**Supermarkets/Warehouse (ANNUAL FEES PER SITE)**		
6.1	Small Scale	20,000.00	NA
6.2	Medium/Large Scale	40,000.00	
6.3	Mega Scale	100,000.00	
7.0	**All other types of Facility inspections (per product/Per activity)***	30,000.00	
8.0	**Other Manufacturers using already inspected foreign sites - Risk based desk review**	**NA**	$5,000.00
9.0	**Inspection of imported products at Ports**		
9.1	**All Retail Products (per 20ft container)**		
9.1.1	Donated (Drugs, Medical Devices, Food,Cosmetics)	NA	37,500.00
9.1.2	Medical Devices		27,000.00

S/No	Description	Local	Foreign
9.1.3	Registered Orphan Drugs/Antiretrovirals/ Vaccines and Biologicals/Service Medical Devices	NA	13,500.00
9.1.4	Registered Over The Counter Drugs		148,500.00
9.1.5	Registered Prescription Only Medicines/Food/Cosmetics/Agrochemicals		40,000.00
9.2	**Chemicals, Packaging Materials and Raw materials**		
9.2.1	Less than 100MT	NA	8,500.00
9.2.2	Less than 1000MT		35,000.00
9.2.3	Less than 2000MT		90,000.00
9.2.4	Less than 4000MT		229,500.00
9.2.5	Above 4000MT		344,250.00
9.3	**Finished Chemicals, Food Raw Materials, Semi-finished Bulk Food and Global Listing for Supermarket operators (1 x 20ft to 10 x 20ft)**		40,000.00
9.4	**Bagging at the Ports**	400,000.00	

EXPLANATORY NOTES*

D 2.0 All processes including Permit to Import Field Trial Samples

D 4.0 and D 5.0

i. Foreign Facility Inspections are valid for three years

ii. A dosage form represents line(s)

D 7.0 All other types of facility inspections including:

i. Pre-Registration: 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. GMP/GHP Reassessment/GDP: Full Audit of production facilities

v. Follow-up Inspection: For CAPA purposes.

vi. For-Cause: For Specific concerns

vii. Chemical facilities etc

viii. GMP Renewal shall be based on Company Risk Status

D 8.0 The office-based risk assessment fee will be charged per applicant where an assessment that does not lead to inspection is carried out. Only manufacturers with satisfactory GMP Inspections shall qualify for contract manufacture and risk-based assessment.

SECTION E	FORMS/CERTIFICATES		
S/No	**Description**	**Local**	**Foreign**
1.0	**Application Forms**	2,500.00	
2.0	**cGMP Certificate**	20,000.00	
3.0	**Cold Room Certification**	20,000.00	NA
4.0	**Certificates issued for Export purposes**		
4.0.1	Certificate of Manufacture and Free Sales (Per issued Certificate)*	10,000.00	NA
4.0.2	Certificate of Free Sales (Per issued Certificate)*	25,000.00	
4.0.3	Health Certificate (Per issued Certificate)*	5,000.00	
4.0.4	Export Certificates (Per issued Certificate)*	5,000.00	
5.0	**Re-issuance of Lost Certificate for Listed Products**	20,000.00	
6.0	**Re-issuance of Lost Certificate for Registered Product**	20,000.00	
7.0	**Listing of Chemical Marketers/Manufacturers**	62,000.00	NA
7.0.1	Listing of Micro Agro input Dealers	31,000.00	NA

EXPLANATORY NOTES

E 4.0.1 Certificates of Manufacture and Free Sales are issued to registered products that are manufactured and sold in Nigeria

E 4.0.2 Certificate of Free Sales are issued to registered imported products meant for re-export

E 4.0.3 Health Certificates are issued for semi processed food commodities such as melon, garri, beans in retail packages and processed food where country of destination requests the document for processed food.

E 4.0.4 Export certificates are issued for registered NAFDAC regulated products exported through land borders.

SECTION F	PERMITS		
S/No	Description	Local	Foreign
1.0	**Permit to Import: Agrochemicals and Restricted Chemicals (3 items per page) New Applicant**		
1.0.1	Businesses and Manufacturers	NA	54,000.00
1.0.2	Educational Institutions		20,000.00
2.0	**Permit to Import: Chemicals and other Raw Materials**		
2.0.1	Permit to Import: Chemicals and other Raw Materials:New Applicant (1st 25 Items)	NA	135,000.00
2.0.2	Permit to Import: Chemicals and other Raw Materials: Raw Materials: (1st 25 Items) Renewal		50,625.00
2.0.3	Permit to Import: Chemicals and other Raw Materials: Additional Raw Materials (25 Items/Page) (New/Renewal)		40,500.00
3.0	**Permit to Import: Controlled Drugs and Chemicals/ Precursor Chemicals/ Solvents and Bulk Narcotics (3 items/page)**		
3.0.1	Businesses and Manufacturers	NA	54,000.00
3.0.2	Educational Institutions		20,000.00
4.0	**Permit to Clear: Agrochemicals and Restricted Chemicals/Controlled Drugs and Chemicals/ Precursor Chemicals/ Solvents and Bulk Narcotics**		
4.0.1	Businesses and Manufacturers	NA	14,850.00
4.0.2	Educational Institutions		13,500.00
5.0	**Permit to Import: Active Pharmaceutical Ingredients (1 item per permit)**		
5.0.1	Businesses	NA	27,500.00
5.0.2	Educational Institutions		7,500.00
5.0.3	Manufacturers		5,000.00
6.0	**Permit to Import Pharmaceutical Grade Excipients (25 items/page)**		
6.0.1	Businesses	NA	135,000.00
6.0.2	Educational Institutions		27,000.00
6.0.3	Health Institutions and Community Pharmacies		27,000.00
6.0.4	Manufacturers		74,250.00
7.0	**Permit for Service Drugs (Including orphan drugs)/Medical Devices***		
7.0.1	Medical Devices (per product)	NA	11,000.00
7.0.2	Prescription Only Medicines (per product)		25,000.00
7.0.3	Over The Counter Drugs (per product)		30,000.00
7.0.4	101-250 items (maximum)		5,625,000.00
8.0	**Permit for Speciality Drugs* (per product) (Drugs of limited use)**		35,000.00
9.0	**Permit to Import Investigational Medicinal Products (per product) Based on approved clinical trials protocols**		40,000.00

EXPLANATORY NOTES

F 7.0

i. Service drug/medical devices: Special need drugs and medical devices that are not registered or may not be available in Nigeria but are requested for use by expatriates or patients who may desire or were advised by their physicians to stick to such brands.

ii. Orphan drugs are used for patients with a population of less than 200,000 having very rare medical conditions. They are not registered because there is no good commercial viability without government support.

F 8.0 Specialty Drugs: Medicines that are high-cost and highly complex medicines used in highly specialized fields for patient treatment of complex or rare chronic conditions.

SECTION G	REGISTRATION*		
S/No	Description	Local	Foreign
1.0	**Animal Feed/Food/Premixes**		
1.1	Imported Class 1*	NA	$1,350.00
1.2	Imported Class 2*		$1,252.00
1.3	Micro Enterprise*	22,000.00	NA
1.4	Small*	30,000.00	
1.5	Medium/Large*	40,000.00	
2.0	**Fast Food Listing (Import)**		
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 (Import)**		
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**	85,000.00	$972.00
5.0	**Cosmetics (per product)**		
5.0.1	Micro Enterprise	22,000.00	NA
5.0.2	Small	66,000.00	NA
5.0.3	Medium/Large	85,000.00	$1,252.00
6.0	**Pharmaceuticals**		
6.1	Herbal and Nutraceuticals/Alternative Medicines (per product)		**Full Registration: $1,252.00 Listing: $612.63**
6.1.1	Micro Enterprise	20,000.00	NA
6.1.2	Small	30,000.00	
6.1.3	Medium/Large	40,000.00	
6.2	Medical Devices 1*	20,000.00	$750.00
6.2.1	Medical Devices 2*	20,000.00	$874.00
6.3	Over the Counter Medicines (OTC)	80,000.00	$967.00
6.4	Orphan Drugs	80,000.00	$967.00
6.5	Prescription Only Medicines (POM) 1*	80,000.00	$1,280.00
6.5.1	Prescription Only Medicines (POM) 2*	80,000.00	$1,200.00
6.6	Vaccines/Biologicals	80,000.00	$1,200.00
6.7	Veterinary Medicines and Supplements	80,000.00	$1,200.00
6.8	Clinical Data Review New Chemical Entities	50,000.00	
7.0	**Registration Renewal**		
7.1	Registration Renewal	80% of New Registration cost	
7.2	Additional source/site or change of source	Same as fees for New Registration	

S/No	Description	Local	Foreign
	EXPLANATORY NOTES **G** **i. REGISTRATION IS PER PRODUCT** **ii. LABORATORY, CERTIFICATE FEES AND PERMIT (FOR IMPORTED PRODUCTS) ARE ALREADY EMBEDDED INTO THEIR RESPECTIVE REGISTRATION FEES** **G 1.0. 10% of the total Registration fee is to process for permit to import; 80% is Processing fee which tracts 5% VAT and 10% of the total Registration fee is for Certificate** **G 1.1. Imported Class 1: Food products that can be manufactured in Nigeria;** **G 1.2. Imported Class 2: Food products with no existing manufacturing facility in Nigeria** **G 6.1.1. Micro Enterprise cannot register more than four (4) products.** **G 6.2. Medical Devices 1: Others except items in Medical Devices 2** **G 6.2.1 Medical Devices 2: Diapers and Sanitary Pads** **G 6.5 POM 1: Medicines that can be manufactured in Nigeria;** **G 6.5.1 POM 2: Medicines with no existing manufacturing facility in Nigeria** **G 7.0 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.**		

SECTION H	INVESTIGATION CHARGES		
S/No	Description	Local	Foreign
1.0	**Unauthorized Clinical trial**	5,000,000.00	
2.0	**Dispensing of Chemicals and raw materials in containers other than the original/primary container without authorization**	1,350,000.00	
3.0	**Drug Hawking**	67,500.00	
4.0	**False Declaration and concealment of imported products**	1,687,500.00	
5.0	**Importation without a Clean Report of Inspection & Analysis (CRIA)***	1,000,000.00	
6.0	**Labeling Lapse/Change (per product)**	537,500.00	
7.0	**Late Renewal of Registration License/Listing Certificate**	156,250.00	537,500.00
8.0	**Marketing without Listing Certificate/Importation/Clearing without Permit (per category)/Use of expired license**	843,750.00	
9.0	**Non Endorsement of shipping documents**	675,000.00	
10.0	**Non-compliance with Good Manufacturing, Hygiene, Distribution and Storage Practices**	2,000,000.00	
10.0.1	Micro Enterprise	200,000.00	
11.0	**Possession/Importation of unauthorized labelled packaging materials**	1,250,000.00	
12.0	**Production without Production/Quality Control Manager***	200,000.00	
13.0	**Sale and Distribution of diverted products meant for relief organisations**	2,500,000.00	
14.0	**Sale of Drugs without Issuance of sales Receipt / Invoice**	200,000.00	
15.0	**Sale of expired Regulated Products**	1,500,000.00	
16.0	**Tampering with products on Hold/Unauthorised Removal of "Hold" Label**	3,375,000.00	
17.0	**Unauthorized Advert (per concept/medium/per product)**	168,750.00	
18.0	**Unauthorized breaking of container seal**	135,000.00	
19.0	**Unregistered products (per product)**	5,000,000.00	
19.0.1	Micro Enterprise	200,000.00	
20.0	**Registered products (with formulation issues)***	5,000,000.00	
20.0.1	Micro Enterprise	200,000.00	
21.0	**Destruction by burning (per 20ft container)**	375,500.00	
22.0	**Destruction by Crushing & burning (per 20ft container)**	551,000.00	
23.0	**Destruction by Crushing & burying (Other products (per 20ft container)**	621,200.00	
24.0	**Destruction by Crushing & burying (Fish) product (per 20ft container)**	726,500.00	
25.0	**Destruction (Small quantities) (per 20ft container)**	375,500.00	
25.0.1	300– 400 Cartons	287,750.00	
25.0.2	100 – 299 Cartons	252,650.00	
25.0.3	1 – 99 Cartons	221,200.00	
26.0	**Infringements leading to Prosecution***	Please see explanatory notes below	

S/No	Description	Local	Foreign
	EXPLANATORY NOTES*		
	H 5.0		
	i. All regulated products from China		
	ii. All medicines from India and China		
	H 11.0 This infringement would require seizure and destruction of labelled packaging materials intended for product counterfeiting		
	H 12.0 Applies only to small, medium and large enterprises		
	H 19.0 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		
	H 20.0 Unauthorized change of formulation/use of unauthorized additives/non compliance with mandatory food fortification will require product recall after payment of administrative charge.		
	H 25.0 Any quantity above 400 cartons shall be categorized as containers		
	H 26.0 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		

SECTION I	LABORATORY ANALYSIS		
S/No	Description	Local	Foreign
1.0	**All analysed raw materials**		67,500.00
2.0	**Bread Registration**		
2.0.1	Micro Enterprise	5,000.00	NA
2.0.2	Medium/Small/Large	15,000.00	
3.0	**Cosmetics**		
3.0.1	Micro Enterprise	5,000.00	NA
3.0.2	Medium/Small/Large	60,000.00	135,000.00
4.0	**Donated Items**	NA	135,000.00
5.0	**Drugs**		
5.0.1	Orphan Drugs	NA	13,000.00
5.0.2	Over the Counter Drugs (OTC)	54,000.00	297,000.00
5.0.3	Prescription Only Medicines (POM)	54,000.00	135,000.00
5.0.4	Vaccines and Biologicals	13,000.00	13,000.00
5.0.5	Veterinary Drugs	54,000.00	135,000.00
6.0	**Enforcement Samples**	108,000.00	270,000.00
7.0	**Food**		
7.0.1	Micro Enterprise	5,500.00	NA
7.0.2	Medium/Small/Large	40,000.00	135,000.00
8.0	**Herbals and Nutraceuticals**		
8.0.1	Herbal Extracts	29,700.00	135,000.00
8.0.2	Herbal Supplements/ Vitamins & Minerals	29,700.00	135,000.00
9.0	**Medical Devices**		
9.0.1	Diapers	29,700.00	101,250.00
9.0.2	Other Medical Devices	29,700.00	67,500.00
10.0	**Pesticides and other retail Agrochemicals**	29,700.00	135,000.00
11.0	**Pesticide Formulation**	29,700.00	135,000.00
12.0	**Water Registration**		
12.0.1	Bottle	20,000.00	NA
12.0.2	Sachet	10,000.00	
13.0	**Fee for Service***	270,000.00	
	EXPLANATORY NOTES* **13.0 Fee for service are rendered to other Agencies and Organizations by the laboratory**		