

ANNEX A

FEES ON GENERAL CERTIFICATION
(Common to all Centers)

Certification	Fees (in PhP)*
1. Re-issuance of an Authorization or License (Lost or Damaged Original)	500.00
2. Sales Promotion Permit	
2.1. Discount scheme type of promotion	
NCR only or in several regions including NCR or nationwide	500.00
More than one region but excluding NCR	500.00
Several provinces/cities/municipalities within a single region	200.00
Single province/city/municipality	100.00
2.2. Non-discount scheme type of promotion	
<u>Amount of Prize/s</u> Up to P50,000.00	250.00
P50,001.00 - P150,000.00	500.00
P150,001.00 - P300,000.00	1000.00
P300,001.00 - P500,000.00	2000.00
P500,001.00 - P1,000,000.00	3000.00
Above P1,000,000.00	5000.00
2.3. Amendment	300.00
3. Pre-assessment	500.00
4. Permit to Carry/Mail (Personal Use)	160.00
5. Permit to Carry/Mail (R& D Use)	160.00
6. Authentication/ CTC	100.00 per page
7. Certificate of Free sale	1650.00

* All fees are subject to an additional 1% for Legal Research Fee (LRF)

ANNEX B

CENTER FOR COSMETICS AND HOUSEHOLD/URBAN HAZARDOUS SUBSTANCES REGULATION AND RESEARCH

I. COSMETICS				
A. License to Operate	Fees per year (in PhP) *		Fees per application (in PhP) *	
	Initial	Renewal	Major Variation (w/ Inspection)	Minor Variation
1. Manufacturer	14,000.00	14,000.00	7,000.00	600.00
2. Distributor/Trader	7,000.00	7,000.00	N/A	600.00
B. Certificate of Product Notification	Fees per year (in PhP) *			
	Initial		Revalidation	
Basic Notification	1,000.00		1,000.00	
Per Variant	100.00		100.00	

II. HOUSEHOLD/URBAN PESTICIDES (HUPs)				
A. License to Operate	Fees per year (in PhP) *		Fees per application (in PhP) *	
	Initial	Renewal	Major Variation (w/ Inspection)	Minor Variation
1. Manufacturer	14,000.00	14,000.00	7,000.00	600.00
2. Distributor/Trader	7,000.00	7,000.00	N/A	600.00
B. Certificate of Product Registration	Initial	Renewal	Variation	Emergency Exemption Permit (EEP)
	Basic Registration	8,000.00	8,000.00	5,000.00

III. TOYS AND CHILDCARE ARTICLES (TCCAs)				
A. License to Operate	Fees per year (in PhP) *		Fees per application (in PhP) *	
	Initial	Renewal	Major Variation (w/ Inspection)	Minor Variation
1. Manufacturer	9,000.00	9,000.00	7,000.00	600.00
2. Distributor/Trader	7,000.00	7,000.00	N/A	600.00
B. Certificate of Product Notification	Fees per year (in PhP) *			
	1,000.00 (maximum of 5 SKUs)			

IV. HOUSEHOLD/URBAN HAZARDOUS SUBSTANCES (HUHS)				
A. License to Operate	Fees per year (in PhP) *		Fees per application (in PhP) *	
	Initial	Renewal	Major Variation	Minor Variation

			(w/ Inspection)	
1. Manufacturer	14,000.00	14,000.00	7,000.00	800.00
2. Distributor/Trader	7,000.00	7,000.00		
B. Certificate of Product Registration	Initial	Renewal	Variation	Emergency Use Permit (EUP)
Basic Registration	5,000.00	3,000.00	3,000.00	4,000.00
	(up to 5 variants)			(per variant)

V. OTHER PERMITS AND CERTIFICATES	Fees per application (in Php) *
1. Certificate of GMP (Local Cosmetics/HUHS Manufacturer)	1,400.00 (per year)
2. Import Permit/Clearance	2,000.00
3. Certificate of Exemption (TCCAs)	2,000.00
4. Pre-Approval of Modified and Non-Standard Bio-Efficacy Test Protocol (HUPs)	14,000.00

*All fees are subject to an additional PhP 10.00 or 1% of the application fee, whichever is higher, for Legal Research Fee (LRF)

ANNEX C

CENTER FOR DRUG REGULATION AND RESEARCH

LICENSE TO OPERATE (LTO)	Fees (in PhP) per Year*
1. Drug Manufacturer	
a. Low risk	27,500.00
b. Medium risk	47,500.00
c. High risk	56,000.00
2. Drug Trader	8,000.00
3. Drug Distributor (Importer/Exporter/Wholesaler)	8,000.00
4. Drugstore	3,000.00
5. Retail Outlet for Non-Prescription Drug	3,000.00
6. Sponsor/ Contract Research Organization	36,500.00
Variation	Fees (in PhP) per Variation*
1. Drug Manufacturer	
a. Major variation with inspection	56,000.00
b. Minor variation	1,170.00
2. Drug Trader/ Drug Distributor	
a. Major variation with inspection	8,000.00
b. Minor variation	620.00
3. Drugstore / Retail Outlet for Non-prescription drug	
a. Major variation with inspection	3,000.00
b. Minor variation	620.00
4. Sponsor/ Contract Research Organization	
a. Major variation with inspection	36,500.00
b. Minor variation	620.00
Other Permit/ Certificate/Clearance (LTO/Pharmacist Verification request from private individual/law firm, etc.)	1000.00
Certificate of GMP Compliance	Fees (in PhP) per Year*
1. Foreign Manufacturer	Covered by a separate FC No. 2014-016
2. Local Manufacturer	
a. Low risk	27,500.00
b. Medium risk	47,500.00
c. High risk	56,000.00
Certificate of Accreditation of Bioequivalence Testing Center (local and foreign)	Fees shall follow AO No. 2012-0024

CERTIFICATE OF PRODUCT REGISTRATION	Fees (in PhP) per Year*
New Drug	43,000.00
Biological	43,000.00
Generic Drug Rx	18,000.00
Non-prescription Drug (Pharmacy only & General Sales List)	17,000.00
Medical Gas	9,000.00
Traditional Medicine	14,500.00
Herbal Medicine	17,000.00
PCPR Conversion	1,000.00
CLIDP	16,700.00
Foreign Donation	2,000.00
Variation	Fees (in PhP) per Variation*
Major variation turned initial	18,000.00
Other Major variation	14,000.00
Minor variation	7,000.00
Notification	1,800.00
Reapplication (Initial/Renewal/Variation)	2,000.00
Reconsideration	18,000.00
Brand name	600.00
Certificate of Pharmaceutical Product, Certificate of Free Sale, Export Certificate, Generic Labeling Exemption	1,650.00
Clinical Trial (Phase I, II, III)	Fees (in PhP)*
Clinical Trial Approval and Import License	56,000.00
Prior Approval CT Protocol Amendment	9,000.00
Other CT Protocol Amendment/Notification	3,000.00
Import License Amendment	3,500.00
PMS (Phase IV) CT Approval	34,000.00
Prior Approval CT Protocol Amendment	9,000.00
Other CT Protocol Amendment/Notification	3,000.00
Compassionate Special Permit (CSP)	1,200.00

Import/Export Permit (e.g., samples for registration, one-time importation (drug shortage), BE/Biowaiver comparator/sample)	1,200.00
Product classification	6,500.00
Exhaustion of existing labeling materials/ Relabeling/ Repacking, etc.	1,700.00

* All fees are subject to an additional 1% for Legal Research Fee (LRF)

Other Services:

Batch Notification	6500
Lot Release Certification	5300

ANNEX D

CENTER FOR DEVICE REGULATION, RADIATION HEALTH, AND RESEARCH

I. RADIATION FACILITIES

Category	LICENSE TO OPERATE	Fees (in Php)*
		(per machine) per year
Group A	Radiation facilities utilizing radiation emitting devices used for General Radiography/Fluoroscopy (fixed, mobile or transportable), Computed Tomography (CT), Single Photon Emission Computed Tomography/Computed Tomography (SPECT/CT), Positron Emission Tomography/Computed Tomography (PET/CT), Mammography (fixed or transportable), Lithotripsy, Dental Radiology (Panoramic/Cephalometric), Dental Cone Beam CT, Magnetic Resonance Imaging (MRI) and other emerging radiation devices in this category used for diagnosis of diseases	3,200.00
Group B	Radiation facilities utilizing radiation devices used for open-type industrial radiography, non-destructive testing and other emerging technologies in this category used for anti-crime and industrial applications	1,000.00
Group C	Radiation facilities utilizing equipment for interventional radiology (Cardiac Catheterization) and emerging radiation devices in this category used for interventional radiology procedures	5,000.00
Group D	Radiation facilities utilizing, Linear Accelerator, Tomotherapy or any combination, and emerging radiation devices in this category used for therapeutic/treatment of diseases	8,900.00
Group E	Radiation facilities utilizing Linear Accelerator for anti-crime and industrial application and emerging radiation devices in this category used for anti-crime and industrial application	3,100.00
	FACILITY REGISTRATION	
Group F	Radiation facilities utilizing radiation emitting devices used for bone densitometry (DEXA), security and baggage inspection system, education, training, research, closed-type industrial radiography, dental radiography utilizing periapical/intraoral x-ray devices and other emerging radiation devices in this category	1,900.00
OTHER AUTHORIZATIONS-RADIATION FACILITIES		
Certification / Permit Category		
Certificate of Safety Evaluation (CSE) for Non-Ionizing Radiation Facility (Extremely Low Frequency (ELF) and Radiofrequency Radiation (RFR) Facilities		2,600.00
Certificate of Radiation Measurement for ELF and RFR Facilities		9,200.00

Pre-Operational Permit for radiation facilities utilizing Linear Accelerator, Tomotherapy and emerging radiation devices in this category used for therapeutic/treatment of diseases and Medical Magnetic Resonance Imaging facilities	12,000.00
Clearance for Customs Release (CFCR)	900.00**
AMENDMENT/ VARIATION (Facility License/Registration)	
1. Inclusion of additional machine	Initial Fee shall apply
2. Change in business name or ownership 3. Change of authorized personnel 4. Removal/deletion of machine from issued authorization	2,400.00

* All fees are subject to an additional 1% for Legal Research Fee (LRF)

**per unit

MEDICAL DEVICES AND HEALTH-RELATED DEVICES

LICENSE TO OPERATE	Fees (in Php)*			
	Initial	Renewal	Variation (Minor) Per variation	Variation (Major) Per variation
Medical Device, Water Purification/Treatment Devices/System, Healthcare Waste Treatment (equipment or devices used for treating sharps, pathological, and infectious waste)				
1. Manufacturer (20 Million and below)	30,900	30,900	1,600	13,200
2. Manufacturer (20 Million and above)	50,800	50,800		
3. Distributor (Importers, Exporters and Wholesalers) & Trader	8,500	8,500		
4. Retailer of Medical Device	3,900	3,900		
Treatment, storage and disposal (TSD) Facility Operator				
TSD Operator	3,800	3,800	1,600	13,200

* All fees are subject to an additional 1% for Legal Research Fee (LRF)

PRODUCT REGISTRATION (Medical Device)	Fees (in Php)*			
	Initial	Renewal	Variation (Minor) Per variation	Variation (Major) Per variation
CIVDR Class A (Registration)	14,500	15,300	3,000	4,000
CIVDR Class B (Registration)	19,400			
CIVDR Class C (Registration)	20,000			

CIVDR Class D (Registration)	20,400			
5. Medical Device Listing	3,400			
Certificate of Medical Device Notification/Registration – Class A	13,500	15,300		
Certificate of Medical Device Registration - Class B	18,000			
Certificate of Medical Device Registration - Class C	18,500			
Certificate of Medical Device Registration - Class D	19,500			
CPR Reapplication	2,800			
Compassionate Special Permit	1,200			

* All fees are subject to an additional 1% for Legal Research Fee (LRF)

PRODUCT REGISTRATION (Water Purification/Treatment Device)	Fees (in Php)*			
	Initial	Renewal	Variation (Minor) Per variation	Variation (Major) Per variation
Water Purification System	9,700	7,800	3,000	4,000
Water Purification Device				
CPR Initial - Healthcare Waste Treatment Equipment (below 1M)	17,500	15,700		
CPR Initial - Healthcare Waste Treatment Equipment (1M-5M)				
CPR Initial - Healthcare Waste Treatment Equipment (5M and above)				
CPR - Healthcare Waste Generators				

* All fees are subject to an additional 1% for Legal Research Fee (LRF)

In Vitro Diagnostic (IVD) Registration	Fees (in Php)*			
	Initial	Renewal	Variation (Minor) Per variation	Variation (Major) Per variation
IVD Pregnancy Test Kits – Existing Regulations	18,800	16,500	3,000	4,000
IVD – Existing Regulations	17,700	15,400		

* All fees are subject to an additional 1% for Legal Research Fee (LRF)

ANNEX E

CENTER FOR FOOD REGULATION AND RESEARCH

LICENSE TO OPERATE	Fees per year (in Php)*		Fees per application (in Php)*	
	Initial	Renewal	Variation (Minor & Major w/o inspection)	Variation (Major with inspection)
1. Manufacturer – Micro-Small	9,800.00	9,800.00	700.00	9,600.00
2. Manufacturer - Medium and Large	15,000.00	15,000.00	700.00	13,700.00
3. Distributor & Trader	6,900.00	6,900.00	700.00	6,700.00

* All fees are subject to an additional 1% for Legal Research Fee (LRF)

CERTIFICATE OF PRODUCT REGISTRATION	Fees per year (in Php)*		Fees per application (in Php)*
	Initial	Renewal	Amendment
1. Bottled Water	4,600.00	4,600.00	225.00
2. Food Supplement	4,500.00	4,500.00	225.00
3. Raw Materials/ Low Risk Food Product	3,500.00	3,500.00	225.00
4. Medium Risk Food Product	3,600.00	3,600.00	225.00
5. High Risk Food Product	3,700.00	3,700.00	225.00
6. CPR Reapplication			225.00

* All fees are subject to an additional 1% for Legal Research Fee (LRF)

CERTIFICATION	Fees per application (in Php)
1. GMP Certificate Small-Micro	9,700.00
Medium-Large	13,900.00
2. HACCP Certificate Small-Micro	9,700.00
Medium-Large	13,900.00
3. Sangkap Pinoy Seal	900.00
4. Use of Seal	8,000.00
5. IAC (Milk Code) Certificate - (Ads)	2,020.00
6. IAC (Milk Code) Certificate - Sponsorship and Donation	940.00
7. Import Permit	650.00 (per invoice)

* All fees are subject to an additional 1% for Legal Research Fee (LRF)

Other Services (Voluntary Application)

Evaluation for Suitability (food-contact) per product type	3200
Export Certification for Woodenwares	3200

**ANNEX F
COMMON SERVICES LABORATORY**

COST OF LABORATORY ANALYSIS		
CLASSIFICATION		Fees (in PhP)*
General Tests		
	pH	600
	Visual Examination	500
	Organoleptic	1000
	Alcohols	8400
<u>Physico-chemical Analysis</u>		
1.1	Drugs and Antibiotics	
	Assay/ Potency (Single component)	5300
	Assay/ Potency (Multi- component)	8400
	Two/ Three-component TB Drugs	8400
	Four-component TB Drugs	12600
	TB Drugs Kit	15800
	Dissolution	
	Single component	6300
	Multiple component (other than TB drugs)	9500
	Two/ Three-component TB Drugs	9500
	Four-component TB Drugs	13700
	TB Drugs Kit	16800
	Disintegration Test	700
	Hardness Test	700
	Identification Test	
	Single component	3700
	Multiple component	5300
	Uniformity of Dosage Units	
	Weight variation	5000
	Content uniformity	11000
	Test for Impurities / Related Substances/ Adulterants/	15800
	Moisture content	1500
	Loss on Drying	3000
	Minimum fill	600
	Deliverable volume	600
1.2	Cosmetics	
	Single analyte	7900
	Heavy Metal in Cosmetic Products	12000

	Parabens in Cosmetic Products	8400
1.3 Food Products		
	Additives / Preservatives	
	Acesulfame K	5300
	Aspartame	5300
	BHA	5300
	BHT	5300
	Bromates	500
	Cyclamates	5300
	Food colors (ID)	2100
	Nitrate	3700
	Nitrite	3700
	Saccharin	5300
	Sodium Benzoate	5300
	Sodium metabisulfite	3700
	Sorbic Acid	5300
	Two-component preservative	7900
	Multi -component artificial sweeteners (Max.of 3 analytes)	8400
	Multi-component caloric sweeteners (max of 3)	8400
	Proline	2600
	Ash	2600
	Caffeine	5300
	Contaminants	
	Borax	1100
	Pesticides Residues	15800
	Veterinary Drug Residues	15800
	3-MPCD	15800
	DEHP	7900
	Odor	1100
	Filth	500
	Formalin	2600
	Histamine	11000
	Melamine	11000
	Mycotoxins (per mycotoxin)	11000
	Trans Fatty Acids	11000
	Fatty Acid Profile (VCO)	8400
	Fat	2600

	Free Fatty Acids	2600
	% NaCl	2600
	Calcium	2600
	Gas Volume	1100
	Glucose	5300
	Fructose	5300
	Sucrose	5300
	Heavy Metals	
	Arsenic	5300
	Cadmium	5300
	Chromium	5300
	Lead	5300
	Mercury	5300
	Tin	5300
	Lactose	5300
	Micronutrients	
	Beta Carotene	5300
	Iodine	2700
	Iron	3700
	Moisture	2600
	Permanganate Oxidation Number (PON)	2600
	Peroxide Value	2600
	Protein	3700
	Soluble Solids	2600
	Total Acidity	2600
	Total Solids	2600
	Total Soluble Solids (Brix)	500
	Water-Insoluble Solids	2600
	Vitamins	
	Vitamin A	7900
	Vitamin B1, B6, Niacin	7900
	Vitamin C	2600
	Vitamin E	7900
<u>2. BIOLOGICAL TESTS</u>		
	2.1 Antibiotics	
	Microbiological Assay (Potency of Antibiotics)	6300
	Sterility Test	6300

	(Injectables, Medical Devices, and Large Volume Parentals)	
	2.2 Microbiological Tests	
	<i>For food samples a minimum of five (5) samples are analyzed</i>	
	<i>For pharmaceutical, herbal and cosmetic samples, minimum of one sample is analyzed</i>	
	Microbial Enumeration Tests	
	Aerobic Plate Count/ Heterotrophic Plate Count/ Total Aerobic Microbial Count (Food: 5 samples)	4200
	per sample	1300
	Coliform Count (Solid Media method) (Food: 5 samples)	4200
	per sample	1300
	Coliforms (MPN) (Food: 5 samples)	5300
	per sample	1400
	Lactic Acid Bacteria (Food: 5 samples)	5300
	per sample	1400
	Osmophilic Yeast (Food: 5 samples)	4200
	per sample	1300
	Psychrotrophic Bacteria (Food: 5 samples)	4200
	per sample	1300
	Yeast and Mold Count/ Total Yeast and Mold Count (Food: 5 samples)	4200
	per sample	1300
	Microbial Identification Tests	
	<i>Bacillus cereus</i> (Food: 5 samples)	5300
	per sample	1300
	<i>Bacillus subtilis</i> (Food: 5 samples)	5300
	per sample	1300
	<i>Candida albicans</i> per sample	1300
	<i>Clostridium perfringens</i> (Food: 5 samples)	5300

	per sample	1400
	<i>Cronobacter spp.</i> (Food: 5 samples)	5300
	per sample	1400
	<i>Enterobacteriaceae</i> (Food: 5 samples)	5300
	per sample	1400
	<i>Enterococci</i> (Food: 5 samples)	4200
	per sample	1400
	<i>Escherichia coli</i> (Solid Media) (Food: 5 samples)	5300
	per sample	1500
	<i>Escherichia coli</i> (MPN) (Food: 5 samples)	6300
	per sample	1600
	<i>Fecal streptococci</i> (Food: 5 samples)	5300
	per sample	1500
	<i>Listeria monocytogenes</i> (Food: 5 samples)	7400
	per sample	1900
	<i>Pseudomonas aeruginosa</i> (Food: 5 samples)	5300
	per sample	1500
	<i>Salmonella spp.</i> (Food: 5 samples)	7400
	per sample	1900
	<i>Staphylococcus aureus</i> (Food: 5 samples)	6300
	per sample	1500
	<i>Vibrio parahaemolyticus</i> (Food: 5 samples)	7400
	per sample	1600
	Rapid Bacterial Identification Tests	
	<i>Bacillus cereus</i> (Food: 5 samples)	7400
	<i>Escherichia coli</i> (Food: 5 samples)	7400
	<i>Listeria monocytogenes</i> (Food: 5 samples)	7400
	<i>Salmonella</i> (Food: 5 samples)	7400
	<i>Staphylococcus aureus</i> (Food: 5 samples)	7400

	Other microbiological tests	
	Commercial sterility (Food)	7400
	Evaluation of Antimicrobial Protection (Preservative Efficacy Test)	15800
	2.3 Bioassay Tests	
	Bacterial Endotoxin Test (LAL)	7400
3	Toxicological Tests	
	Bottled Water - Total package	10500
	conductivity	800
	Cyanide	1300
	Heavy Metals (per metal)	4200
	Nitrate	1700
	Total Dissolved Solids	800
	Hypochlorite	
	Assay	2800
	Residual Chlorine	2800
	Toys / School Supplies	
	Migration of Certain Elements (3 elements)	6300
	Additional element	2100
	Test for Packaging Materials	
	Material Testing (Pb and Cd)	4200
	Migration Testing (package)	6300
	Medical Devices	
	Efficacy/ Reproducibility	1100
	Water Leak Test (Condom)	1600
	Lead in Spray Paint	4200
	HUP Active Ingredient by HPLC	8900
	Phthalates in Toys	16800
4	<u>OTHER SERVICES</u>	
	Audit of Testing Laboratory (per visit)	
	Within Metro Manila	20000 ^a
	Outside Metro Manila	20000 ^b
	Accreditation of Testing Laboratory (per year)	20000 ^c
	Batch Notification	6500
	Lot Release Certification	5300

	Evaluation for Suitability (food-contact) per product type	3200
	Export Certification for Woodenwares	3200
	ASEAN REFERENCE SUBSTANCE (ARS)	50 USD
	Amendment of Test Report and/or Certificate (per copy)	1000
	Re-issuance of Test Report and/or Certificate (per copy)	500
5	<u>PHYSICS LABORATORY SUPPORT DIVISION (PLSD)</u>	
	Performance Testing of Radiological Equipment	10500
	Quality Audit of Radiotherapy Facilities	10500
	Calibration of Radiotherapy Dosimeters	9500
	** testing and quality audit activities were done in the health care facilities (hospitals/clinics) and all expenses (i.e plane fare, per diem, hotel accommodations, etc) incurred for the travel of at least 2 PLSD personnel were charged to the client	
	^a Plus transportation cost ^b Plus per diem/ per inspector/auditor plus transportation cost ^c per year validity of accreditation	

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